Questionnaire

Part II

Information provided by the Government of the Republic of Moldova to the Questionnaire of the European Commission

CHAPTER 28:

CONSUMER AND HEALTH PROTECTION

May 2022

The *acquis* on consumer and health protection protects consumers' economic interests and, in relation to product safety, dangerous imitations and liability for defective products. The EU also ensures high common standards for tobacco control, blood, tissues, cells and organs, and medicines for human and veterinary use. The EU also ensures high common standards for upholding patients' rights in cross-border healthcare and tackling serious cross-border health threats including communicable diseases.

The *acquis* in the area of **consumer protection** includes legislation on product safety and the European Union's Rapid Alert System (RAPEX), cross-border enforcement cooperation, consumer redress, injunctions for the protection of consumer interests, sale of consumer goods and digital content, unfair contract terms, price indications, consumer rights, distance marketing of financial services, consumer credit, misleading and comparative advertising, unfair commercial practices, timeshare, and package travel.

In regard to **public health**, the *acquis* covers areas related to tobacco control, serious cross-border health threats including communicable diseases, blood, tissues, cells and organs, patients' rights in cross-border healthcare, medicinal products (human and veterinary), cosmetics and medical devices, drug abuse prevention, health inequalities, nutrition, alcohol related harm reduction, cancer screenings, healthy environments including limitation of exposure of the general public to electromagnetic fields (EMF), prevention of injury, promotion of safety, active and healthy ageing as well as European action in the field of rare diseases.

Implementation and enforcement of consumer protection and health promotion, prevention and protection policies require adequate administrative capacities and infrastructure at national, regional and local level. As regards consumer protection, this refers to effective market surveillance and access to consumer redress, including appropriate independent judicial and out-of-court dispute resolution mechanisms. It also encompasses consumer education, information and awareness-raising activities, and entails the active involvement of consumer representatives in the design and implementation of policies, thus ensuring a role for consumer associations.

NB: in several areas below the question is asked "*To what extent is national legislation aligned with the EU acquis in this area*?" – the acquis is listed in annex, below the questions. At this stage the Commission does not expect a detailed analysis for each question, but rather an overview of the situation.

I. CONSUMER PROTECTION

A. Horizontal issues

1. Please describe the scope of the consumer protection policy. Is consumer protection recognised as a specific policy in Moldova? Are there specific rules on consumer protection in other policy areas?

The purpose of consumer protection policy is to guarantee consumers' rights when dealing with traders. Consumer protection is regulated by Law No. 105/2003 on consumer protection1, which lays down the general requirements for protecting consumers, ensuring the necessary framework for unrestricted access to products and services, providing full information on their main characteristics, defending and ensuring the legitimate rights and interests of consumers in the event of unfair commercial practices, enabling them to participate in the decision-making process and in the decisions which concern them as consumers, and regulating aspects of the sale of products and associated guarantees. The Consumer Protection Act also lays down the conditions under which the authorities responsible for enforcing legislation protecting consumer interests cooperate across borders to ensure compliance with such legislation and the proper functioning of the internal market and to improve the protection of consumers' economic interests.

In addition, in the Republic of Moldova there are in force multiple laws and regulations with full or partial applicability in the sphere of consumer protection. Thus, each area (food, transport, health, financial, energy, etc.) with which the citizen of the Republic of Moldova comes into contact as a consumer has a series of regulations protecting his rights and interests.

2. Please describe the institutional set-up for consumer affairs in Moldova.

The institutional framework in the field of consumer protection is determined, first of all, by the Law No.105/2003 on consumer protection, which establishes the central specialized body of the public administration empowered with the function of elaborating and promoting the state policy in the field of consumer protection and the central specialized bodies of the public administration that are empowered with consumer protection functions in the respective fields, as follows:

The central specialized body of the public administration empowered with consumer protection functions;

- other competent administrative authorities with consumer protection functions;

[1] Law No. 105/2003 on consumer protection, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110237&lang=ro

- local public authorities on consumer protection;
- public associations for consumer protection;

The Ministry of Economy is the central specialized body of the public administration responsible for the elaboration of state policy in the field of consumer protection.

Coordinating Council for Consumer Protection and market Surveillance[2] is a consultative body which brings designated representatives of central government authorities, market surveillance authorities, the customs authority, public consumer associations and sectoral trade associations.

Agency for Consumer Protection and Market Surveillance is an administrative authority that coordinates at national level the enforcement of consumer protection legislation, having the status of national contact point.

Other competent administrative authorities with consumer protection functions		
Areas of activity	**Public authorities with regulatory functions in the field of consumer protection**	**Public administration authorities empowered to control compliance with consumer protection legislation**
In the field of consumer life and health protection	Ministry of Health	The National Public Health Agency
In interurban and international transport	Ministry of Infrastructure and Regional Development	The National Transport Agency
In the field of construction		Agency for Technical Supervision
In the field of tourism	Tourism Agency	Agency for Consumer Protection and Market Surveillance
In the field of telecommunications	Ministry of Economy	The National Regulatory Agency for Electronic Communications and Information Technology
In the field of insurance	The National Commission for Financial Market	**The National Commission for Financial Market**
In the field of banking	National Bank of Moldova	
In food, at all stages of the food chain	Ministry of Agriculture and Food Industry	The National Food Safety Agency

[2] Coordinating Council for Consumer Protection and market Surveillance approved by Government Decision No. 964/2016, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=94477&lang=ro

3. General co-ordination of consumer affairs: is general competence on consumer policy allocated to one designated authority, which is responsible for taking initiatives and for coordinating actions in the consumer area?

The central specialized body of the public administration responsible for the development of state policy in the field of consumer protection is the Ministry of Economy, which has the following main tasks in the field of consumer protection:

- coordinates and promotes state consumer protection policy;
- ensures the development of the legislative framework in the field of consumer protection, including by transposing relevant European acts into national law;
- coordinates the work of public administration bodies with consumer protection functions;
- coordinates activities to inform and educate citizens about their rights as consumers;
- organizes the work of the Coordinating Council for Consumer Protection and Market Surveillance;
- ensures that the third-countries and the European Union Commission are informed by the competent authorities and the single liaison office for cross-border consumer protection cooperation and how they can be contacted.

4. How is enforcement of consumer rights organised? Is there any specific consumer protection authority and what is the remit of competence of this authority?

In the Republic of Moldova there are several public authorities with competences in the field of consumer protection, as follows:

Agency for Consumer Protection and Market Surveillance - in the field of non-food products and services (including tourism), legal metrology, gambling;

The National Food Safety Agency - in the food sector, at all stages of the food chain;

The National Public Health Agency - in the field of medicinal, pharmaceutical and parapharmaceutical products, services provided by pharmaceutical and medical institutions, and other products and services made available to the consumer by pharmaceutical and medical enterprises and institutions

The National Transport Agency – in road transport;

Civil Aviation Authority - in the field of aeronautical transport;

Naval Agency - in the field of naval transport;

Agency for Technical Supervision - in the field of industrial and construction safety;

The National Agency for Energy Regulation - in the fields of energy, water supply and sewerage;

The National Regulatory Agency for Electronic Communications and Information Technology - in the field of telecommunications.

The Agency for Consumer Protection and Market Surveillance is the administrative authority that coordinates at national level the enforcement of consumer protection legislation, having the status of national contact point and is responsible for monitoring consumer protection activities of the other competent administrative authorities. The Agency for Consumer Protection and Market Surveillance, with the participation of the other competent consumer protection authorities, makes out and approves the annual report on consumer protection activity[3] and ensures its publication on its official website.

5. Are bodies competent for consumer rights allowed to receive and act upon complaints by consumers and consumer associations? What investigation powers do those authorities have (e.g. compel testimony, compel information from business and third parties, enter premises, block web sites, etc.)? What enforcement powers do those authorities have (e.g. possibility to impose civil or administrative penalties, possibility to initiate proceedings, etc.)? Is there any framework for enforcement cooperation between authorities and/or with other consumer protection stakeholders (e.g. consumer organisations and ADR entities) at national level and/or others established in EUMS?

If the consumer does not agree with the results of the examination of the complaint or if the seller/service provider refuses to satisfy the complaint, the consumer has the right to apply to the competent consumer protection bodies or, according to civil procedure, to court.

Protection of the economic rights and interests of consumers. The number of complaints

Authority	The number of complaints		
	2019	2020	2021
Agency for Consumer Protection and Market Surveillance	1870	1400	1403
The National Food Safety Agency	1545	555	1852
The National Public Health Agency	68	40	50
The National Transport Agency	98	38	35
Civil Aviation Authority	342	250	227
Naval Agency	-	-	24

[3] The annual report on consumer protection activity, available in Romanian at: https://consumator.gov.md/eng/rapoarte-1#tree_827

The National Agency for Energy Regulation	825	872	652
Agency for Technical Supervision	117	6	220
The National Commission for Financial Markets	105	355	129
The National Regulatory Agency for Electronic Communications and Information Technology	-	217	141

In order to resolve the petitions, the following were registered:

Name of indicator	2020	2021
Unannounced checks, based on petitions, from total unannounced checks	50	19
Violations detected in the control	25	11
Complaints settled amicably within the framework of state control	121	130
Complaints submitted to other competent authorities	307	309
Complaints submitted by other authorities	274	313
Number of consumers who have benefited from the refund of the value of products / services, non-compliant	89	87
in amount of, MDL	625469,00 (≈ EUR 31273,45)	632269,00 (≈ EUR 31613,45)

Thus, in addition to the judicial protection of consumer rights, the national legal framework regulates the powers of the public authorities responsible for enforcing appropriate measures to ensure consumer protection.

We note that the measures applied by the market surveillance authorities are regulated by Law No. 7/2016 on market surveillance of the marketing of non-food products[4]. The conditions for carrying out control activities, as well as the rights of inspectors in the framework of state control are regulated by Law No.131/2012 on state control of entrepreneurial activity[5].

In the process of carrying out the inspection, the inspector has the right:

- -to enter any room used by the entrepreneur in his activity, insofar as it is part of the object of the control, with the exception of the domicile, if the permission of the legal owner is missing. In case of necessity, the inspector may enter the home or the room assimilated to the home only with the assistance of the police, in accordance with the law;

[4] Law No. 7/2016 on market surveillance of the marketing of non-food products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106102&lang=ro
[5] Law No.131/2012 on state control of entrepreneurial activity, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=96045&lang=ro

- to request information, certificates, licenses, permits and other mandatory documents;
- to make copies, photo or video recordings of documents or other information-bearing objects;
- to inspect and measure goods, take samples from them, with the information on sampling included in the inspection report. For this purpose, the inspector has the right to open packages, packaging, break seals. At the request of the injured party, the inspector shall, where appropriate, also take a second sample, unless otherwise provided for in the legislation;
- to inspect means of transport only if it has information that they contain goods subject to control or if the means of transport are subject to control in accordance with the scope of control.

In accordance with the provisions of the Law on market surveillance of the marketing of non-food products, the activities carried out and measures applied by the market surveillance authorities include:

- control of products by checks of documentation and, where appropriate, by sampling and examination of products and laboratory testing of appropriate samples;
- corrective measures, which include:
  - temporary suspension or prohibition of the making available on the market of products;
  - withdrawal of products from the market;
  - recall of products from consumers (users);
- control of the execution of the corrective measures applied;
- warning consumers (users) of dangerous products detected.

In addition, the consumer protection authorities detect contraventions, examine contravention cases and impose sanctions in accordance with the provisions of the Contravention Code[6].

Republic of Moldova does not have out-of-court consumer dispute resolution entities. However, consumer disputes may be subject to mediation where the consumer alleges damage as a result of the purchase of defective products or services, non-compliance with contractual terms or guarantees, unfair terms in the contract between the consumer and the economic operator or infringement of other rights laid down in consumer protection legislation. Moreover, public consumer protection associations may be registered as mediation organisations and/or accredited as training providers under the terms of the law on mediation.

6. Does the government ensure education, information and awareness-raising on consumers' rights and how to exercise them? Does the government support independent

[6] The Contravention Code, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125094&lang=ro

consumer associations that pursue the objective of consumer advocacy and to defend consumer rights?

In accordance with Art. 27 of Law No. 105/2003 on consumer protection, the Agency for Consumer Protection and Market Surveillance cooperates with public associations of consumers to inform consumers of their legitimate rights and how to defend them; informs consumers of products and services that pose risks to their health and safety and of unfair commercial practices that may affect their economic interests.

Developing the knowledge of economic agents,
in training and developing the decision-making capacities of consumers

Authority	2020				2021			
	Type of information				Type of information			
	Information campaigns	Information published on the website	Virtual communication channels	Consulting visits	Information campaigns	Information published on the website	Virtual communication channels	Consulting visits
Agency for Consumer Protection and Market Surveillance	2	187	26	35	3	201	68	111
The National Food Safety Agency	-	144	-	1630	-	100	-	2450
The National Public Health Agency	-	291	3	-	23	-	-	26
The National Transport Agency	-	250	-	-	13	84	123	-
Civil Aviation Authority	-	52	-	25	-	58	-	-
Naval Agency	-	-	-	8	-	8	-	-
The National Agency for Energy Regulation	-	115	-	25	-	166	-	20
Agency for Technical Supervision	-	41	-	28	-	51	-	10
The National Commission for Financial Markets	-	93	2	-	-	46	165	-

The Republic of Moldova citizens have the right to organise themselves voluntarily in public consumer associations, which operate in accordance with the law. Consumer information programmes, projects and activities proposed by public benefit consumer associations may be financed by the State, in accordance with the law, if these associations act exclusively on behalf and in the interest of consumers.

7. Do measures facilitate consumers' access to justice for redress? Who/what can stop illegal commercial practices and remove their effects? Do out-of-court bodies provide effective and efficient alternative dispute resolution systems?

According to Art. 31 of Law No. 105/2003 on consumer protection, actions on consumer rights protection may be filed with the court by the consumers themselves or their representatives, by the competent public administration authorities or by public consumer associations. Actions on the protection of consumer rights shall be filed with the court in accordance with the time limits laid down by the legislation. Consumers are exempt from the state tax in actions concerning the protection of their rights. Consumer protection bodies may represent the interests of consumers in court for the purpose of protecting consumer rights.

In order to resolve disputes related to the protection of consumer rights, consumers and economic operators may voluntarily initiate the mediation procedure as an alternative way of resolving them.

The mediation procedure, in the case of the settlement of disputes related to the protection of consumer rights, is regulated by the Law on mediation No. 137/2015[7].

B. Safety-related issues

8. To what extent is national legislation aligned with the EU *acquis* in this area?

The Republic of Moldova has made considerable progress in approximating national legislation to the EU normative acts and international instruments, as referred to in Annex IV of the EU-Moldova AA. Therefore, the progress on legal approximation envisaged the adoption of several laws transposing EU Directives. Notably, most of the acts listed in Annex IV have been fully or partly transposed into national law, in most cases ahead of the Association Agreement calendar.

a) Consumers - Safety related issues:

[7] The law on mediation No.137/2015, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110536&lang=ro

General Product Safety Directive (2001/95/EC) is partially transposed in Law No. 422/2006 on general product safety[8] and in Law No. 231/2010 on internal commerce[9];

Commission implementing Decision laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' ((EU) 2019/417) is not yet transposed into national legislation;

Commission Implementing Decision on European standards for products drafted in support of Directive 2001/95/EC ((EU) 2019/1698) is not yet transposed into national legislation;

Food-imitating Products Directive (Directive 87/357/EEC) is fully transposed by the Government Decision No. 1246/2016 on approval of Technical Regulation on food imitating products[10] ;

Liability for defective products (Directive 85/374/EEC) is fully transposed in the Law No. 184/2012 on modifications of some laws[11] in the Civil Code of Republic of Moldova[12] .

9. Do market surveillance/enforcement authorities use a defined methodology, have sufficient powers and resources to monitor product safety, to react to complaints, and take appropriate measures?

The general requirements for product safety are regulated by the Law No.422/2006 on general product safety[13].

It should be noted that conformity of a product with the criteria ensuring compliance with the general safety requirement does not prevent the competent authorities from taking appropriate measures to impose restrictions on making the product available on the market or to require withdrawal from the market or return of the product if there is evidence that it is dangerous.

The market surveillance authorities may collaborate, in accordance with the tasks laid down by law, where appropriate, with other specialist bodies responsible for market surveillance in order to take action to ensure compliance with product safety requirements. For the purpose of market surveillance, the tasks, duties, organisation and modalities of collaboration of the specialised bodies shall be laid down, as appropriate, in protocols or within the Coordinating Council for Consumer Protection and Market Surveillance.

[8] Law No. 422/2006 on general product safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106998&lang=ro
[9] Law No. 231/2010 on internal commerce, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=127948&lang=ro#
[10] Government Decision No. 1246/2016 on approval of Technical Regulation on food imitating products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=111690&lang=ro
[11] Law No. 184/2012 on modification of some laws, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=22366&lang=ro
[12] Civil Code of Republic of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129081&lang=r
[13] Law No.422/2006 on general product safety, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106998&lang=ro

The market surveillance authorities will carry out state control in the field of product conformity in compliance with the provisions of the Law No.131/ 2012 on state control of entrepreneurial activity.

10. Do Moldova surveillance/enforcement authorities use a risk assessment system/guidelines? Are systems in place to ensure co-operation/information with producers, distributors & consumer associations, and rapid information to consumers & businesses?

By Government Decision No.1212/2016 the Methodology on risk assessment of non-food consumer products and selection of corrective measures was developed, which establishes the methodological framework for assessing the level of risk posed by non-food consumer products, the conditions under which market surveillance authorities, within their area of competence, select and apply corrective measures in relation to the marketing and use of products posing a risk to public interests, such as health and safety in general, health and safety at work, consumer protection, environmental protection and security.

Cooperation/information actions with producers, distributors, as well as informing consumers about the risks of a product are regulated by law No.422/2006 on general product safety.

Non-safety related issues

11. To what extent is Moldova legislation aligned with current EU *acquis* in this area? Are public authorities equipped to protect the economic interests of consumers?

Chapter III of the Law No.105/2003 on consumer protection entitled PROTECTION OF CONSUMERS' ECONOMIC INTERESTS regulates general rules on the protection and enforcement of consumers' legitimate rights and interests. The law defines the notion of economic interest as the totality of the demands submitted by the consumer towards the seller, the supplier for the remedy or replacement free of charge or for obtaining the countervalue of the product, the defective service and for the reparation of the damage caused, as well as other demands related to the material interest of the consumer.

In addition, provisions related to the protection of consumers' economic interests are regulated by the Civil Code of the Republic of Moldova, Law No.231/2010 on domestic trade, Government Decision No.966/2010 approving the Regulation on the manner of indicating the prices of products offered to consumers for sale; Law No.157/2014 on the conclusion and execution of distance contracts on consumer financial services; Law No.202/2013 on consumer credit agreements, etc.

At the same time, in accordance with the regulatory framework governing consumer rights , the competent inspector shall be authorized to check whether the trader displays the prices in line with the Law, states commercial purpose of information to consumers before concluding a contract, has unfair commercial practices, sends packages that the consumer has not ordered, advertises via means of long distance communication contrary to the law, abuses the term "guarantee", responds to the consumer's complaint within 14 days, advertises or offers package travel contrary to the law.

In the context of the above, we stress that in order to protect the economic interests of consumers, the national regulatory framework has been aligned with the EU acquis summarized hereunder:

Non-safety related measures (protection of economic interests of consumers)

Certain aspects concerning contracts for the supply of digital content and digital services (Directive (EU) 2019/770) is not yet transposed into national legislation;

Sale of goods (Directive (EU) 2019/771) - Directive 1999/44/EC is fully transposed înto Law No. 105/2006 on protection of consumers[14] and in the Civil Code of Republic Moldova. The approximation with the Directive 2019/771/EU is planned for 2022 by the The Government Action Plan for 2021-2022;

Unfair terms in consumer contracts (Directive 93/13/EEC) is fully transposed by the Law No. 133/2018 on modernization of the Civil Code of Republic of Moldova[15]

Indication of the prices of products offered to consumers (Directive 98/6/EC) is fully transposed by the Government Decision No. 366/2010 on approval of Regulation on indication of the prices of products offered to consumers[16]

Consumer rights (Directive 2011/83/EU) is fully transposed by the Law No. 133/2018 on modernization of the Civil Code of Republic of Moldova;

Distance marketing of consumer financial services (Directive 2002/65/EC) is fully transposed by the Law No. 157/2014 on the distance marketing of consumer financial services[17]

[14] Law No. 105/2006 on protection of consumers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129082&lang=ro
[15] Law No. 133/2018 on modernization of the Civil Code of Republic of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=34327&lang=ro
[16] The Government Decision No. 366/2010 on approval of Regulation on indication of the prices of products offered to consumers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103304&lang=ro
[17] The Law No. 157/2014 on the distance marketing of consumer financial services, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106040&lang=ro

Credit agreements for consumers (Directive 2008/48/EEC) is fully transposed by the Law No. 202/2013 on the credit contracts with the consumers[18]

Misleading and comparative advertising (Directive 2006/114/EEC) is fully transposed by the Law No. 62/2022 on advertising[19]

Unfair commercial practices (Directive 2005/29/EC) is fully transposed by the Law No. 105/2006 on protection of consumers;

Better enforcement and modernisation of consumer protection rules (Directive (EU) 2019/2161) is not yet transposed into national legislation, but is planned for 2022 according to the Government Action Plan for 2021-2022;

Certain aspects of timeshare, long term holiday product, resale and exchange contracts (Directive 2008/122/EC) is fully transposed by the Law No. 200/2016 on modification of some laws[20] in the Civil Code of Republic of Moldova;

Package travel and linked travel arrangements (Directive (EU) 2015/2302) is fully transposed by the Law No. 133/2018 on modernization of the Civil Code of Republic of Moldova;

Representative actions for the protection of the collective interests of consumers (Directive 2020/1828) is not yet transposed into national legislation;

Consumer Protection Cooperation Regulation (Regulation 2017/2394) is not yet transposed into national legislation, but is planned for 2022 according to the Government Action Plan for 2021-2022. Regulation 2006/2004/EC which is repealed by the Regulation 2017/2394 is fully transposed in Government Decision No. 315/2019 on establishing the List of competent authorities responsible for the cooperation on consumer protection[21]

Alternative dispute resolution for consumer disputes (Directive 2013/11/EU) is not yet transposed into national legislation;

Online dispute resolution for consumer disputes (Regulation (EU) No 524/2013) is not yet transposed into national legislation;

Pre-contractual information to be given to consumers by lenders offering home loans (Commission Recommendation 2001/193/EC) is not yet transposed into national legislation;

[18] The Law No. 202/2013 on the credit contracts with the consumers, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=131199&lang=ro#
[19]Law No. 62/2022 on advertising, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130742&lang=ro
[20] Law No. 200/2016 on modification of some laws, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=95306&lang=ro
[21] Government Decision No. 315/2019 on establishing the List of competent authorities responsible for the cooperation on consumer protection, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=116443&lang=ro

Cooperation between national authorities responsible for the enforcement of consumer protection laws (Regulation (EU) 2017/2394) is not yet transposed into national legislation, but is planned for 2022 according to the Government Action Plan for 2021-2022. Regulation 2006/2004/EC which is repealed by the Regulation 2017/2394 is fully transposed in Government Decision No. 315/2019 on establishing the List of competent authorities responsible for the cooperation on consumer protection.

II. HEALTH PROTECTION

12. Does Moldova have a health strategy (what are its main priorities)?

Currently, the health system of the Republic of Moldova is undergoing a continuous transformation and improvement. Since the launch of the first National Health Strategy in 2007, aimed at improving the health of Moldovans through system-wide changes, healthcare has seen significant progress. The Healthcare System Development Strategy 2008–2017 (HSDS 2008-2017)[22] was developed from a health system perspective and its focus was to improve four action areas: (i) management/stewardship of the health care system; (ii) funding of the health care system and payment mechanisms for health care services; (iii) provision of health care services; and (iv) resource management. Investing in the modernization of medical facilities and their equipment, expanding the benefits package, implementing reforms of payment mechanisms, upgrading models of care, introducing treatment technology and implementing international standards have all be driven by the HSDS 2008-2017.

Moldova also developed several sectoral strategies, including the National Public Health Strategy 2014-2020[23], the Strategy on Noncommunicable DiseasesPrevention and Control[24], the Strategy for the Development of Human Resources in Health 2016–2025[25], each of these strategies providing an overarching framework upon which the country can strengthen its health system.

In addition, a number of national programmes were implemented, aiming to improve integration of services, accessibility of them, and achieve better health outcomes. A few examples are the emergency national programme that reorganized emergency services across the whole country; the strengthening of PHC services – in particular the improvement of the physical infrastructure and the training and management of human resources; the introduction of community mental health services by developing legislation, combatting stigma and discrimination of psychiatric patients, and building up community-based mental health care provision; and proposals for the reorganization of hospital services to reduce fragmentation. Several disease-specific national programmes are being developed in areas such as vaccine-preventable diseases, communicable diseases and noncommunicable diseases (NCDs).

[22] Government Decision No. 1471/2007 regarding the approval of the Strategy for the development of the health system in the period 2008-2017, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=88242&lang=ro

[23] National Public Health Strategy 2014-2020 approved by the Government Decision No. 1032/2013, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103097&lang=ro#

[24] National Strategy on Noncommunicable DiseasesPrevention and Control 2012-2020 approved by the Parliament Decision No. 82/2012, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=17816&lang=ro

[25] Strategy for the Development of Human Resources in Health 2016–2025 approved by the Government Decision No. 452/2016, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=92216&lang=ro

The HSDS 2008-2017 resulted in stronger governance, increased financial stability of the health system and better financial protection for the whole population, transformation of health services and models of care, and increased resources in health[26]. Building on this strong foundation the National Healthcare System Strategy 2031 will introduce a new approach to existing health challenges, aligned to European priorities on improving health of the population and strengthening health systems.

In 2022 the Government of the Republic of Moldova is going to launch the new National Healthcare System Strategy 2031 (NHSS 2031), a commitment set out in the Government Action Plan 2021-2022, approved by the Government Decision No. 235/2021[27]. The NHSS 2031 is oriented towards the long-term development of the healthcare system and has the following vision: *A healthier Moldovan population through active contribution of a modern and efficient healthcare system, which meets the needs of each individual.* NHSS 2031 deepens the strategic aspects of health, included in the National Development Strategy Moldova 2030 that recognizes the importance of both healthcare delivery and improving the population's health and is focused on achieving the goals set by the Sustainable Development Goals with an impact on human health.

The following fundamental principles have been identified to guide all stakeholders and institutions throughout NHSS 2031 delivery and implementation: leave no one behind; person-centered health system; fairness and non-discrimination; respect and dignity; response capacity; rational and efficient use of resources; transparency and accountability; professional ethics; empowerment of health personnel; individual responsibility; commitment to strategic objectives.

To effectively respond to Moldovans' present and future healthcare needs, the NHSS 2031 has identified the following priority areas of focus:

- *Integrated quality medical services for everyone* with the objective: ensuring integrated person-centered healthcare services that are equitable and accessible throughout the life course.
- *Public health performance* with the objective: strengthening the public health system in terms of proactive health promotion, disease prevention, including improved crisis response capacity.
- *Medicines and medical devices* with the objective: ensuring access to quality, safe and effective medical products.
- *Human resources for health* the objective: ensuring universal coverage of the health system with well-trained and motivated staff.

[26] Assessment of the Healthcare System Development Strategy 2008–2017 of the Republic of Moldova, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2020/09/Assessment-of-the-Healthcare-System-Development-Strategy-2008%E2%80%932017-of-the-Republic-of-Moldova-Final-Report-.pdf
[27] The Action Plan of the Government of the Republic of Moldova, Government Decision No. 235/2021, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128407&lang=ro

- *Digitalization of the health system* with the objective: developing sustainable digital solutions to achieve universal coverage with health services.
- *Health financing* with the objective: ensuring equitable financial protection of citizens and financial sustainability of the health system.
- *Good governance* with the objective: improving the governance of the health system
- by strengthening the evidence informed policy making with a holistic and cross-sectoral approach to health.

The NHSS 2031 is supported by a number of national programmes designed to address priority public health issues and meet specific needs of the population, including vulnerable groups: National the Programme for the Prevention and Control of HIV/AIDS and Sexually Transmitted Infections[28], the National Tuberculosis Response Programme for 2022-2025[29], the Strategy for the development of human resources in the health system for the years 2016-2025[30], the National Cancer Control Program for 2016-2025[31]. Aiming to strengthen disaster management through advance planning, the country has updated the Public Health Emergency Preparedness and Response Plan[32], which provided an operational framework to establish procedures and response to COVID-19 and, more recently, the refugee crisis. The following programmes are in process of drafting and approving: the National Immunization Programme, the National Programme for the Prevention and Control of Antimicrobial Resistance, the National Programme on Noncommunicable Diseases Prevention, and the National Mental Health Programme.

By implementing the NHSS 2031, Moldova will pave the way to a high-performing healthcare system and a healthy population, physically and mentally.

[28] National Programme for the Prevention and Control of HIV / AIDS and Sexually Transmitted Infections, approved by Government Decision No. 134/2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130469&lang=ro

[29] National Tuberculosis Response Programme for 2022-2025, approved by Government Decision No. 107/2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130171&lang=ro

[30] Strategy for the development of human resources in the health system for the years 2016-2025,approved by Government Decision No. 452/2016, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=92216&lang=ro

[31] National Cancer Control Program for 2016-2025, approved by Government Decision No. 1291/2016, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=96628&lang=ro

[32] Public Health Emergency Preparedness and Response Plan, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2020/09/Plan-USP-07.09.2020.pdf

13. Does Moldova keep and regularly update data on life expectancy at birth, self-perceived health, self-reported unmet need for medical examination and care, death rate due to chronic diseases, suicide death rate, obesity rate (where breakdowns are possible by gender, age group, regions, educational level, and income).

The National Bureau of Statistics (NBS) is the central administrative authority subordinated to the Government in charge of collecting and managing demographic, social, and other types of data, maintaining and updating the statistical database, conducting regular population censuses and other surveys, as well as drafting and publishing reports. The NBS receives the health indicators that are submitted by the Ministry of Health, whereas the National Public Health Agency (NPHA) is the entity in charge of the production of health statistical data.

Regarding the above-mentioned indicators:

- **Life expectancy at birth** – NBS develops and annually publishes this indicator; the data are broken down by sex and residence. The data are available in the statistical databank, domain: *Population and demographic processes*[33].
- **Self-perceived health and self-reported unmet needs for medical examination and care** are collected by the National Bureau of Statistics based on a selective sample-based survey, *Access of population to healthcare services,* which represents a module of the survey on households, the *Households Budget Survey*. The data provided by survey are broken down by sex, age group, residential area, welfare, and, where applicable, compulsory healthcare insurance. The reports are published on the web page of the NBS[34]. The population survey *Access of population to healthcare services* has been conducted periodically since 2008; the last survey was carried out in 2021. The results have to be validated and shall be published in the second semester of 2022.
- **Death rate due to chronic diseases** – population mortality rate by main causes of death, in particular chronic conditions, is calculated quarterly and annually by the National Public Health Agency (NPHA). The data are disaggregated by age groups, residential area, sex, and regions and are available on the NPHA web page, section Healthcare Data Management in the Statistical Year Books of the Moldovan Healthcare System, Demographics[35].

[33] The National Bureau of Statistics, Statistical Databank, available in English at: https://statbank.statistica.md/PxWeb/pxweb/en/20%20Populatia%20si%20procesele%20demografice/20%20Populatia%20si%20procesele%20demografice_POPrec_POP020/POP020700rcl.px/?rxid=b2ff27d7-0b96-43c9-934b-42e1a2a9a774

[34] The National Bureau of Statistics, Publications, available in Romanian at: https://statistica.gov.md/pageview.php?l=ro&idc=350&id=5877

[35] Statistical Year Book Public Health in Moldova, available in Romanian at: https://drive.cloud.gov.md/index.php/s/ksctWJqXnstjRRW?dir=undefined&path=%2F3.ANUARE%20%20STATISTICE%20%20AL%20%20SISTEMULUI%20%20DE%20%20S%C4%82N%C4%82TATE%20%20DIN%20%20MOLDOVA%2FSanatatea%20publica%20in%20Moldova%202020&openfile=113434

- **Suicide death rate** – population mortality rate by suicide is calculated quarterly and annually by the NPHA based on death certificates issued by Forensic Medicine Centre. The data are disaggregated by age groups, residential area, sex, and regions and are available on the NPHA web page, section Healthcare Data Management in the Statistical Year Books of the Moldovan Healthcare System, Demographics.
- **Obesity rate** – is collected quarterly and annually according to the statistical Report on the number of diseases registered in patients residing in the medical facility catchment area, (statistical form no.12-health[36]). It comprises information disaggregated by age groups, sex and residential area. Data on obesity prevalence in the population is also collected through periodically conducted population surveys.

14. What was the health expenditure in Moldova in the last financial year (% of GDP & total in million euro), and how was it structured? Are there any constraints?

The total expenditures of the health system of the Republic of Moldova are covered from the mandatory health insurance funds, state budget, local budgets, household expenses and other sources such as donations, grants, sponsorships, etc.

In 2019, **the total health expenditures** in the Republic of Moldova amounted to 682 million euro or 6.5% of GDP[37]. The largest share of total health expenditure is held by the domestic general Government health expenditure 60% or 409 million euro. Domestic private health expenditure constitutes 37% or 252 million euro, while external health expenditure accounts for 3% or 21 million euro out of total health expenditure[38].

In 2004, the Republic of Moldova introduced a system of publicly financed mandatory health insurance with a defined benefits package managed by a single purchasing agency, the National Health Insurance Company (NHIC). NHIC pools mandatory health insurance contributions (payroll taxes) with transfers from the state budget and uses these funds to contract and pay a mix of public and private health service provides.

The right to mandatory health insurance (MHI) is granted to the citizens of the Republic of Moldova by the Law on Mandatory Health Insurance, No. 1585/1998[39], regardless of a person's income and the size of contributions to MHI funds.

[36] Statistical form, available in Romanian at: https://drive.cloud.gov.md/index.php/apps/onlyoffice/s/ksctWJqXnstjRRW?fileId=112903
[37] WHO Global Health Expenditure Database, available in English at: (https://apps.who.int/nha/database/ViewData/Indicators/en)
[38] WHO Global Health Expenditure Database, available in English at: (https://apps.who.int/nha/database/ViewData/Indicators/en)
[39] Law No.1585/1998 on mandatory health insurance, available in Romanian at:

The revenues of the MHI funds consist of MHI premiums paid by taxpayers, transfers from the state budget and other revenues (fines, administrative penalties, etc.).

The amount of transfers from the state budget to MHI funds for categories of people insured by the Government is established annually by the state budget law, representing the approved amount of transfers from the state budget to MHI funds for the previous year, indexed with the consumer price index for the previous year[40]. As a share of contribution to the MHI funds, this type of revenue constituted 49% in 2021.

The public expenditures for health in the Republic of Moldova in 2021 amounted to 646.5 million euros (13527.9 million lei) or 5.6% of GDP, of which: state budget - 365.5 million euros (7648.1 million lei) , including transfers to MHI funds - 278.8 million euros (5835.0 million lei), local budgets - 7.8 million euros (162.7 million lei), MHI funds - 552.1 million euros (11552.1 million lei)), including transfers from the state budget - 278.8 million euros (5835.0 million lei). The largest share in total public expenditures it is owned by the MHI funds, increasing from 70% in 2004 to 85.4% in 2021[41].

The public funding for health care in 2009-2021 was influenced by existing budgetary constraints, with public health expenditures accounting for 5.6% of GDP in 2021 compared to 6.4%. in 2009[42].

Out-of-pocket share of 36.8%[43] (a.2019) indicates the degree of dependence of the health system financing on household spending. Although declining, the share of out-of-pocket payments in total health expenditure remains significant.

Outpatient medicines consistently account for the largest share of out-of-pocket spending. Among the poorest quintiles, the share of outpatient drug spending rose from about 78% in 2008 to 92% in 2016[44].

https://www.legis.md/cautare/getResults?doc_id=128122&lang=ro

[40] Law No.1593/2002 on amount, methodology and terms of payment of compulsory health insurance contributions, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130909&lang=ro

[41] Ministry of Finance, Open Data Catalog of the Ministry of Finance for 2021, available in Romanian at: https://www.mf.gov.md/ro/content/catalogul-de-date-deschise-al-mf-pentru-anul-2021

[42] Ministry of Finance, Open Data Catalog of the Ministry of Finance for 2021, available in Romanian at: https://www.mf.gov.md/ro/content/catalogul-de-date-deschise-al-mf-pentru-anul-2021

[43] WHO Global Health Expenditure Database, available in English at: https://apps.who.int/nha/database/ViewData/Indicators/en

[44]National Bureau of Statistics

15. Is universal health coverage provided in Moldova? What measures are in place to allow the poorest people, those in rural and remote areas, people with disabilities, people living with HIV, children, elderlies and adults who use drugs, prisoners, women in prostitution, LGBTI, internally displaced persons, and Roma access to healthcare?

Ensuring universal health coverage (UHC) is one of the goals set by the United Nations in adopting the Sustainable Development Goals by 2030.

The Republic of Moldova has clearly defined state policies in healthcare. The principles of universal access to healthcare and the elimination of inequalities in coverage with health services are set out in the National Health Policy[45], which fully corresponds to the UHC 2030 Agenda.

In the Republic of Moldova, mandatory health insurance is the financial instrument to facilitate the achievement of universal coverage by increasing funding, improving access to health services, reducing informal payments, and ensuring an efficient use of funds in health.[46] Individuals enrolled in the mandatory health insurance scheme receive a benefit package of covered services, including emergency care, primary and secondary care services, hospital care, dental care, high performance services, home care visits.

At the same time, pursuant to the provisions of the Law on mandatory health insurance, pre-hospital emergency care and primary care services are extended, free of charge, to all, irrespective of insurance status. In case of socially conditioned diseases with a major impact on public health, such as tuberculosis[47], oncological diseases[48], mental conditions[49], HIV/AIDS[50], infectious diseases, medical services, including specialized outpatient and hospital care, are also guaranteed at no cost to both insured and uninsured individuals. In addition, services and medications provided within National Programs addressing priority public health issues (tuberculosis, HIV, viral hepatitis, diabetes, mental health, etc.) are state funded and universally available.

Over the years, the population's access to compensated medicines has been facilitated, both the number of preparations and the spectrum of pathologies treated

[45]Government Decision No. 886/2007 on approving of the National Health Policy, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=31871&lang=ro

[46]Law No. 1585/1998 on mandatory health insurance, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128122&lang=ro

[47] National Tuberculosis Response Programme for 2022-2025, approved by Government Decision No. 107/2022, available in Romanian at, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130171&lang=ro

[48] National Cancer Control Program for 2016-2025, approved by Government Decision No. 1291/2016, available in Romanian at : https://www.legis.md/cautare/getResults?doc_id=96628&lang=ro

[49] National Mental Health Programme for 2017-2021, approved by Government Decision No. 337/2017, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=100948&lang=ro

[50] National Programme for the Prevention and Control of HIV / AIDS and Sexually Transmitted Infections, approved by Government Decision No. 134/2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130469&lang=ro

with them being extended.[51] Prescription of compensated drugs is performed not only in long-term outpatient treatment[52], but also in the episodic one performed in day healthcare, procedure offices or at home[53].

Regarding the access of vulnerable groups to medical services:

According to the Law on mandatory health insurance, the Government provides state-guaranteed insurance for a number of categories of unemployed persons residing in the Republic of Moldova and registered with the competent institutions of the Republic of Moldova.

People Living with HIV and key populations: The National Program for prevention and control of HIV and sexually-transmitted infections 2022-2025[54] sets provisions for universal access to rights-based and people centered prevention, testing, diagnosis, treatment and support through basic and comprehensive service packages for people who inject drugs, sex workers, men who have sex with men and transgender people, people in prisons and other close settings, and people who live with HIV. Both people in communities, as well as those deprived of liberty benefit from equal access to HIV services, opioid agonist therapy and full access to general health services. The services are tailored to different needs of key populations, age-specific (for people who use drugs of all ages, including children, adults and older people) and are gender-responsive. These have been aligned to service standards as set by technical guidance of WHO, UNFPA, UNODC.[55],[56],[57] The full range of biomedical interventions are provided free of charge through public health sector and community-based service platforms using rights-based approaches and aligned to international standards of care. Funding for services, including comprehensive community-based services is provided by the National

51 Government Decision No. 106/2022 on the prescription and dispensing of medicines and compensated medical devices for the outpatient treatment of persons registered with the family doctor, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130165&lang=ro

52 Ministry of Health Order No . 492/ 139/2013 on reimbursed medicines from the compulsory insurance funds of healthcare, available in Romanian at : https://www.legis.md/cautare/getResults?doc_id=129700&lang=ro#

53 Ministry of Health Order No . 727/494/2016 on the approval of the Regulation on the organization of episodic treatment in the treatment room / day hospital, procedure offices and at home, with medicines reimbursed from the funds of the compulsory health insurance, of some diseases frequently encountered in the practice of the family doctor, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=129709&lang=ro

54 National Program for the Prevention and Control of HIV and STIs 2022-2025 approved by Government Decision No. 134/2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130469&lang=ro

55 Ministry of Health Order No. 551/2011 approving Standards on harm reduction for injecting drug users and psychosocial assistance for drug users, available in Romanian at: : http://msmps.gov.md/wp-content/uploads/2020/06/9040-Ordin.pdf

56 Standards on harm reduction for injecting drug users, available in Romanian at: http://msmps.gov.md/wp-content/uploads/2020/06/9041-STANDARD20reducerea20riscurilor202011.pdf

57 Standards on psychosocial assistance for drug user, available in Romanian at: : http://msmps.gov.md/wp-content/uploads/2020/06/9042-STANDARD20Asistenta20psihosociala202011.pdf

Health Insurance Agency, as well as donors. For refugees access to these services has been extended and fully ensured.[58][59]

LGBTQI: The Law No. 121/2012 on assuring equality[60], sets provisions for prevention and combating of discrimination, as well as for assuring equality of all persons who are found on the territory of the Republic of Moldova in political, economic, social, cultural and other spheres of life, without distinction of race, color, nationality, ethnic origin, language, religion or beliefs, sex, age, disability, opinion, political belonging or any other similar criterion. There are express provisions on gender, sexual orientation and sexual practices as protection criteria, which refer to the men who have sex with men and transgender persons. Comprehensive health and social services are provided to men who have sex with men and transgender people via community-based platforms. These include provision of condom and lubricant; testing HIV, Syphilis, Hepatitis B and C, TB screening, health products, disinfectants, information, education and communication, male sexual health services, including gender-based violence and trafficking prevention, client navigation, psychosocial support, peer support, medical consultations, legal aid and sexually-transmitted infections testing.

Similarly, the National Program for TB Response 2022-2025[61] sets provisions for universal access to people-centered services across the continuum spectrum and prioritizes key and vulnerable populations through a mix of service delivery at different levels of care (primary care, specialised care), community-based platforms and social services. Among priority populations for TB prevention and screening are mentioned people living with HIV, people who use drugs, homeless people, internally displaced people, ethnic minorities. The TB law is currently under revision to integrate rights-based, people-centered, multisectoral response to eliminate tuberculosis in Moldova.

Children. The parental migration influences children's access to healthcare, with children whose mothers are away being more affected. At the same time, children with development delays, requiring increased attention from an early age to ensure their proper development and integration into society, as well as neglected or family abused children are vulnerable in terms of access to activities related to a healthy lifestyle and medical services.

[58] Ministry of Health Order No. 166/2022 on the organization of medical assistance to refugees, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2022/02/Ordinul-MS-nr.-166-din-26.02.2022.pd
[59] Ministry of health Order No. 210/2022 on the organization and provision of medical assistance to refugees from Ukraine, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2022/03/Ordin-nr.-210-din-04.03.2022-Modul-de-organizare-si-acordare-a-AM-refugiatilor-din-Ucraina-2.pdf
[60] Law No. 121/2012 on assuring equality, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106454&lang=ro
[61] National Tuberculosis Response Programme for 2022-2025, approved by Government Decision No. 107/2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130171&lang=ro

In this context, state policies are geared towards the development of early intervention services[62], services with multisectoral involvement, meant to contribute to the improvement of children's health indicators, but also to the decrease of infant mortality indicators.[63]

An important role for the children's health care surveillance and monitoring is the standardization of services for children at certain stages of age, including patronage of children at home[64], with identification in the process of monitoring of both medical and social aspects, including abuse and violence.

Adolescents and youth. In recent years, a number of measures have been taken in the Republic of Moldova to improve the health of adolescents and young people and to increase their access to youth-friendly health services. In 2005, the Ministry of Health approved the concept document for the development of youth-friendly health services - the National Concept for youth-friendly health services (YFHS Concept), followed by the establishment of the Youth Clinics network. Initiated as pilot projects supported by development partners, YFHS has expanded at the national level and since 2008 are financed through the NHIC funding. Development of these services have greatly improved coverage for young people. In 2018, the Youth Clinics network covered about 27% of young people aged 10-24 with services, compared to 5% in 2011[65].

They offer a minimum or an extended package of services, which include information, counseling, integrated health services with psychosocial assistance and referral, aimed at reducing a number of priority issues, such as: 1. STIs/HIV/AIDS; 2. Early pregnancy; 3. Mental health problems following substance abuse (alcoholism, drug dependence); 4. Psycho-emotional and personality disorders; 5. Health problems as a result of violence; 6. Nutritional disorders, especially malnutrition (I, Fe); 7. Developmental disorders in puberty.

Adolescent Services are currently provided in 41 youth-friendly health centers in municipalities and districts that cover the entire country. The process of expanding YFHS is supported by SDC, UNICEF through the "Healthy Generation – scaling up youth-friendly health services" Project.

People with disabilities. By Government Decision no. 723/2017, the 2017-2022 National Program for Social Inclusion of Persons with Disabilities and the Action

[62]Government Decision No .816/2016, for the approval of the Framework Regulation on the organization and operation of early intervention services and minimum quality standards for early intervention services available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=93683&lang=ro

[63] Government Decision No . 1182/2010 for the approval of the Regulation on the mechanism of intersectoral collaboration in the medical-social field in order to prevent and reduce the mortality rate of mothers, infants and children up to 5 years of age at home, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103311&lang=ro

[64] Ministry of health Order No. 964/2019 on the approval of the Standard for the supervision of the growth and development of the child in outpatient conditions and of the Child Development Card, available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordin_nr._964_din_020919.pdf

[65] Adolescent pregnancy in the Republic of Moldova. New York: UNFPA; 2019, available in English at: https://moldova.unfpa.org/en/publications/adolescent-pregnancy-republic-moldova-qualitative-study-summary

Plan on its implementation were approved[66]. This program provides for an intersectoral approach to the social inclusion of people with disabilities and to ensure that their fundamental rights are respected in the same way as other citizens in all areas of social life.

Older Adults. The provisions of the normative acts ensure full and equitable access to health services for older people. In accordance with the Law on Mandatory Health Insurance No. 1585/1998, the Government has the status of insured for subjects of mandatory health insurance, including the older people (pensioners, people with disabilities, etc.).

At the level of primary health care, a complex assessment of the older adults' health status is carried out annually for an early detection of diseases that need integrated care, in order to promote healthy aging. Similarly, services are provided to address specific issues in older adults, long-term care related issues, emphasis on specific services for long-term treatment of chronic diseases, geriatric treatment, rehabilitation (kinesitherapy, physical medicine).

Women of reproductive age. The right to sexual and reproductive health is considered a fundamental human right in the Republic of Moldova. Access to safe and efficient sexual and reproductive healthcare services, as an integral part of the right to healthcare, is established by the Constitution of the Republic of Moldova and Law no. 138/2012 on reproductive health[67].

The 2018-2022 National Program on Sexual and Reproductive Health and Rights, approved by Government Decision No. 681/2018[68] establishes national interventions in the field of sexual and reproductive health and rights, based on the principle of ensuring the right of every person to all components of sexual and reproductive health at any stage of life and access to sexual and reproductive health services, tailored to the needs of beneficiaries, including people with special needs (for example, adolescents, victims of sexual violence and trafficking in human beings, socio-economically vulnerable people, people with disabilities, older people, etc.), without discrimination.

Roma population. In accordance with the law, persons of Roma ethnicity have the same rights and obligations in the field of mandatory health insurance as all citizens of the Republic of Moldova.

[66] Government Decision No . 723/2017 on the approval of the National Social Inclusion Program of people with disabilities for the years 2017-2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=101863&lang=ro

[67] Law No. 138/2012 on reproductive health, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106297&lang=ro

[68]Government Decision No. 681/2018 for the approval of the National Program on Sexual and Reproductive Health and Rights for the years 2018-2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108813&lang=ro

Following the interventions of the state in this field, according to the UNICEF Study[69], there is a decrease in births at an early age and a higher share of Roma women accepting contraceptive methods.

Children in the Republic of Moldova, regardless of their ethnicity and religious affiliation, are a state-insured category that benefits from free vaccination according to the national immunization programs. An important role in promoting vaccinations and informing parents about their role, need and impact in the compact or mixed localities populated by Roma is played by the community mediator.[70] The proportion of vaccinated Roma children aged 0-6 years is quite high - 94%, the differences compared to non-Roma being insignificant by 2 p.p. less compared with non-Roma communities.

16. Is there a national law on health in Moldova? Is data collected on all diseases and how? Do you have a Health Information System in place? Is it based on European Core Health Indicators (ECHI) or on indicators included in the State of Health in the EU?

A comprehensive legislative framework regulates the health sector in the Republic of Moldova with the focus set to ensure universal health coverage and equitable access of the population to qualitative medical services. The Law No. 411/1995 on Health Care[71] is the national organic law that sets the structure and the principles of organization and functioning of the healthcare system of the Republic of Moldova. It has undergone a number of amendments over the years to align to evolving policies and concepts. There is also an extensive number of laws regulating specific areas of the healthcare, as following: Law No. 263/2005 on the rights and responsibilities of the patients; Law No. 264/2005 on medical profession, Law No. 1585/1998 on mandatory health insurance; Law No. 1593/2002 on amount, methodology and terms of payment of compulsory health insurance contributions; Law No. 1402/1997 on mental health; Law No. 1456/1993 on the pharmaceutical activity; Law No. 10/2009 on state surveillance of public health, etc.[72]

On data reporting, the National Agency for Public Health is the entity responsible for producing health statistic, including data on health status and diseases, in accordance with the Programme of Statistical Work approved annually by Government Decision[73]. The National Agency for Public Health collects and

[69] Roma children and their access to services, UNICEF, 2016, available in English at: https://www.unicef.org/moldova/en/reports/roma-children-and-their-access-services

[70] Government Decision No. 557/2013 for the approval of the Framework Regulation on the organization of the activity of the Community Mediator, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125326&lang=ro

[71] Law No. 411/1995 on Health Care, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128014&lang=ro

[72] The healthcare legislative framework repository, available in Romanian at: https://msmps.gov.md/legislatie/sanatate/legislatie-nationala/

[73] Government Decision No. 441/2021 on approving Programme of Statistical Work for 2022, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=124758&lang=ro

centralizes health data based on a unique system for collecting and processing primary data submitted by medical institutions via statistical forms in electronic format, which provides disaggregation by age groups (children and adults) and regions/rayons. Morbidity and mortality data for all diseases are classified according to the International Classification of Diseases, 10-th revision (ICD-10). All indicators are calculated applying WHO definitions and are part of the Health for All Database[74].

The general morbidity is collected, quarterly and annually, via statistical form on diseases diagnosed in persons living within the area covered by medical institution (Statistical Form No 12-san[75]). The specific morbidity statistics is collected via statistical forms for a number of specific conditions, including TB, syphilis, gonorrhea and dermatomycosis, malignant tumors, mental and behavioral disorders, neurological disorders. Syndromic surveillance is in place for key conditions (e.g., acute flaccid paralysis). Rotavirus surveillance has been instituted at sentinel surveillance sites.

Data on health statistics and medical care is published on the webpage of the National Agency for Public Health, under the heading *Health data management*, Statistical Yearbooks of the Health System of Moldova.[76]

Related to Health Information System, digitalization and e-transformation of the health system is among the immediate priorities included in the Activity Program of the Government[77]. Currently, there are following HISs developed (Government Decision No. 586/2017 on Regulation on keeping the Medical Register[78]): for primary health care, hospital services, human resources in the health system, blood services, and transplant. Available systems operated by different institutions within the health sector lack interoperability and data sharing. The HIS in place is overly fragmented and needs reengineering to create one cohesive information system. A roadmap to modernize the current HIS and introduce key digital health services for citizens (e.g. Electronic Health Record and ePrescription facilities) is being developed in line with EU and global standards in this area, as part of the support provided by the WHO for development of a new national digital health strategy for Moldova by the end of 2022.

[74] European Health Information Gateway, Health for All, available in English at: https://gateway.euro.who.int/en/hfa-explorer/

[75] Statistical Form, available in Romanian at: https://drive.cloud.gov.md/index.php/apps/onlyoffice/s/ksctWJqXnstjRRW?fileId=112903

[76] Statistical Year Book Public Health in Moldova, available in Romanian at: https://drive.cloud.gov.md/index.php/s/ksctWJqXnstjRRW?path=%2F3.ANUARE%20%20STATISTICE%20%20AL%20%20SISTEMULUI%20%20DE%20%20S%C4%82N%C4%82TATE%20%20DIN%20%20MOLDOVA

[77] The Activity Programme of the Government "Moldova Vremurilor Bune", available in Romanian at: https://gov.md/sites/default/files/document/attachments/programul_de_activitate_al_guvernului_moldova_vremurilor_bune.pdf

[78] Government Decision No. 586/2017 on Regulation on keeping the Medical Register, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=114512&lang=ro

17. What share of mental health services are provided by institutions in Moldova (vs. community-based care), what are their admission/release criteria, and what are the rights of mental health patients?

Mental health and mental well-being is a right of every citizen of the Republic of Moldova. The state guarantees access to the highest standards of living and health, including mental health, to all citizens, without discrimination on grounds of gender, nationality, age, religion, social status or disability.

The Republic of Moldova, a state with pro-European and democratic aspirations, by adhering to international conventions on respect for human rights and human dignity has shown that it pays special attention to the physical and mental well-being of its citizens.

The promotion of international mental health standards and good practices, as evidenced by the signing of the Helsinki Declaration on Mental Health in 2005, the ratification of the United Nations Convention on the Rights of Persons with Disabilities in 2010, the adoption of the European Mental Health Action Plan, created the necessary premises to improve the situation regarding mental illness and increase mental well-being in the Republic of Moldova.

In the context of the World Health Organization recommendations and the provisions of the United Nations Convention for the Protection of the Rights of Persons with Disabilities, the Republic of Moldova, in accordance with the European Mental Health Action Plan 2013-2020 (EUR / RC63 / 11) in 2019, the action plan of the extended until 2030 (72nd World Health Assembly), the Republic of Moldova has developed a complex system of mental health services provided in medical facilities (primary care institutions, community mental health centers, acute psycho-narcological beds in general hospitals) and social at community level and specialized tertiary health institutions, designed to prevent mental illness, treatment and psychosocial rehabilitation of people with mental health problems.

The development of the network of Community Mental Health Centers has favored the deinstitutionalization process by reducing the flow of patients to psychiatric hospitals and increasing the number of referrals to community services. Thus, during the period 2012-2021, the number of people treated in inpatient care decreased from 21153 (on 2080 beds) in 2012 to 12894 (on 1635 beds) in 2021.

Government Decision no. 55/2012 approves the Framework Regulation for the functioning of the Community Mental Health Center and the Quality Standards (Annex No. 1 to the Framework Regulation of the Community Mental Health Center).[79]

[79] Government Decision No. 55/2012 on Framework Regulation for the functioning of the Community Mental Health Center and the Quality Standards, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=20525&lang=ro

Hospitalization in specialized inpatient institutions can be with or without free consent. The admission criteria in the specialized inpatient institutions, with free consent, are stipulated in Article 27 of the Law no. 1402/1997 on mental health[80]. Thus, the basis for hospitalization in the psychiatric hospital can serve the decision of the psychiatrist to perform the examination or treatment in inpatient conditions for mental disorders, the need for a psychiatric examination in cases and the manner provided by law or court decision

The grounds for hospitalization without free consent, stipulated in Art. 28 of Law No. 1402/1997, are in the following situations: the person suffering from mental disorders can be hospitalized in the psychiatric hospital without his free consent or that of his legal representative who acts according to the wishes expressed by the person suffering from mental disorders, until the issuance of the court decision, if its examination or treatment is possible only in inpatient circumstances, and the mental disorder is serious and conditions: a) the direct social danger; b) serious harm to his health if he is not given psychiatric assistance.

The rights of patients with mental health problems

According to Article 36, paragraph (1) of the Constitution of the Republic of Moldova, "The State guarantees every person the right to health care."

The rights of persons with mental health problems are ensured by the provisions of the legislative and normative acts of the Republic of Moldova and internationally:

- Article 5 of Law No. 1402/1997 on mental health
- 2. Law No. 166/2010 ratifying the United Nations Convention on the Rights of Persons with Disabilities[81]
- 3. Article 5, letter e) of Law No. 138/2012 on reproductive health.[82]
- 4. Regulation on the safe termination of pregnancy in a safe manner, which stipulates mandatory counseling, as well as consent by signing the patient's informed consent[83]

[80] Law No. 1402/1997 on mental health, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=108889&lang=ro

[81] Law No. 166/2010 ratifying the United Nations Convention on the Rights of Persons with Disabilities, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=24019&lang=ro

[82] Law No. 138/2012 on reproductive health, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=106297&lang=ro

[83] Ministry of health Order No. 647/2010 on the safe termination of pregnancy in a safe manner, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=37226&lang=ro

18. What reforms (if any) have taken place on mental health in the national health system of Moldova?

The Ministry of Health is committed to designing and implementing a profound structural reform of the mental health sector in the Republic of Moldova. Thus, several policy documents were approved and implemented:

The strategy for the development of mental health services at the community level and the integration of mental health in primary health care for 2013-2016, has allowed the change of the paradigm of approaching patients with mental health problems, in the context of World Health Organization recommendations and provisions of the United Nations Convention on the Protection of the Rights of Persons with Disabilities, the modernization of Mental Health Services and their Transfer from Hospitals and Specialized Institutions to Primary Health Care and Community Services.

Mental health reforms have been supported over the years by the World Health Organization, the Swiss Agency for Development and Cooperation. Thus, between 2005 and 2011, occupational therapy workshops and community mental health centers were created. The new services served as a basis for subsequent regulations on psychiatric care standards, funding mechanisms and the introduction of new modules in the university medical curriculum.

The process of developing community mental health services at the national level started in 2014[84] by creating a network of community mental health centers at the national level[85] (in municipalities and each second-level administrative-territorial unit)[86], in accordance with the Framework Regulation of the Community Mental Health Center and the Quality Standards[87]

In order to improve mental health, the well-being of the whole population and reduce the burden of mental disorders, by promoting, preventing and intervening in mental health determinants, with a focus on vulnerable groups, the National Mental Health Program (NMHP) was approved and implemented for the years 2017-2021[88] .

[84] Ministry of health Order No. 71/2015, on the Implementation of mental health reformes implementation, available in Romanian at: http://www.ms.gov.md/sites/default/files/legislatie/ord_No.._71/.2015-cu_privire_la_implimentarea_proiectului_reforma_ssm_din_moldova_in_raioanele_pilot.pdf

[85] Ministry of Health Order No. 407/2014 on the Community mental health centres, available in Romanian at: http://www.ms.gov.md/sites/default/files/legislatie/ord_No._407/2014-cu_privire_la_centrele_comunitare_de_sanatate_mintala.pdf

[86] Ministry of Health Order No. 71/2015, on the Implementation of mental health reformes implementation, available in Romanian at: http://www.ms.gov.md/sites/default/files/legislatie/ord_No._71/.2015-cu_privire_la_implimentarea_proiectului_reforma_ssm_din_moldova_in_raioanele_pilot.pdf

[87]Government Decision No. 55/2012 on Framework Regulation for the functioning of the Community Mental Health Center and the Quality Standards, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=20525&lang=ro

[88]Government Decision No. 337/2017 "On the approval of the National Program for mental health for the years 2017-2021, the available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=100948&lang=ro

The full realization of the NMHP for the years 2017-2021 contributed to the achievement of the following results:

- 50% reduction in the number of hospitalizations in psychiatric beds by providing quality mental health services at the community level, according to needs, at all stages of life;
- Harmonize the national legislative framework with international rigors and improve the quality of life of people affected by mental illness[89];
- Adjusting the normative acts regarding the organization and functioning of the mental health services to the needs of the beneficiaries[90];
- Providing mental health services to all groups of the population, particularly vulnerable groups. At present, 40 National Mental Health Centers (NMHC) operate and are contracted by the National Medical Insurance Company, serving a population of 2,622,000. NHMCs have the capacity to provide the following medical-psycho-social services, financed from the sources of the compulsory health insurance funds. Psychotropic drugs with a 100% compensation rate are provided for the treatment of people affected by chronic mental illness[91].

[89] Law No.1402/1997 Mental Health Act ,available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=99483&lang=ro#

[90] Ministry of Health Order No. 225 /2017 regarding the approval of the primary medical records used by the Community Mental Health Centers ,available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordin_nr._225_din_17.03.2017_cu_privire_la_aprobarea_formularelor_de_evidenta_medicala_primara_utilizate_de_catre_centrele_comunitare_de_sanatate_mintala_0.pdf
Ministry of Health Order No . 415 / 2017 regarding the organization of the activity of the psychiatry department in the general profile hospital, available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordin_nr._415_din_31.05.17-_cu_privire_la_organizarea_activitatii_sectiei_de_psihiatrie_in_spitalul_de_profil_general.pdf
Ministry of Health Order No. 474/2017 on the approval of the activity monitoring indicators and the performance indicators of the Community Mental Health Center, available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordinul_nr._474_din_15.06.2017_cu_privire_la_aprobarea_indicatorilor_de_monitorizare_a_activitatii_si_indicatorilor_de_performanta_a_centrului_comunitar_de_sanatate_mintala.pdf
Ministry of Health Order No. 1031/ 2018 on the Examination Regulations of the mental capacity of the applicants to hold and use weapons and ammunition, engage in social activities and professionals with increased responsibility,available in Romanian at : https://www.legis.md/cautare/getResults?doc_id=111356&lang=ro
Ministry of Health Order No . 368/2020 on some additional measures to ensure the access of the population to narcological psychiatric mental health services in conditions of emergency, available in Romanian at : .https://msmps.gov.md/sites/default/files/legislatie/ordinul_nr._368_din_06.04.2020_cu_privire_la_asigurarea_accesului_populatiei_la_servicii_de_sanatate_mintala_psihiatrice_si_narcologice_in_conditiile_starii_de_urgenta.pdf
Government Decision No. 234/2019 for the approval of the Framework Regulation on organization and operation of the Specialized Center intervention in autism spectrum disorders and a Minimum quality standards , available in Romanian at : ,https://www.legis.md/cautare/getResults?doc_id=114122&lang=ro

[91] Ministry of Health Order No . 492/ 139/2013 on reimbursed medicines from the compulsory insurance funds of healthcare, available in Romanian at : https://www.legis.md/cautare/getResults?doc_id=129700&lang=ro#

National clinical protocols[92] and standardized clinical protocols for family physicians[93] have been developed, and approved by the Ministry of Health.

In the context of deinstitutionalization and transformation of residential institutions, the National Program for deinstitutionalization of persons with intellectual and psychosocial disabilities in residential institutions for the years 2018-2026 was implemented[94]. Thus, the Plans for the Transformation of Placement Centers were elaborated and approved, which establish the necessary actions to ensure the process of transforming the institutions from the provider of residential services into a provider of community social services for people with intellectual and psychosocial disabilities.

The Government Action Plan for 2021-2022 includes activities to develop and approve the National Mental Health Program for 2022-2026 and the draft law on mental health and well-being, both of which are under development.

A. Tobacco control, Alcohol abuse prevention & Drug abuse prevention, Electromagnetic fields

19. To what extent is national legislation in Moldova aligned with the EU acquis in these areas?

a) tobacco control domain:

At the national level the area of tobacco control is regulated by the Law No. 278/2007 on tobacco control[95]. In 2015, the law was comprehensively amended to comply with the key provisions of the WHO Framework Convention on Tobacco Control (FCTC), the Republic of Moldova being a Part to the Convention since 2009. The state regulatory mechanisms necessary to effectively protect people from hazardous effects of tobacco use and exposure to tobacco smoke are laid down in the following regulations:

Sanitary Regulation on Ingredients of Tobacco and Related Products (Approved by Government Decision No. 1065/2016[96]);

[92] National clinical protocols Ministry of Health, available in Romanian at : https://msmps.gov.md/legislatie/ghiduri-protocoale-standarde/psihiatrie-2/
[93] Standardized clinical protocols for family physicians ,available in Romanian at: http://msmps.gov.md/legislatie/ghiduri-protocoale-standarde/psihiatrie/
[94] Government Decision No. 893 /2018 on the approval of the National Program for the deinstitutionalization of persons with disabilities intellectual and psychosocial activities in residential institutions managed by the National Assistance Agency Social Policy for the years 2018-2026 and the Action Plan on its implementation,available in Romanian at : https://www.legis.md/cautare/getResults?doc_id=109067&lang=ro
[95] Law No. 278/2007 on tobacco control, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128322&lang=ro#
[96] Sanitary Regulations on tobacco and related products approved by the Government Decision No. 1065/2016, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=121485&lang=ro#

Sanitary Regulation on the notification and reporting of information on tobacco and related products (approved by Government Decision No. 1065/2016);

Sanitary Regulation on the sale of unfermented tobacco and fermented tobacco, tobacco and related products (approved by Government Decision No. 1065/2016)

Sanitary regulations on **health warnings and labeling of tobacco products, rolled tobacco and related products** (approved by Government Decision no.613/2017[97]).

In order to facilitate a proper functioning of the internal market for tobacco and related products, aiming at a high level of health protection, especially for young people, and to fulfill Moldova's obligations under the WHO FCTC, the national legislative and regulatory framework has been aligned with the EU acquis as summarized below:

Ingredients and emissions of tobacco and related reporting obligations

-Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products and repealing Directive 2001/37 / EC

transposed by:

- Law no. 278/2007 on tobacco control

- Government Decision No. 1065/2016 for the approval of the Sanitary Regulations on Tobacco and Related Products

Labeling and packaging of tobacco products

- Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products and repealing Directive 2001/37 / EC

- Commission Delegated Directive 2014/109 / EU of 10 October 2014 amending Annex II to Directive 2014/40 / EU of the European Parliament and of the Council by establishing the Image Warning Library to be used on tobacco products

- Commission Implementing Decision (EU) 2015/1842 of 9 October 2015 on the technical specifications for the appearance, design and form of the combined health warnings for smoking tobacco products

[97] Sanitary Regulation on health warnings and labeling of tobacco products, rolled tobacco and related products approved by the Government Decision No. 613/2017, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=121486&lang=ro

transposed by:

-Law no. 278/2007 on tobacco control

- Government Decision no.613/2017 for approval Sanitary Regulations on health warnings and labeling of tobacco products, rolled tobacco and related products

Advertising and sponsorship of tobacco products

-Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products

transposed by:

-Law no. 278/2007 on tobacco control

Smoking prevention and health protection

- Council Recommendation 2003/54/EC of 2 December 2002 on smoking prevention and initiatives to improve tobacco control

- Council Decision 2004/513/EC of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control

- Council Recommendation of 30 November 2009 on smoke-free environments (2009 / C296 / 02).

transposed by:

- Law No. 278/2007 on tobacco control

- Law No. 124/2007 on the ratification of the World Health Organization Framework Convention on Tobacco Control[98].

b) in the prevention of alcohol abuse:

National legislation on prevention of alcohol abuse is partly aligned with the EU acquis. The national regulatory and legislative framework well reflects the provisions of the Global Strategy to Reduce Harmful Alcohol Consumption (WHO, 2010) and the European Action Plan to Reduce Harmful Alcohol Consumption 2012-2020 (WHO Regional Office for Europe, 2012).

[98] Law No. 124/2007 on the ratification of the World Health Organization Framework Convention on Tobacco Control, available in Romanian at: https://www.legis.md/search/getResults?doc_id=24971&lang=ro

In the context of the implementation of the National Program on alcohol control for the years 2012-2020[99], the national legislative and regulatory framework has been aligned with the EU acquis as summarized below:

Protecting children from alcohol underage use

Recommendation 2001/458/EC of 05.06.2001 on the drinking of alcohol by young people, in particular children and adolescents

transposed by

Law No. 1100/2000 on the production and circulation of ethyl alcohol and alcoholic products[100]

Media advertising of alcoholic products

Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive)

transposed by

Code No. 174/2018 of audiovisual media services of the Republic of Moldova[101]

Law No. 1100/2000 on the production and circulation of ethyl alcohol and alcoholic beverages

Presentation and labeling of spirit drinks

Regulation (EC) No. 110/2008 of the European Parliament and of the Council of 15 January 2008 concerning the definition, designation, presentation, labeling and protection of geographical indications for spirit drinks

transposed by

Government Decision No. 317/2012 on approval of the Technical Regulation "Requirements for definition, description, presentation and labeling of alcoholic products"[102].

[99] Government Decision No.360/2012 for the approval of the National Program on alcohol control for the years 2012-2020 , available in Romanian at: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=343538

[100] Law No. 1100/200 on the production and circulation of ethyl alcohol and alcoholic products, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=131004&lang=ro#

[101] Code No. 174/2018 of audiovisual media services of the Republic of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130823&lang=ro

[102] Government Decision No. 317/2012 on approval of Technical Regulation "Requirements for definition, description, presentation and labeling of alcoholic products", available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=113716&lang=ro

At the same time, the draft of the National Program on non-communicable diseases prevention and control for the years 2022-2030, which is at the final stage of development (the action included in the Action Plan of the Ministry of Health for 2022, item 30.1[103]), integrates behavioral risk factors, including harmful alcohol consumption, and plans to align with the EU acquis in the field of alcohol control.

c) drug abuse prevention

The legal framework on the drug use prevention is based on the three United nations (UN) Conventions on Drugs, ratified by the Republic of Moldova in 1995 (Single Convention on Narcotic Drugs of 30 March 1961, Convention on Psychotropic Substances of 21 February 1971, Convention against Illicit Drug Trafficking and psychotropic substances from December 201988) and seek continuously to strike a balance between punishment and treatment.

Legislative acts were drafted to regulate the circuit of narcotic and psychotropic substances in the Republic of Moldova and to sanction possible violations of the established rules. In this sense, Law No. 382/1999 on the circulation of narcotic and psychotropic substances and precursors[104], establishes the general rules and restrictions on the circulation of drugs on the territory of the Republic of Moldova. At the same time, the Contravention Code of the Republic of Moldova[105] and the Criminal Code of the Republic of Moldova[106] define the legal framework for bringing to justice individuals and legal persons that have violated the provisions of the legislation on the circulation of narcotic and psychotropic substances. The codes provide for the grounds and conditions for the application of sanctions, as well as the types of penalties applied.

Action in the area of drug use is guided by the National Anti-Drug Strategy 2020-2027[107], which provides for coordination between law enforcement, treatment providers, and prevention professionals to address substance abuse and related problems. The Strategy relies on a balanced approach in which restricting supply and reducing demand are equally important components.

By Government Decision No. 481/2011, the National Anti-Drug Commission was established[108]. In order to implement the National Anti-Drug Strategy for 2020-2027, as well as to fulfill the commitments assumed by the Republic of Moldova

[103] Ministry of Health Order No.1213/2021 Regarding the approval of the Action Plan of the Ministry of Health for 2022 , available in Romanian at: https://msmps.gov.md/wp-content/uploads/2022/01/PA-al-MS-2022-pdf.pdf
[104] Law No. 382/1999 on the circulation of narcotic and psychotropic substances and precursors, available in Romanian at: https://www.legis.md/search/getResults?doc_id=108388&lang=ro
[105] Contraventional Code of the Republic of Moldova No. 218/2008, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=131058&lang=ro#
[106] Criminal Code of the Republic of Moldova No. 985/2002, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130983&lang=ro#
[107] National Anti-Drug Strategy 2020-2027 approved by the Government Decision No. 233/2020, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130564&lang=ro#
[108] Government Decision No. 481/2011 on establishing National Anti-Drug Commission, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130562&lang=ro#

on combating illicit drug trafficking and consumption, the National Anti-Drug Commission, as an advisory, coordinating and initiative body of the Government, creates a platform for continuous communication with ministries, the United Nations Office on Drugs and Crime, other representatives of the central and local public administration, public associations, other entities that contribute to the implementation of drug policy (including non-profit organizations).

d) electromagnetic fields

In order to protect the workers from adverse health effects arising from exposure to electromagnetic fields in working conditions, the Government adopted the Decision No. 697/2018 on the approval of the occupational health and safety minimum requirements regarding the exposure of workers to risks generated by electromagnetic fields[109], which transposes the Directive 2013/35/EU *of the European Parliament and of the Council of 26 June 2013 on minimum health and safety requirements regarding the exposure of workers to the risks posed by physical agents*(electromagnetic fields) (Twentieth Special Directive within the meaning of Article 16 (1) of Directive 89/391 / EEC) and repealing Directive 2004/40 / EC.

In order to protect the public from adverse health effects arising from exposure to electromagnetic fields in the living environments, a draft sanitary regulation on electromagnetic fields exposure limit (0 Hz to 300 GHz) is under development. The Regulation will transpose Recommendation of the European Parliament and of the Council 1999/519/EC of July 12, 1999 on the limitation of exposure of the general population to EMF (0 Hz to 300 GHz). and is planned for approval in August 2022, according to the Government Action Plan.

20. Has Moldova ratified the WHO Framework Convention on Tobacco Control (FCTC) and the Protocol to Eliminate Illicit Trade in Tobacco Products (and are they being implemented)? What are country data on smoking prevalence?

Republic of Moldova ratified the WHO Framework Convention on Tobacco Control (FCTC) in 2007 (Law No. 124/2007[110]), and became a Party to the FCTC on May 4, 2009. Consequently, the country aligned national legislation with the requirements under the Convention through comprehensive amendments to the Law No. 278/2007 on tobacco control[111] adopted in 2015. The law covers many aspects of tobacco control that gradually have entered into force, including: comprehensive smoking ban in enclosed public places and workplaces, pictorial

[109] Occupational health and safety minimum requirements regarding the exposure of workers to risks generated by electromagnetic fields approved by Government Decision No. 697/2018, available in Romanian at: https://www.legis.md/search/getResults?doc_id=108830&lang=en

[110] Law No. 124/2007 on ratification of the WHO Framework Convention on Tobacco Control, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=24971&lang=ro#

[111] Law No. 278/2007 on tobacco control, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128322&lang=ro

health warnings, point-of-sale display ban for all tobacco products, e-cigarettes and devices, ban on all direct and indirect forms of tobacco advertising, regulations on cigarette contents, including flavors ban, sales restrictions. Enforcement mechanisms are in place, including penalties for violations of the tobacco control law provided in the Contravention Code of the Republic of Moldova No. 218/2008[112] (Art. 91^1, Art. 364^1). In addition, the country has implemented FCTC tobacco control measures related to raising tobacco taxes, establishing tobacco cessation services[113], monitoring and surveillance system of tobacco products and tobacco consumption.

In March 2022, Moldovan Parliament adopted the law on accession to the Protocol to Eliminate Illicit Trade in Tobacco Products (Law No. 61/2022[114]) and the country is going to become a Party to the Protocol in the coming months. To implement the obligations under the Protocol, a cross-sectorial task force established on the Prime Minister's request is drafting legal and regulatory changes required to achieve full compliance, including establishment and operation of a tracking and tracing system aligned with EU regulations.

The Republic of Moldova participates regularly in the work of the Conference of Parties, as well as submits to the Convention Secretariat periodic reports on implementation of the Convention[115].

With regard to smoking prevalence, according to the latest available data from 2017 (KAP Survey. Knowledge, Attitudes and Practices regarding tobacco consumption, 2017[116]) the total rate of current smokers among adults (18-69 years old) was 25.2% for both genders, 51.4% for men and 4.9% for women. The STEPS Survey on non-communicable disease risk factors, including tobacco use prevalence has been conducted in 2021, with the data going to be available in coming months after WHO validation. The most recent prevalence of current tobacco smoking among adolescents (13-15 years), according to Global Youth Tobacco Survey conducted in 2019, was 17.5% in boys and 9.5% in girls.

[112] Contravention Code of the Republic of Moldova No. 218/2008, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130832&lang=ro#

[113] Ministry of Health Order No. 139/2016 on establishing tobacco cessation services, available in Romanian at: https://untobaccocontrol.org/impldb/wp-content/uploads/reports/moldova_2016_annex8_moh_ordinance_cessation_service_2016_ro.pdf

[114] Law No. 61/2022 on accession of the Republic of Moldova to the Protocol to Eliminate Illicit Trade in Tobacco Products, available in Romanian at: https://www.parlament.md/ProcesulLegislativ/Proiectedeactelegislative/tabid/61/LegislativId/5897/language/en-US/Default.aspx)

[115] WHO Framework Convention on Tobacco Control Secretariat webpage, Republic of Moldova profile, available in English at: https://untobaccocontrol.org/impldb/republic-of-moldova/

[116] KAP Survey. Knowledge, Attitudes and Practices regarding tobacco consumption, 2017, available in English at: https://msmps.gov.md/sites/default/files/kap_study_2017_tobacco_control_en.pdf

21. How are healthy lifestyles and disease prevention promoted in Moldova?

The national legislation recognises health promotion as an integral part of the legislation, policies and programmes implemented at the central and local levels. Law No. 10/2009 *on state surveillance of public health*[117] lays down the following health promotion priorities (Chapter VII, Art. 46):

- family planning
- mother and child health
- personal and community hygiene
- reduction of alcohol consumption
- tobacco and drugs control
- rational nutrition
- reducing obesity and physical inactivity.

Government-approved national programs to address priority risk factors such as tobacco use, alcohol use, unhealthy diets, reduced physical activity, and the National Health Promotion and Health Education Program play a special role in promoting healthy lifestyles and preventing disease. The majority of policy documents in this field completed their implementation cycle during the time that coincided with the COVID-19 pandemic (2020-2021), which impacted drafting and adoption of follow-up policies. The comprehensive programme for noncommunicable disease prevention and control is close to finalisation. It embeds priority actions that aim to change the risk behaviours associated with common chronic conditions (action included in the 2022 Action Plan of the Ministry of Health, item 30.1[118]). The National Public Health Agency (NPHA) is responsible for the coordination and monitoring of these actions at the national and regional levels.

The healthy lifestyles promotion and disease prevention programmes ensue from a cross-sector approach and contain complex measures to influence health-related behaviours and create favourable environments for healthy lifestyles. The health promotion strategies include a series of approaches:

Regulation – the state applies its legal instruments to limit unhealthy options and promote the consumption of healthy products. For instance, there is a regulatory framework referring to advertising (ban on direct and indirect advertising of tobacco products, restrictions on advertising of alcohol products and restrictions on marketing unhealthy food to children); taxes on tobacco and alcohol products; food labelling.

[117] Law No. 10/2009 on state surveillance of public health, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125959&lang=ro#
[118] Ministry of Health Action Plan for 2022, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2022/01/PA-al-MS-2022-pdf.pdf

Health information and education – As primary educational institutions, schools integrate health promotion in their ordinary teaching and learning practices. The topics on healthy lifestyles are integrated in the curricula of primary schools, high schools, and secondary and vocational schools. Additionally, a series of educational programmes are developed and implemented in the healthcare facilities and the community for different population groups, such as the school for future parents, 'diabetes school', and 'hypertension school'. The education of patients with chronic diseases is part of the comprehensive management of these diseases, as laid down in the national clinical protocols[119] applied at primary health care level.

Awareness raising and communication campaigns – the communication actions are the main component of health promotion programmes and involve the development and dissemination of multiple information products. In this respect, the *Regulation on the development and continuous use of health promotion education and information materials*[120] was developed and is implemented. It establishes unique requirements, the principles and stages of education and information materials development for health promotion and continuous informing of the population on healthy lifestyles and disease prevention. Furthermore, special days and weeks dedicated to the fight against high-impact priority diseases are observed by the community annually, and a series of measures focusing on raising the population's awareness of health-related issues are put in place.

To support health promotion awareness-raising and communication campaigns, the legislation obliges the advertisers (art. 48 of the Law No. 10/2009 on state surveillance of public health) to dedicate at least 5% of the daily advertising time slot to health promotion information. Moreover, the Audiovisual Coordinating Council approved a series of messages to promote healthy lifestyles.[121] These are broadcast by the broadcasters as public warning messages.

Activities implementation through primary healthcare providers – provision of preventive measures at the primary health care level, as one of priority areas of their activity, have been strengthened over the years, both in terms of policies and practices. Some examples include: expanding the range of preventive services for target groups, establishing youth-friendly health centers, integrating a community nurse with competences in community health promotion in the family doctor team.

Cross-sector partnerships for community-based health promotion – cross-sector cooperation and coordination mechanisms enable the implementation of health promotion actions, including at the local level. In this respect, one example

[119] Ministry of Health, Repository of National Clinical Protocolos, available in Romanian at: https://msmps.gov.md/legislatie/ghiduri-protocoale-standarde/cardiologie-2/

[120] Ministry of Health Order No. 524/2021on development and continuous use of health promotion education and information materials, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=42671&lang=ro

[121] Audiovisual Coordinating Council Decision No. 1/2013 on broadcasting messages on healthy lifestyle, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=104958&lang=ro#

is the establishment of the Territorial Public Health Council[122], which represents a coordination body under the local public administration authorities. The members of the Council are representatives of the healthcare sector and related areas who coordinate the implementation of health protection and promotion and disease prevention policies.

The national health promotion programmes are financed from the state budget. In addition, the National Health Insurance Company manages the **Prevention Fund**, which constitutes 1% of the total resources of the Mandatory Health Insurance Fund (MHIF)[123]. There is a transparent and efficient mechanism for planning, managing, and monitoring the projects implemented with the financial means of the Prevention Fund of the MHIF, as foreseen in the Regulation on project-based funding of prophylaxis and prevention activities tackling the risks of disease by using the financial means of the Prevention Fund[124]. Furthermore, based on the cooperation agreements in the field of public health, the development partners of the Republic of Moldova support a series of measures included in the health promotion programmes.

22. What is the state of play regarding prevention, rehabilitation and social reintegration programmes for drug addicts, if any?

The Republic of Moldova has acceded to the International Convention on drugs control in 1994 and established, since then, a legal and institutional framework to address the harm caused by substance misuse, based on the international standards, as well as the rights and freedoms of persons. The reduction of drug use is regulated by the Law No. 713/2001 on the control and prevention of alcohol abuse, illicit drug use and other psychotropic substances.[125] The law sets legal provisions on controlling and preventing alcohol abuse, illicit drug use and other psychotropic substances, reducing and excluding such consumption, educating the population in the spirit of abstinence and a healthy lifestyle, and eliminating the consequences of physical and/or mental dependence. The law aims to provide an integrated public health approach to drug use that is treated first and foremost as a health issue.

[122] Ministry of Health Order No. 230/2016 on Territorial Public Health Council, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=100546&lang=ro

[123] Regulation on the procedure for creating and managing mandatory health insurance funds approved by the Government Decision No. 594/2002, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=126828&lang=ro

[124] Regulation on the procedure for financing project-based activities from the prevention fund approved by the joint Order Ministry of Health and Health Insurance Company No. 286/154/2017, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130140&lang=ro

[125] Law No. 713/2001 on the control and prevention of abusive alcohol abuse consumption, illicit drug use and other psychotropic substances, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=107967&lang=ro

The non-discrimination of people who use drugs is expressly provided for in para. (1) of Art. 17 of the Law on Health Protection No. 411/1995, as well as by Law no. 263/2005 on the rights and responsibilities of the patient.

Action in the area of drug use is guided by a coordinated **National Anti-drug Strategy 2020-2027**[126], which aims for a multidisciplinary and balanced approach to drug use issues, based on interdepartmental, interdisciplinary and cross-sectoral cooperation at all levels and focused on three general strategic areas of modern drug policy, which complement each other. In the context of the balanced application of these components, the following general objectives of the National Anti-Drug Strategy are distinguished:

Reducing drug demand (primary prevention of drug use, treatment, rehabilitation and resocialization of people who use drugs);

Reducing conditional drug use risks (risk reduction projects and programs through health education, information on the risks of drug use, syringe exchange, substitution treatment, HIV testing, screening for sexually transmitted infections, psychological counseling);

Reducing the supply of drugs (exercising control over the legal circulation of drugs and combating illicit drug trafficking and distribution).

The policy framework provides a model that focuses on preventive efforts, care and treatment, social measures and measures to improve the health of individuals with substance abuse and dependence problems.

Prevention services

In the Republic of Moldova, *community-based harm reduction programs* started in 1997 and have significantly expanded geographically since. Prevention programs for people who inject drugs are implemented in the civilian and penitentiary sectors, including the Transnistrian region, and are covered in 40 localities of the republic, serving as important links in the prevention of the spread of HIV infection, other blood-borne infections and other harms associated with injecting drug use, as well as entry points to universal access to full range of health and social services. The basic service package includes needle and syringe programs, injection safety, condoms, testing for HIV, TB, STIs. The extended service package includes gender-specific services for women and adolescents, counseling for opiate substitution treatment (OST) initiation and adherence, overdose prevention and Naloxone, health products and disinfectants, information and communications, client navigation, psychosocial support, peer support, medical consultations, legal aid, referral to sexual and reproductive health and gender-based violence services for women who use drugs. Services are provided

[126] National Anti-Drug Strategy 2020-2027 approved by Government Decision No. 233/2020, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=130564&lang=ro#

through a range of platforms: fixed sites, outreach, virtual and online, and through pharmacies. By providing accessible services that meet the needs of people who use drugs, risk reduction programs often serve as a significant point of contact that can connect the people who use drugs with another community, with the resources of medical and social services.

In 2015, in Geneva, the PCB (UNAIDS, Program Coordination Board) recognized Moldova internationally as good practices for implementing the comprehensive package of services in prisons, Moldova implementing 13 out of 15 services. Moreover, since 2015 it has been also implemented in penitentiaries the overdose management programs, Naloxone is available in harm reduction programs. It is one of only seven countries in the world that offer needle exchange and opioid treatment in prisons. In the penitentiary sector, HIV prophylaxis activities for people who inject drugs are implemented in 18 penitentiary institutions in the country, including 3 in the Transnistrian region.

School and extracurricular programmes

Preventive work is also based on measures in schools and other educational institutions, as provided in the Law No. 713/2001 on the control and prevention of alcohol abuse, illicit drug use and other psychotropic substances. Topics on drug, alcohol and tobacco use prevention are integrated in curricula in primary and secondary education, both in mandatory disciplines (Civic education, Personal development, Education for society, Biology) and optional disciplines (Health education), as well as are delivered through a series of interactive extracurricular programmes and activities. The objective is to strengthen protective factors around children and adolescents through cross-cutting measures in schools and running work on prevention together with the police, social services, youth workers and non-governmental organizations.

Care and treatment of people with drug drug use disorders

Pursuant to the provisions of Law No. 713/2001 on the control and prevention of alcohol abuse, illicit drug use and other psychotropic substances, the state guarantees to people with drug disorders medical and social assistance, which is granted on the principles of legality, humanism and respect for human rights. Healthcare for drug misuse or dependence is coordinated by the Republican Narcology Dispensary, which offers a range of care and treatment measures, from psychosocial to purely medical.

Since 2004, the Republic of Moldova implements opioid agonist therapy (OAT), including using methadone and buprenorphine, to treat opiate dependence; since 2005 the OAT has been also available in the penitentiary system. OAT is implemented based on the National Clinical Protocol (NCP) No.225

Pharmacological Treatment of Opiate Dependence[127], is funded by the government, and has been scaled-up and become available in eight administrative territories of the civil sector and in 13 penitentiary institutions. Since 2022, the country has started piloting the mobile application for video-supported combined medical and psychosocial treatment of OAT patients.

Knowledge base on effective evidence-based measures and practices is regularly updated via clinical protocols and standards[128],[129] to provide guidance to health care workers.

In 2022, the National Clinical Protocol on *Disorders associated with the use of new substances with psychoactive and stimulating properties (in adults and children)* was developed based on the recommendations of NEPTUN, EMCDDA, UNODC, and NIDA and provides for pharmacotherapy and psychosocial interventions, as well as complex rehabilitation at all levels from emergency, specialized medical assistance to residential rehabilitation services based on therapeutic communities.

The National Clinical Protocol *Mental and behavioral disorders related to opiate use* contains methodological recommendations for medical workers on substitution therapy in order to improve public health, to abandon intravenous drug use among young people, to reduce the risk of viral hepatitis and HIV transmission among people who use drugs.

Rehabilitation and psychosocial services for people who use drugs: Psychosocial assistance is provided under the regulations stipulated in the *Framework Regulation on Organisation and Functioning of the Integrated Social Service for Psychoactive Substance Users and Substitution Therapy Patients and Minimum Quality Standards* (approved by Government Decision No. 232/2017[130]). The standard of psychosocial assistance to people who use drugs provides for the achievement of equity, continuity of care for people who use drugs and is based on experience. Available care for users of psychoactive substances includes several areas of intervention, related to the distinct stages of dependence, such as in case of emergencies or the need for immediate assistance, treatment and assistance of dependence itself or social reintegration.

The integrated services focus on three basic elements: day services, transitional housing services and rehabilitation service through the therapeutic community.

[127] National Clinical Protocol No.225 Pharmacological treatment of opiate dependence, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2020/07/15650-PCN20-22520Tratamentul20farmacologic20al20dependentei20de20opiacee.pdf

[128] Standards on harm reduction for injecting drug users, available in Romanian at: http://msmps.gov.md/wp-content/uploads/2020/06/9041-STANDARD20reducerea20riscurilor202011.pdf

[129] Standards on psychosocial assistance for drug user, available in Romanian at: http://msmps.gov.md/wp-content/uploads/2020/06/9042-STANDARD20Asistenta20psihosociala202011.pdf

[130] Government Decision No.232/2017 on the approval of the Framework Regulation on the organization and operation of the Integrated Social Service for Consumers of Psychoactive Substances and Substitute Therapy Patients and Minimum Quality Standards, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=98912&lang=ro

There are day centers for people who use drugs in 5 districts of the country administered by non-governmental organizations with over 20 years of experience that provide short and long-term psychosocial rehabilitation.

Starting with 2017, a prison-based therapeutic community for long-term rehabilitation for people who are in prisons and who are released operates in the penitentiary. Since the launch of this service, 48 people in prison have benefited from psychosocial rehabilitation, and currently, 12 people in prisons are enrolled in the program within the therapeutic community. In order to legislate and extend the model of the therapeutic community in other institutions, the Parliament of the Republic of Moldova is currently examining the draft amendment to the Executive Code, specifically amendment of art. 219¹, which will allow organization in penitentiary institutions of therapeutic communities for those with a history of drug and other psychotropic substances use[131] (the draft amendment was voted in the first reading in April 2022). Another therapeutic community with a capacity of 30 seats (women and men) operates in one of the districts. Center is running mutual support groups for both patients and their families.

Since 2021 there have been gender-sensitive services offered, women who use drugs with their children can benefit from crisis services and complex assistance if they are subject to domestic violence. To limit drug use, the police and social services also collaborate to offer social support at an early stage.

23. Has the country legislation on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)?

The Republic of Moldova is in the process of developing legislation that enables competent agencies to limit the exposure of people to electromagnetic fields (EMF) and introduce appropriate measures to protect the public and workers from potential adverse effects of EMF. Currently, the regulatory framework on the risks generated by electromagnetic fields is regulated by Government Decision No. 697/2018 *on the approval of occupational health and safety minimum requirements regarding the exposure of workers to risks generated by electromagnetic fields*[132], which transposes Directive 2013/35/EU of the European Parliament and of the Council *on the health and safety minimum requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields)* and repealing Directive 2004/40/EC. The approved requirements set reference levels as EMF exposure limits and designate

[131] Draft legislative act on the organization in penitentiary institutions of therapeutic for those with a history of drug and other psychotropic substances use, available in English at: https://www.parlament.md/ProcesulLegislativ/Proiectedeactelegislative/tabid/61/LegislativId/5337/language/en-US/Default.aspx

[132] Occupational health and safety minimum requirements regarding the exposure of workers to risks generated by electromagnetic fields approved by Government Decision No. 697/2018, available in Romanian at*:* https://www.legis.md/cautare/getResults?doc_id=108830&lang=ro

compliance arrangements, aiming to protect the workers from health effects arising from exposure to electromagnetic fields in the working environments.

In addition, electromagnetic fields exposure limit regulation (transposing the Recommendations of the European Parliament and of the Council of 12 July 1999 (1999/519/EC) on the limitation of exposure of the general public to electromagnetic fields (0 Hz – 300 GHz)), is under the development and is planned to be adopted in the coming months (as per Government Action Plan for 2021-2022, Chapter V Communications infrastructure, item 5.2.4[133]). The Regulation will set EMF exposure limits for public areas, to which the public has access, in order to protect the population from levels of exposure to EMF that could produce adverse health effects.

B. Communicable diseases, non-communicable diseases, & cancer screening

24. To what extent is national legislation in Moldova aligned with the EU acquis in these areas?

a) Communicable diseases

The national system of epidemiological surveillance and control of communicable diseases and public health events provides for integrated collaborative and coordination activities aimed at improving the prevention and control of communicable diseases based on the following legislative acts which provide for partial transposition of the European Parliament and of the Council Decisions as follows:

a) on the organization of communicable disease epidemiological surveillance and reporting system:

Government Decision No. 475/2008 *on the approval of the Action Plan on the implementation of the International Health Regulations in the Republic of Moldova*[134]. The purpose of the document is to fulfill the commitments of the Republic of Moldova on to prevent, protect against, control and provide a public health response to the national and international spread of disease in ways that are commensurate with and restricted to public health risks, determined by biological, chemical and radiological factors, and which avoid unnecessary interference with international traffic and trade, in accordance with the provisions of the International Health Regulations (2005);

Government Decision No. 951/2013 *for the approval of the Regulation on the national system of epidemiological surveillance and control of communicable*

[133] Government Action Plan 2021-2022 approved by the Government Decision No. 235/2021, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128407&lang=ro

[134] Government Decision No. 475/2008 on the approval of the Action Plan on the implementation of the International Health Regulations in the Republic of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103472&lang=ro#

diseases and public health events[135]. This Regulation partially transposes the provisions of Decision 2119/98/EC of the European Parliament and of the Council of 24 September 1998 establishing a network for the epidemiological surveillance and control of communicable diseases in the Community, of the International Health Regulations (2005) and establishes the modus operandi of the national system of epidemiological surveillance and control of communicable diseases and public health events.

b) in the field of early warning and rapid response for the prevention and control of communicable diseases and public health events:

Government Decision No. 1431/2016 for the approval of the *Regulation on the early warning and rapid response system for the prevention and control of communicable diseases and public health events*[136]. The Regulation lays down the operation of the early warning and rapid response system in the framework of public health surveillance and partially transposes the Commission Decision 2000/57/EC of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No. 2119/98/EC of the European Parliament and the Council and the provisions of the International Health Regulations (2005). Recently, the Republic of Moldova has been granted access to the EC Early Warning and Response System (EWRS) for EU/EEA.

c) in the field of preventing the cross-border transmission of public health hazards:

Government Decision No. 531/2014 *on the actions for implementation of the International Health Regulations in preventing the cross-border transmission of public health hazards*[137]. The provisions of the Regulation on the prevention of cross-border transmission of public health hazards apply to biological hazards (communicable diseases, antimicrobial resistance and healthcare associated infections, biological toxins or other toxic biological agents unrelated to communicable diseases; chemical and radiological hazards, environmental hazards, including those caused by the climate change effects, hazards of unknown origin, events that may constitute an international public health emergency, in accordance with the International Health Regulations (2005), provided that they fall into one of the categories of hazards stipulated in the Regulation.

The Regulation partially transposes the provisions of Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious

[135] Government Decision No. 951/2013 for the approval of the Regulation on the national system of epidemiological surveillance and control of communicable diseases and public health events, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103100&lang=ro#

[136] Government Decision No. 1431/2016 for the approval of the Regulation on the early warning and rapid response system for the prevention and control of communicable diseases and public health events, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102615&lang=ro#

[137] Government Decision No. 531/2014 on the actions for implementation of the International Health Regulations in preventing the cross-border transmission of public health hazards, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=102913&lang=ro#

cross-border threats to health and repealing Decision No. 219/98/EC, and stipulates planning, training, monitoring activities, early warning, risk assessment and coordinated response to public health hazards, prevention and control of their cross-border transmission, and further implementation of the provisions of the International Health Regulations (2005), approved on 23 May 2005 at the 58th World Health Assembly (Resolution WHA58.3 Revision of the International Health Regulations).

d) Non-communicable diseases

As one of the countries of the WHO European Region, the Republic of Moldova respects the commitments made by the UN General Assembly Political Declaration on the Prevention and Control of Noncommunicable

Diseases (resolutions of 2011, 2014, 2015, 2018 and 2019) and has developed a clear policy in this area, in close alignment with the provisions of the strategies and global and European plans in the field of prevention and control of NBT, including: the 2013-2020 Global Action Plan for NCD prevention and control (Resolution WHA66.10), The European Strategy for the Prevention and Control of Non-Communicable Diseases (Resolution EUR/RC56/R2) and the Action Plan for the implementation of the Strategy for the period 2016-2025 (Resolution EUR/RC66/R11), as well as the Sustainable Development Goals (SDG 3.4). As a proof, the realization of the National NCD Prevention and Control Strategy 2012-2020[138] and the 2016–2020 National Strategy implementation Action Plan, the National Public Health Programs targeting major NCDs (cardiovascular disease, cancer, diabetes) and their common risk factors (tobacco, alcohol, unhealthy diet, physical inactivity).

Currently, the draft 2022-2030 National Program for the priority non-communicable diseases prevention and control in the Republic of Moldova is being adopted by the Government, which represents a continuity of the National NCD Prevention and Control Strategy priorities.

e) Cancer screening

In the Republic of Moldova, cancer screening services are provided by primary health care institutions, pursuant to Law No. 411/1995 on health care[139], Law No. 1585/1998 on compulsory health insurance[140]. At the same time, the 2016-2025 National Cancer Control Program was approved by Government Decision no.1291/2016[141] in accordance with the provisions of European guidelines on

[138] Parliament Decision No. 82/2012 on National Noncommunicable Disease Prevention and Control Strategy 2102-2020, available in Romanian at: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=343682

[139] Law No. 411/1995 on health care, available in Romanian at: https://www.legis.md/search/getResults?doc_id=119465&lang=en

[140] Law No. 1585/1998 on compulsory health insurance, available in Romanian at: https://www.legis.md/search/getResults?doc_id=128122&lang=en.

[141] The National Cancer Control Program 2016-2025 approved by the Government Decision No.1291/2016, available in Romanian at: https://www.legis.md/search/getResults?lang=en&doc_id=96628

cancer control, which aims to reduce the burden of this disease on the society in general and on the individuals in particular.

A specific objective of the Program is to increase the rate of early detection of cancer, especially *cervical, colorectal and breast cancer screening*. In this regard, the following screening programs have been established and are being implemented in the country, based on the national standards for the organization and operation of screening services approved by orders of the Ministry of Health:

- Colorectal cancer screening - coordinated by the Colorectal Cancer Screening Center established within the Oncological Institute, with the application of colonoscopy;
- Breast cancer screening - performed by mammography, including mobile facilities that provide access to screening services for women in rural and peripheral areas;
- Cervical cancer screening - an organized screening program with cytological test application.

The standards for screening programs organization[142,143] are developed based on the provisions of the European guidelines for quality assurance in cancer screening and diagnosis.

25. Is there a national surveillance, risk assessment and early warning and response system for communicable diseases? Is there an adopted national epidemic preparedness plan? Is it in line with the implementation of International Health Regulations?

The legal and regulatory framework in the Republic of Moldova covering the field of epidemiological surveillance includes the following basic normative acts:

Law no. 10/2009 ***on state surveillance of public health***[144]- establishes complex public health actions in communicable diseases prevention and control, including epidemiological surveillance, prevention of the international spread of diseases, organization of measures to respond to public health emergencies.

Government Decision no. 951/2013 ***for the approval of the Regulation on the national system of epidemiological surveillance and control of communicable***

[142] The standard of organization and functioning of the cervical screening service in the Republic of Moldova, available in Romanian at:
https://msmps.gov.md/sites/default/files/legislatie/standard_screening_cervical_aprobat.pdf
[143] National Standard of Operational Procedures on Colorectal Cancer Screening, available in Romanian at:
https://msmps.gov.md/wp-content/uploads/2020/06/15431-SPO20-20SCREENING20CCR20varianta20finala200520aprilie202017.pdf
[144] Law No. 10/2009 on state surveillance in public health, available in Romanian at:
https://www.legis.md/cautare/getResults?doc_id=125959&lang=ro#

diseases and public health events[145] - establishes the way of functioning of the national system of epidemiological surveillance and control of communicable diseases and public health events. The Regulation partially transposes the provisions of Decision 2119/98/EC of the European Parliament and of the Council establishing a network for the epidemiological surveillance and control of communicable diseases in the Community and of the International Health Regulations (IHR) (2005).

The National Agency for Public Health is the institution responsible for coordinating the functioning of the national system of epidemiological surveillance and control of communicable diseases and public health events.

The epidemiological surveillance system collects data on cases of communicable diseases and public health events based on case definitions that include clinical, microbiological and epidemiological features. The volume, content of collected data and the way of their transmission in the epidemiological surveillance system are approved by the Ministry of Health.

Since 2019, the Republic of Moldova has strengthened its Event Based Surveillance (EBS) by becoming a community under the global Epidemic Intelligence from Open Sources (EIOS) initiative for early detection and communication around public health signals and events of potential international concern.

The Ministry of Health ensures the rapid exchange of information with the institutions of the health system, the competent authorities for the application of response measures at territorial and national level. In the event of risks of the international spread of communicable diseases and for the coordination of public health measures, prevention and control actions are consulted with the WHO and other international institutions in the field, in accordance with the provisions of IHR (2005).

An automated information system has been developed to extend the functionality of the surveillance system and to digitize the processes of data collection, analysis and dissemination, which will allow integration with international surveillance networks. The project is in the design stage and will be approved by the end of the year (Government Action Plan 2021-2022, Domain X Health, p. 10.30.2[146])

Government Decision no. 1431/2016 ***for the approval of the Regulation on early warning and rapid response system for the prevention and control of***

[145] Government Decision No. 951/2013 on the approval of the Regulation on the national system of epidemiological surveillance and control of communicable diseases and public health events, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103100&lang=ro

[146] Action Plan of the Government of the Republic of Moldova 2021-2022 approved by the Government Decision No. 235/2021, available in Romanian at: https://gov.md/sites/default/files/document/attachments/pag_2021-2022_ro.pdf

communicable diseases and public health events[147] - lays down the operation of the early warning and rapid response system in the framework of public health surveillance and partially transposes the Commission Decision 2000/57/EC of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No. 2119/98/EC of the European Parliament and the Council and the provisions of the International Health Regulations (2005).

The National Public Health Agency is the competent authority responsible for monitoring health hazards and determinants, assessing the risks of triggering public health emergencies, communicating risks and implementing public health measures.

The Regulation lays down general rules for the operation of the early warning and rapid response system, the mechanism, information, consultation and enforcement of response measures, as well as the standard procedures to be followed in the event of a possible, probable or imminent risk of emergency. public health. The list of notified events and the list of diseases / syndromes included in the early warning and rapid response system are established. The system is integrated with the rapid alert system for food and forages[148]. The Ministry of Health, the Ministry of Internal Affairs, the Ministry of Agriculture and Food Industry, the Ministry of Environment, the National Agency for Food Safety ensure the exchange of information on the occurrence of events in the country that may affect public health.

Government Decision No. 475/2008 ***on the approval of the Action Plan on the implementation of the International Health Regulations in the Republic of Moldova***[149]- establishes an inter-ministerial plan for the IHR implementation with a clear division of responsibilities of the institutions involved in responding to public health emergencies. In line with WHO recommendations, medium- and long-term strategic directions have been identified to strengthen emergency response and management, including review and improvement of the national legislation; elaboration and implementation of the preparedness and response plan; strengthening human resources; strengthening the surveillance system for communicable diseases and public health crises. National Focal Points (NFP) capacities have been regularly updated, including with WHO support, through NFP workshops, Simulation Exercises (JADE – Joint Assessment and Detection of Events) in 2018 and 2019, with another one scheduled for June 2022.

[147] Regulation on early warning and rapid response system for the prevention and control of communicable diseases and public health events, approved by the Government Decision No. 1431/2016, available in Romanian at: https://www.legis.md/search/getResults?doc_id=102615&lang=en

[148] Government Decision No. 59/2017 on measures for the implementation of the national rapid alert system for food and feed, available in Romanian at: https://www.legis.md/search/getResults?doc_id=125631&lang=en

[149] Government Decision No. 475/2008 on the approval of the Action Plan on the implementation of the International Health Regulations in the Republic of Moldova, available in Romanian at: https://www.legis.md/search/getResults?doc_id=103472&lang=en

Government Decision No. 531/2014 ***on the actions for the implementation of the International Health Regulations in preventing the cross-border transmission of public health hazards***[150]-stipulates activities of planning, preparation, monitoring, risk assessment and coordinated response in case of public health hazards, prevention and control of their cross-border transmission, as well as implementation of the provisions of the International Health Regulations (2005) and partially transposes the provisions of Decision No. 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No. 2119/98/EC.

The state border crossing points are designated for endowment in accordance with the IHR provisions, and minimum endowment capacities are established for them.

Regarding the National Epidemic Preparedness Plan, in 2020 the Public Health Emergency Preparedness and Response Plan[151] was jointly developed by the Ministry of Health and Ministry of Internal Affairs. The Plan serves as a basic operational document for the national level coordination of preparedness and medical response actions to public health emergencies, which may occur on the territory of the Republic of Moldova. The plan is based on the principle of a single approach to all hazards, has a strategic approach and reflects the generic and conceptual aspects related to the health system preparedness and response to public health emergencies at national level.

The plan is developed to implement the provisions of national legislation in the field of public health emergency preparedness and response, as well as p. 6 (g) of Annex 1 of the International Health Regulations (2005), to which the Republic of Moldova has acceded, according to which Member States are responsible for taking action to prevent or reduce the international spread of public health diseases and emergencies.

The Public Health Emergency Preparedness and Response provided an operational framework to establish procedures and response measures at the national level to COVID-19 pandemic and, more recently, the refugee crisis.

26. Is there a legal basis for monitoring anti-microbial resistance and how is this system organised?

Antimicrobial resistance is recognized by the national legislation as a serious threat to public health and is included in the approved list of special health problems subject to registration and notification set out in the Regulation on the national

[150] Government Decision No. 531/2014 on the actions for the implementation of the International Health Regulations in preventing the cross-border transmission of public health hazards, available in Romanian at: https://www.legis.md/search/getResults?doc_id=102913&lang=ro

[151] Public Health Emergency Preparedness and Response Plan, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2020/09/Plan-USP-07.09.2020.pdf

system of epidemiological surveillance and control of communicable diseases and public health events by Government Decision No. 951/2013[152].

Competences in the field of antimicrobial resistance monitoring (AMR) are assigned to the National Agency for Public Health, whose organizational structure includes the Section for Epidemiological Surveillance of Infections Associated with Healthcare and Antimicrobial Resistance and the Antimicrobial Resistance Reference Laboratory, including the Surveillance Laboratory responsible for the research component[153].

The national AMR surveillance system[154] is based on monitoring the circulation of identified microbial agents, generating partial data, which are integrated and/or affiliated with international AMR surveillance networks: since 2015 to the Central Asian and Eastern Europe Antimicrobial Resistance Surveillance Network (CAESAR), and from 2021 to the Global Antimicrobial Resistance Surveillance Network (GLASS). Within the network of AMR laboratories, the procedures and practices regarding the diagnosis of microbial agents included in the surveillance system have been aligned to international standards[155,156,157,158]. Methods and standards developed and updated by EUCAST (*The European Committee on Antimicrobial Susceptibility Testing*) are implemented. The updated version of this standard is used to evaluate and interpret AMR data: The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 12.0, 2022[159]. The reference laboratory is equipped with automated equipment for mass spectrometry for microbial identification and molecular biology equipment for rapid detection of AMR pathogens, competent staff which contributes to improving clinical results by supporting early interventions and reducing AMR development. The improvement of the laboratory quality management system and the quality assurance of carried out investigations

[152] Regulation on the national system of epidemiological surveillance and control of communicable diseases and public health events approved by the Government Decision No. 951/2013, available in Romanian at:lex.justice.md/index.php?action=view&id=350538&lang=1&view=doc

[153] Government Decision No. 1090/2017 on the organization and functioning of the National Agency for Public Health, available in Romanian at: HG1090/2017 (legis.md)

[154] Order of the Ministry of Health, Labor and Social Protection No. 711/2018 on the National System of Epidemiological Surveillance of Antimicrobial Resistance, available in Romanian at: https://ansp.md/wp-content/uploads/2021/04/ordin-711-din-07.06.18Supraveghere-reziztenta-antimicorobiene.pdf

[155] Guidelines on Quality assurance in the microbiological diagnosis of urinary tract infections, approved by the Ministry of Health, Labor and Social Protection Order No. 651/2021, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2021/08/GHIDUL1.pdf

[156] Guidelines on Management of *Clostridioides difficile* infection approved by the Ministry of Health, Labor and Social Protection Order No. 288/2021, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2021/11/Ghid_Management_infectia_Clostridioides_26.04.2021.pdf

[157] Guidelines on Microbiological diagnosis of respiratory tract infections approved by the Ministry of Health, Labor and Social Protection Order No.6/2021, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2021/04/Ghid_Diagnostic_Microbiologic_08.04.2021.pdf

[158] Guidelines on Principles and procedures in microbiological testing of blood cultures approved by the Ministry of Health, Labor and Social Protection Order No. 696/2020, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2021/11/Ghid_hemocultura_final_16.10.2020.pdf

[159] National Breakpoint tables based on the European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 12.0, 2022, available in Romanian at: https://ansp.md/wp-content/uploads/2021/04/RO_EUCAST_breakpoints_22_03_2022.pdf

is confirmed by the annual participation in external quality assurance (EQA) programs.

At the same time, there is a network of laboratories for the diagnosis of tuberculosis, including the reference laboratory for the diagnosis of resistant and multidrug-resistant tuberculosis.

There is a political commitment to strengthen the national policy framework in the field of AMR, addressing the issue in accordance with the "One Health" principle, taking into account animal, human health and environmental issues. The development of the National Strategy for AMR surveillance and control is included in the Government Action Plan 2021-2022, Chapter X Health, item 10.28.5[160].

At the same time, there is the regulatory framework regarding the way of prescribing and releasing antimicrobials, established by the Order of the Ministry of Health No. 960/2012 on how to prescribe and release medicines[161], which allows monitoring the release of preparations. Monitoring of antimicrobial consumption is based on the WHO methodology (import and production) from 2011. Data are available and reported annually to the WHO[162].

Annually, for seven consecutive years, activities are organized during World Antimicrobial Resistance Awareness Week under the auspices of the Ministry of Health jointly with the National Agency for Food Safety, the Agency for Medicines and Medical Devices, other partners with the WHO support.

27. Is there a list of communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions? If yes, which communicable diseases are included in the list? Are there a National Cancer Control Plan/ Registry / regional cancer site registries in Moldova? Are there national programme(s) on early detection and treatment of cancer(s), which ones?

The national system of epidemiological surveillance and control of communicable diseases and public health events has a list of diseases and special health problems, which are covered by epidemiological surveillance and are subject to mandatory notification. *The Regulation of the national system of epidemiological surveillance and control of communicable diseases and public health events*, approved by

[160] Action Plan of the Government of the Republic of Moldova 2021-2022 approved by the Government decision No. 235/2021, available in Romanian at: https://gov.md/sites/default/files/document/attachments/pag_2021-2022_ro.pdf

[161] Order of the Ministry of Health No. 960/2012 on how to prescribe and release medicines, available in Romanian at: https://www.legis.md/search/getResults?doc_id=99320&lang=ro

[162] The WHO Essential Medicines and Health Products Information Portal, available in English at: http://apps.who.int/medicinedocs/documents/s23195en/s23195en.pdf

Government Decision No. 951/2013[163] establishes the **List of categories of communicable diseases and special health issues**, as follows:

1. Communicable diseases

- Vaccine preventable diseases (under the Extended Immunization Programme), according to the national vaccination schedule
- Sexually transmitted diseases
- Viral hepatitis
- HIV/AIDS infection
- Foodborne diseases
- Waterborne diseases and which come from the environment
- Other diseases communicable through unconventional agents
- Airborne diseases
- Communicable diseases that can lead to public health emergencies with a risk of international spread in IHR (2005)
- Vector-borne diseases
- Zoonoses (common to animals and humans)
- Other communicable diseases of public health importance, including diseases caused by deliberate spread

2. Special health issues

- Nosocomial infections
- Antimicrobial resistance
- Adverse reactions and post-vaccine complications

Medical institutions, medical laboratories, regardless of the type of property and legal form of organization, ensure the detection of cases of communicable diseases and public health events, identification of biological agents and notification in the epidemiological surveillance system.

The epidemiological surveillance system collects data on cases of communicable diseases and public health events based on case definitions that include clinical, microbiological and epidemiological features. The case definitions are provided in the National Clinical Protocols developed for each nosology and approved by order of the Ministry of Health.

[163] The Regulation of the national system of epidemiological surveillance and control of communicable diseases and public health events, approved by Government Decision No. 951/2013, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=103100&lang=ro

The Republic of Moldova has adopted and is implementing a 2016-2025 National Cancer Control Program[164]. The main defined objectives of this program include: 1) reducing by 10% by 2025 the incidence of cancers: lung, skin, stomach, liver, prostate, colorectal, cervical and breast, by controlling behavioral risk factors (smoking, alcohol consumption, diet, physical activity) and through vaccination; 2) increasing by 25% the rate of early detection of cancer (stages I and II) by 2025; 3) ensuring the access of at least 80% of cancer patients to quality diagnostic, treatment and continuous care services until 2025; 4) developing palliative and rehabilitation services and ensuring the access of cancer patients to these services;

The Republic of Moldova has become a component part of the Joint Action "Innovative Partnership for Action Against Cancer" (iPAAC; http://www.ipaac.eu/) which brings together 24 partners/countries from Europe and has a package of 10 activities, the purpose of which is to develop "CANCON" Joint Action and to implement innovative approaches to cancer control with a Roadmap on Implementation and Sustainability of Cancer Control Actions as the main deliverable.

Within this partnership, the Republic of Moldova participates in the WP7 action, which aims to promote the objective of adjusting and improving cancer information systems – Development, implementation and ensuring the functionality and maintenance of the Cancer Registry. The aim of this action is to "map" cancer and integrate data into a modern information platform, which would provide periodic summaries and essential information of the cancer monitoring and evaluation process, as well as collecting and analyzing information with the development of evaluation reports on qualitative and quantitative data from the Republic of Moldova on cancer, adjusted to the EU indicators rigors.

In 2020, the concept and technical specifications of the cervical screening registry have been developed and validated by the Ministry of Health and the National Agency for Electronic Governance, which will ensure the availability of cervical screening data to be collected regularly by PHC facilities, cytopathology and histopathology laboratories and colposcopy cabinets and used for evidence-based decision making.

In accordance with the National Program provisions, the following screening programs have been established and are being implemented in the country, based on the national standards for the organization and operation of screening services approved by orders of the Ministry of Health:

- Colorectal cancer screening - coordinated by the Colorectal Cancer Screening Center established within the Oncological Institute, with the application of colonoscopy;

[164] The National Cancer Control Program 2016-2025 approved by the Government Decision No. 1291/2016, available in Romanian at: HG1291/2016

- Breast cancer screening - performed by mammography, including mobile facilities that provide access to screening services for women in rural and peripheral areas;
- Cervical cancer screening - an organized screening program with the application of the cytological test

All cancer screening programs are funded by the National Health Insurance Company and are accessible to eligible individuals regardless of their insured status.

C. Blood, tissues, cells and organs

28. To what extent is national legislation aligned with the EU *acquis* in this area?

The activity of blood donation and blood transfusion at national level is regulated by Law No. 241/2008 on blood donation and blood transfusion.[165]

Currently, the national blood transfusion service has normative acts (orders and regulations issued by the Ministry of Health), a total of 56 acts, which regulate the implementation, development, assurance and maintenance of quality management in daily activities, with a major impact on ensuring transfusion safety, quality blood transfusion care provided to patients receiving medical services provided under the healthcare system.

The following European Directives in the field of blood are fully transposed in the legislative and normative framework of the Republic of Moldova (laws, government decisions, MoH orders):

Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, including next legislation and normative acts:

- Law on blood donation and blood transfusion no. 241-XVI of 20.11.08. (Published: 13.01.2009 in the Official Gazette No. 1-2, art. No.: 2)[166]
- Government Decision no. 657 of 23.08.2017 "On the approval of the National Program for transfusion security and self-insurance of the country with blood products for the years 2017-2021"[167]

[165] Law No. 241/2008 on blood donation and blood transfusion, available in Romanian at: LP241/2008
[166]Law on blood donation and blood transfusion no. 241-XVI of 20.11.08, available in Romanian at: LP241/2008
[167]Government Decision no. 657 of 23.08.2017 "On the approval of the National Program for transfusion security and self-insurance of the country with blood products for the years 2017-2021, available in Romanian at: http://cnts.md/programulnational/HG%20nr.657%20din%2023.08.2017.pdf

- Law No. 552 of 18.10.2001 regarding the evaluation and accreditation in health[168]
- Order of the Ministry of Health no. 105 of 23.04.2009 „On the approval of the Guidelines for blood transfusion activity“
- Order of the Ministry of Health no. 1160 of 14.12.2021 "On the approval of the Guide on the organization of the event of voluntary donation of blood and blood components in mobile collections"[169]

Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components, including next legislation and normative acts:

- Order of the Ministry of Health no. 92 of 12.02.2015 Regarding the approval of the Quality System Standards in the activity of the institutions participating in the production of blood products[170]
- Order of the Ministry of Health no. 94 of 12.02.2015 „Regarding the updating of the Guide on the preparation, use and quality assurance of blood components, approved by the order of the Ministry of Health no. 105 of 23.04.2009 "On the approval of the Guidelines for transfusion activity"[171]
- Order of the Ministry of Health no. 464 of 11.06.2015 "On the approval of the Manual of standard procedures for the organization of blood transfusion care in the medical institution"[172]
- Order of the Ministry of Health no. 1060/2013 About the approval of the normative acts regarding the sterility of human blood products and infusion solutions [173]

[168] Law No. 552 of 18.10.2001 regarding the evaluation and accreditation in health, available in Romanian at: LP552/2001

[169] Ministry of Health Order No. 1160/2021 Regarding the approval of the Guide regarding the organization of the voluntary donation event a blood and blood components in mobile collections, available in Romanian at: Ord MS aprob Ghid eghipe mobile nr 1160 din 14.12.2021.pdf (cnts.md)

[170] Order of the Ministry of Health no. 92 of 12.02.2015 Regarding the approval of the Quality System Standards in the activity of the institutions participating in the production of blood products, available in Romanian at: 2015 ordinul ms standarde sistemului de calitate.pdf (cnts.md)

[171] Ministry of Health Order No. 94/2015 Regarding the update of the Guide on in the preparation, use and quality assurance blood components, approved by MS order No. 105/.2009 „Regarding the approval Chives for transfusion activity, available in Romanian at: 2015 ordinul ms actualizarea ghidului producere produse sanguine(1).pdf (cnts.md)

[172] Ministry of Health Order No.464/2015 regarding the approval of the Manual of standard procedures for the organization of hemotransfusion assistance within the medical-sanitary institution, available in Romanian at: 15091-ordinul20MS20nr.46420din2011.06.2015.pdf (gov.md)

[173] Ministry of Health Order No. 1060/2013 About the approval of the normative acts regarding the sterility of human blood products and infusion solutions, available in Romanian at: Ordin_nr99-0_din02_10_2013_Cu_privire la organizarea asigurarii realizarii ordinului MS nr1060 din 30.09.2013.pdf (cnts.md)

- Order of the Ministry of Health no. 1491 of 27.12.2019 "On medical devices in vitro diagnostic and other materials used in ensuring blood safety and their eligibility criteria"[174]
- Order of the Ministry of Health no. 93 of 12.02.2015 On the approval of Instructions for blood collection and processing into blood components[175]

Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life, including next legislation and normative acts:

- Order of Health No. 105 of 23.04.2009 „On the approval of the Guidelines for blood transfusion activity"[176]
- Order of the Ministry of Health No. 94 of 12.02.2015 „Regarding the updating of the Guide on the preparation, use and quality assurance of blood components, approved by the order of the Ministry of Health no. 105 of 23.04.2009 „On the approval of the Guidelines for transfusion activity"[177]
- Order of the Ministry of Health No. 91 of 12.02.2015 "On the approval of the National Nomenclature of Human Blood Products for Therapeutic and Diagnostic Use"[178]

Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events, including next legislation and normative acts:

- Law on blood donation and blood transfusion no. 241-XVI of 20.11.08[179]

[174]Ministry of Health Order No.1491/2019 on in vitro and other diagnostic medical devices materials used to ensure the safety of blood transfusions and their eligibility criteria, ,available in Romanian at: OMSMPS1491/2019 (legis.md)

[175] Ministry of Health Order No. 93/2015 on the approval of "Instructions for blood collection and processing into blood components, available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordinul_nr.93_din_12.02.2015_cu_privire_la_aprobarea_instructiunilor_de_recoltare_a_singelui_si_procesare_in_componente_sangui.pdf

[176]Ministry of Health Order No. 105/2009 „On the approval of the Guidelines for blood transfusion activity", available in Romanian at: http://msmps.gov.md/wp-content/uploads/2020/06/3942-ordin2010520din202320aprilie2009.pdf

[177] Ministry of Health Order No.94/2015 Regarding the update of the Guide on in the preparation, use and quality assurance blood components, approved by MS order No. 105/2009 „Regarding the approval Transfusion activity guidelines ,available in Romanian at: "https://cnts.md/legislatie/2015%20ordinul%20ms%20actualizarea%20ghidului%20producere%20produse%20sanguine(1).pdf

[178] Ministry of Health Order No. 91/2015 Regarding the approval of the "National Nomenclature of human blood products for use Therapeutic and Diagnostic ", available in Romanian at: https://cnts.md/legislatie/2015%20ordinul%20ms%20nomenclator%20produse%20sanguine.pdf

[179] Law No.241/2008 on blood donation and blood transfusion ,available in Romanian at: LP241/2008 (legis.md)

- Government Decision no. 657/2017 "On the approval of the National Program for transfusion security and self-insurance of the country with blood products for the years 2017-2021"[180]
- Order of the Ministry of Health no. 62/2011 "On the traceability of blood products"[181]
- Order of the Ministry of Health no. 88/2015 Regarding the updating of the order of the Ministry of Health no.62/2011 "On the traceability of blood products"[182]
- Order of the Ministry of Health no. 105/2009 „On the approval of the Guidelines for blood transfusion activity“[183]
- Order of the Ministry of Health no. 828/2011 "On the approval of primary medical records forms"[184][185]
- Order of the Ministry of Health no. 91/2015 “On the approval of the National Nomenclature of Human Blood Products for Therapeutic and Diagnostic Use”[186]
- Order of the Ministry of Health no. 92/2015 Regarding the approval of the Quality System Standards in the activity of the institutions participating in the production of blood products[187]
- Order of the Ministry of Health no. 94/2015 „Regarding the updating of the Guide on the preparation, use and quality assurance of blood components, approved by the order of the Ministry of Health no. 105 of 23.04.2009 "On the approval of the Guidelines for transfusion activity"[188]

[180]Government Decision No.657/2017 on the approval of the National Security Program transfusion and self-insurance of the country with blood products for the years 2017-2021, available in Romanian at: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=371164

[181] Ministry of Health Order No. 62/2011 regarding the traceability of blood products , available in Romanian at: http://cnts.md/legislatie/trasabilitatea.pdf

[182] Ministry of Health Order No.88/2015 on updating the order of the Ministry of Health No.62 / 2011 "On the traceability of blood products",available in Romanian at: https://ms.gov.md/sites/default/files/legislatie/ordinul_ms_nr.88_din_11_02.2015_privind_actualizarea_ordinului_ms_nr.62_din_01.02.2011_cu_privire_la_trasabilitatea_produselor_sanguine.pdf

[183] Ministry of Health Order No.105/2009 Regarding the approval of the Guidelines hemotransfusion, available in Romanian at: http://msmps.gov.md/wp-content/uploads/2020/06/3942-ordin2010520din202320aprilie2009.pdf

[184]Ministry of Health Order No.828/2011 Regarding the approval of the primary medical evidence form, available in Romanian at: http://ms.gov.md/sites/default/files/legislatie/ordinul_nr._828_din_31.10.2011.pdf

[185]https://drive.cloud.gov.md/index.php/s/ksctWJqXnstjRRW?dir=undefined&path=%2F2.%20FORMULARE%20DE%20EVIDEN%C8%9A%C4%82%20MEDICAL%C4%82%20%20PRIMAR%C4%82&openfile=113311 pages 22-25

[186] Ministry of Health Order No.91/2015 Regarding the approval of the “National Nomenclature of human blood products for use Therapeutic and Diagnostic ", available in Romanian at: https://cnts.md/legislatie/2015%20ordinul%20ms%20nomenclator%20produse%20sanguine.pdf

[187]Ministry of Health Order No.92/2015 Regarding the approval of the Quality System Standards in the activity of the institutions participating in the production of blood products, available in Romanian at: https://cnts.md/legislatie/2015%20ordinul%20ms%20standarde%20sistemului%20de%20calitate.pdf

[188] Order of the Ministry of Health No. 94/2015 on the updating of the Guide on the preparation, use and quality assurance of blood components, approved by the order of the Ministry of Health no. 105/2009 on the approval of the Guidelines for transfusion activity, available in Romanian at: 2015 ordinul ms actualizarea ghidului producere produse sanguine(1).pdf (cnts.md)

- Order of the Ministry of Health no. 464/2015 "On the approval of the Manual of standard procedures for the organization of blood transfusion care in the medical institution"[189]
- Order of the Ministry of Health no. 671/2018 "On the approval of the Diagnostic Algorithm based on the detection, identification and assessment of the title of incomplete anti-erythrocyte antibodies (immune) in pregnant women/women-birth(s)/abortion(s)/women and women consulted by specialists profile"[190]
- Order of the Ministry of Health no. 1099/2013 on the evaluation procedure of the blood transfusion centres, blood departments, blood banks"[191]
- Order of the Ministry of Health no. 970/2021 on the approval of the branch medical statistical reports for 2021". This order includes Form 39/san: "Statistical report of the activity of the blood center, blood department and blood bank"[192]
- Order of the Ministry of Health no. 381/2011 on the authorization of the import/export of blood products"[193]
- Order of the Ministry of Health no. 161/2009 on the approval of indicators for monitoring and evaluation of blood service activities"
- Order of the Ministry of Health no. 773/2020 on the organization of the hemovigilance system"[194]
- Order of the Ministry of Health no. 644/2020 on the approval of Algorithms of conduct in the management of post-transfusion reactions[195]

[189] Order of the Ministry of Health No. 464/2015 "On the approval of the Manual of standard procedures for the organization of blood transfusion care in the medical institution, available in Romanian at: http://msmps.gov.md/wp-content/uploads/2020/06/15091-ordinul20MS20nr.46420din2011.06.2015.pdf

[190] Order of the Ministry of Health No. 671/2018 "On the approval of the Diagnostic Algorithm, available in Romanian at: http://cnts.md/legislatie/Ordinul%20MSMPS%20nr.671%20din%2029%20mai%202018%20algoritm%20gravide.pdf

[191] Order of the Ministry of Health No. 1099/2013 on the evaluation procedure of the blood transfusion centres, blood departments, blood banks, available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordin_nr._1099_din_09.10.2013_cu_privire_la_procedura_de_evaluare_a_centrului_sectiei_si_cabinetului_de_transfuzie_a_singelui.pdf

[192] Order of the Ministry of Health No. 970/2021 on the approval of the branch medical statistical reports for 2021", available in Romanian at: https://drive.cloud.gov.md/index.php/s/ksctWJqXnstjRRW?dir=undefined&path=%2F1.%20RAPOARTE%20STATISTICE%202022&openfile=112895

[193] Order of the Ministry of Health No. 381/2011 on the authorization of the import/export of blood products", available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordinanexa_nr.381_din_13.05.2011.pdf

[194]Order of the Ministry of Health No. 773/2020 on the organization of the hemovigilance system", available in Romanian at: http://cnts.md/legislatie/Hemovigilenta%20Or.%20MSMPS%20nr%20773%20din%2024.08.2020.pdf

[195]Order of the Ministry of Health no. 644/2020 on the approval of Algorithms of conduct in the management of post-transfusion reaction, available in Romanian at: https://cnts.md/legislatie/Or%20MSMPS%20Algoritm%20reactii%20posttransfuzie%20nr.%20644%20din%2010.07.2020.pdf

Commission Directive 2014/110/EU of 17 December 2014 amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations, including next legislation and normative act:

- Order of the Ministry of Health no. 94/2015 on the updating of the Guide on the preparation, use and quality assurance of blood components, approved by the order of the Ministry of Health no. 105/2009 on the approval of the Guidelines for transfusion activity[196]

Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments, including next legislation and normative acts:

- Law on blood donation and blood transfusion no. 241/2008[197]
- Government Decision no. 657/2017 on the approval of the National Program for transfusion security and self-insurance of the country with blood products for the years 2017-2021[198]
- Order of the Ministry of Health No. 316/2007 on the implementation of the quality system in the blood service"[199]
- Order of the Ministry of Health No. 105/2009 on the approval of the Guidelines for blood transfusion activity"[200]
- Order of the Ministry of Health No. 1099/2013 "Regarding the evaluation procedure of the blood transfusion centers, blood departments, blood banks"[201]
- Order of the Agency of Medicines and Medical Devices No. 24/2013 on the approval of the Guide on Good Manufacturing Practice (GMP) for human use[202]

[196] Order of the Ministry of Health No. 105/2009 on the approval of the Guidelines for transfusion activity, available in Romanian at: 2015 ordinul ms actualizarea ghidului producere produse sanguine(1).pdf (cnts.md)
[197] Law no. 241/2008 on blood donation and blood transfusion, available in Romanian at: LP241/2008 (legis.md)
[198] Government Decision No. 657/2017 on the approval of the National Program for transfusion security and self-insurance of the country with blood products for the years 2017-2021, available in Romanian at: HG657/2017 (legis.md)
[199] Order of the Ministry of Health No. 316/2007 on the implementation of the quality system in the blood service, available in Romanian at: ordin 316.pdf (cnts.md)
[200] Order of the Ministry of Health No. 105/2009 on the approval of the Guidelines for blood transfusion activity, available in Romanian at: Microsoft Word - ordin 105 din 23 aprilie 2009 (gov.md)
[201] Order of the Ministry of Health No. 1099/2013 "Regarding the evaluation procedure of the blood transfusion centers, blood departments, blood banks, available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordin_nr._1099_din_09.10.2013_cu_privire_la_procedura_de_evaluare_a_centrului_sectiei_si_cabinetului_de_transfuzie_a_singelui.pdf
[202] Order of the Agency of Medicines and Medical Devices No. 24/2013 on the approval of the Guide on Good Manufacturing Practice (GMP) for human use, available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordin_nr._1099_din_09.10.2013_cu_privire_la_procedura_de_evaluare_a_centrului_sectiei_si_cabinetului_de_transfuzie_a_singelui.pdf

- Order of the Ministry of Health no. 91/2015 “On the approval of the National Nomenclature of Human Blood Products for Therapeutic and Diagnostic Use”[203]
- Order of the Ministry of Health no. 92/2015 on the approval of the Quality System Standards in the activity of the institutions participating in the production of blood products[204]
- Order of the Ministry of Health no. 94/2015 on the updating of the Guide on the preparation, use and quality assurance of blood components, approved by the order of the Ministry of Health no. 105/2009 "On the approval of the Guidelines for transfusion activity"[205]
- Order of the Ministry of Health no. 464/2015 on the approval of the Manual of standard procedures for the organization of blood transfusion care in the medical institution"[206]
- Order of the Ministry of Health no. 465/2015 "On the approval of the Guide in Immunohematology"[207]
- Order of the Ministry of Health no. 1491/2019 "On medical devices in vitro diagnostic and other materials used in ensuring blood safety and their eligibility criteria"[208]

Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments, including next legislation and normative acts:

- Law on blood donation and blood transfusion no. 241-XVI of 20.11.08. (Published: 13.01.2009 in the Official Gazette No. 1-2, art. No.: 2)[209]

[203] Order of the Ministry of Health no. 91/2015 “On the approval of the National Nomenclature of Human Blood Products for Therapeutic and Diagnostic Use, available in Romanian at: https://cnts.md/legislatie/2015%20ordinul%20ms%20nomenclator%20produse%20sanguine.pdf

[204] Order of the Ministry of Health no. 92/2015 regarding the approval of the Quality System Standards in the activity of the institutions participating in the production of blood products, available in Romanian at: 2015 ordinul ms standarde sistemului de calitate.pdf (cnts.md)

[205] Order of the Ministry of Health no. 94/2015 on the updating of the Guide on the preparation, use and quality assurance of blood components, approved by the order of the Ministry of Health no. 105 of 23.04.2009 "On the approval of the Guidelines for transfusion activity, available in Romanian at: https://cnts.md/legislatie/2015%20ordinul%20ms%20actualizarea%20ghidului%20producere%20produse%20sanguine(1).pdf

[206] Order of the Ministry of Health no. 464/2015 on the approval of the Manual of standard procedures for the organization of blood transfusion care in the medical institution, available in Romanian at: http://msmps.gov.md/wp-content/uploads/2020/06/15091-ordinul20MS20nr.46420din2011.06.2015.pdf

[207] Order of the Ministry of Health no. 465/2015 "On the approval of the Guide in Immunohematology, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2020/06/15093-ordinul20MS20nr.46520din2011.06.2015.pdf

[208] Order of the Ministry of Health no. 1491/2019 "On medical devices in vitro diagnostic and other materials used in ensuring blood safety and their eligibility criteria, available in Romanian at: OMSMPS1491/2019 (legis.md)

[209] Government Decision no. 657/2017 "On the approval of the National Program for transfusion security and self-insurance of the country with blood products for the years 2017-2021, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=125057&lang=ro#

- Government Decision no. 657/2017 "On the approval of the National Program for transfusion security and self-insurance of the country with blood products for the years 2017-2021"
- Order of the Ministry of Health no. 1279/2012 Regarding the responsibilities of access of the beneficiaries to the Automated Information System "Blood Service"[210]
- Order of the Ministry of Health no. 1060/2013 About the approval of the normative acts regarding the sterility of human blood products and infusion solutions[211]
- Order of the Ministry of Health no. 1099/2013 "Regarding the evaluation procedure of the blood transfusion centres, blood departments, blood banks"[212]
- Order of the Ministry of Health no. 1491/2019 "On medical devices in vitro diagnostic and other materials used in ensuring blood safety and their eligibility criteria"[213]
- Order of the Ministry of Health no. 91/2015 "On the approval of the National Nomenclature of Human Blood Products for Therapeutic and Diagnostic Use"[214]
- Order of the Ministry of Health no. 92/2015 Regarding the approval of the Quality System Standards in the activity of the institutions participating in the production of blood products[215]
- Order of the Ministry of Health no. 93/2015 On the approval of Instructions for blood collection and processing into blood components[216]
- Order of the Ministry of Health no. 94/2015 „Regarding the updating of the Guide on the preparation, use and quality assurance of blood

[210] Order of the Ministry of Health no. 1279/2012 Regarding the responsibilities of access of the beneficiaries to the Automated Information System "Blood Service", available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordinul_nr._1279_din_19.12.2012.pdf

[211] Order of the Ministry of Health no. 1060/2013 About the approval of the normative acts regarding the sterility of human blood products and infusion solutions, available in Romanian at: http://msmps.gov.md/wp-content/uploads/2020/06/14422-D094D0BED0BAD183D0BCD0B5D0BDD182.pdf

[212] Order of the Ministry of Health no. 1099/2013 "Regarding the evaluation procedure of the blood transfusion centres, blood departments, blood banks", available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordin_nr._1099_din_09.10.2013_cu_privire_la_procedura_de_evaluare_a_centrului_sectiei_si_cabinetului_de_transfuzie_a_singelui.pdf

[213] Order of the Ministry of Health no. 1491/2019 "On medical devices in vitro diagnostic and other materials used in ensuring blood safety and their eligibility criteria", available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=119842&lang=ro&

[214] Order of the Ministry of Health no. 91/2015 "On the approval of the National Nomenclature of Human Blood Products for Therapeutic and Diagnostic Use", available in Romanian at: https://cnts.md/legislatie/2015%20ordinul%20ms%20nomenclator%20produse%20sanguine.pdf

[215] Order of the Ministry of Health no. 92/2015 Regarding the approval of the Quality System Standards in the activity of the institutions participating in the production of blood products, available in Romanian at: https://cnts.md/legislatie/2015%20ordinul%20ms%20standarde%20sistemului%20de%20calitate.pdf

[216] Order of the Ministry of Health no. 93/2015 On the approval of Instructions for blood collection and processing into blood components, available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordinul_nr.93_din_12.02.2015_cu_privire_la_aprobarea_instructiunilor_de_recoltare_a_singelui_si_procesare_in_componente_sangui.pdf

components, approved by the order of the Ministry of Health no. 105/2009 "On the approval of the Guidelines for transfusion activity"[217]

- Order of the Ministry of Health no. 464/2015 "On the approval of the Manual of standard procedures for the organization of blood transfusion care in the medical institution"[218]
- Order of the Ministry of Health no. 465/2015 "On the approval of the Guide in Immunohematology"[219]
- Order of the Agency of Medicines and Medical Devices no. 24 of 24.04.2013 "On the approval of the Guide on Good Manufacturing Practice (GMP) for human use"[220]
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Transplant activity in the Republic of Moldova is governed by the Law No. 42/2008 On the transplantation of human organs, tissues and cells (Chapter VII)[221].

The following European Directives in the field of cells, tissues and organs are fully transposed into the national legislative and regulatory framework.:

- Directive 2004/23/EC of the European Parliament and the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

- Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells

- Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells

[217] Order of the Ministry of Health no. 94/2015 „Regarding of the Guide on the preparation, use and quality assurance of blood components", available in Romanian at: https://cnts.md/legislatie/2015%20ordinul%20ms%20actualizarea%20ghidului%20producere%20produse%20sanguine(1).pdf

[218] Order of the Ministry of Health no. 464/2015 "On the approval of the Manual of standard procedures for the organization of blood transfusion care in the medical institution", available in Romanian at: http://msmps.gov.md/wp-content/uploads/2020/06/15091-ordinul20MS20nr.46420din2011.06.2015.pdf

[219]Order of the Ministry of Health no. 465/2015 "On the approval of the Guide in Immunohematology", available in Romanian at: https://msmps.gov.md/wp-content/uploads/2020/06/15093-ordinul20MS20nr.46520din2011.06.2015.pdf

[220] Order of the Agency of Medicines and Medical Devices no. 24 of 24.04.2013 "On the approval of the Guide on Good Manufacturing Practice (GMP) for human use", available in Romanian at:https://msmps.gov.md/sites/default/files/legislatie/ordin_nr._1099_din_09.10.2013_cu_privire_la_procedura_de_evaluare_a_centrului_sectiei_si_cabinetului_de_transfuzie_a_singelui.pdf

[221] Law No. 42/2008 On the transplantation of human organs, tissues and cells, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110195&lang=ro.

- Commission Directive 2010/45/EU of the European Parliament and the Council of 7

July 2010 on standards of quality and safety of human organs intended for transplantation

- Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells

- Commission Directive 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells

- Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation

- Corrigendum to Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation

- Council conclusions on organ donation and transplantation

These were transposed in the following normative acts:

- Law No. 42/2008[222]
- Government decision No. 386/2010[223]
- Order of the Ministry of Health No. 427/2017[224]

Some European directives in the field of cells, tissues and organs are not currently implemented in the Republic of Moldova due to the fact that they refer exclusively to EU member states. This is because Moldova is not part of the European community and cannot implement them:

- Commission implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation
- Communication from the Commission Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States

[222] Law No. 42/2008 on organs, tissue and human cells transplant, available in Romanian at: LP42/2008 (legis.md)
[223] Government decision No. 386/2010 on functioning of Agency of Transplant, available in Romanian at: HG386/2010 (legis.md)
[224] Order of the Ministry of Health No. 427/2017 on standard of transplant of organs, tissue and human cells, available in Romanian at: 15457-Ordinul20MS20nr.42720din2006.06.2017.pdf (gov.md)

As well, it is to be mentioned that the Commission Directive 2015/566/EU of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells will be implemented in 2022.

29. How many blood establishments, plasma collection centres and fractionation plants, tissue establishments and transplant programmes are there? Is their vigilance and traceability organised on tissue transplantation assured and is staffing adequate?

The Blood Transfusion Service of the Republic of Moldova is represented by the National Blood Transfusion Center with 3 locations in Chisinau, Balti, Cahul, 19 blood transfusion departments in district hospitals and 69 blood banks in hospitals that offer treatment with blood products.

The activity of the National Blood Transfusion Center is regulated by the Regulation of the National Blood Transfusion Center approved by Order of the Ministry of Health No. 623/2015 on the organization of the activity of the National Blood Transfusion Center.[225] The activity of the blood transfusion departments and blood banks is regulated by Order of the Ministry of Health No. 605/2015 on the approval of the Regulation - framework on the organization of the activity of the blood departments, blood banks".[226]

The Center also has, at national level, a reference laboratory in immunohematology, whose activity is regulated by Order of the Ministry of Health No. 413/2015 "On the approval of the Framework Regulation on the organization of the activity of the Reference and Regional Laboratory in Immunohematology"[227].

The traceability process is organized at national level in accordance with the Order of the Ministry of Health No. 62/2011 on the traceability of blood products[228] that was updated later by Order of the Ministry of Health No. 88/2015 Regarding the updating of the Order of the Ministry of Health No.62/2011 on the traceability of blood products.[229]

[225] Order of the Ministry of Health No. 623/2015 on the organization of the activity of the National Blood Transfusion Center, available in Romanian at: http://cnts.md/legislatie/27-O.pdf
[226] Order of the Ministry of Health No. 605/2015 on the approval of the Regulation - framework on the organization of the activity of the blood departments, blood banks", available in Romanian at: https://cnts.md/legislatie/ordin_regulament_sectii_cabinet.pdf
[227] Order of the Ministry of Health No. 413/2015 "On the approval of the Framework Regulation on the organization of the activity of the Reference and Regional Laboratory in, available in Romanian at: Immunohematology"http://cnts.md/legislatie/2022/Annex%2028.8.42%20Order%20MoH%20413%20of%202015%20Regulation%20activity%20Reference%20Laboratory%20Immunohematology.pdf).
[228] Order of the Ministry of Health No. 62/2011 on the traceability of blood products, available in Romanian at: https://cnts.md/legislatie/trasabilitatea.pdf
[229] Order of the Ministry of Health No.62/2011 on the traceability of blood products, available in Romanian at: https://cnts.md/legislatie/2015%20ordinul%20ms%20trasabilitatea%20produse%20sanguine.pdf

Hemovigilance is ensured at national level in accordance with the provisions of the Order of the Ministry of Health No. 773/2020 on the organization of the hemovigilance system.[230]

The reporting of post-transfusion reactions in patients receiving blood products and in donors in the post-donation period at institutional and national level are reflected in the Order of the Ministry of Health No. 644/2020 on the approval of Algorithms of conduct in the management of post-transfusion reactions.[231]

In the Republic of Moldova there are two tissue establishments: one public, the operation of which established by the Order of the Ministry of Health No. 804 /2019 and one private, established by the Order of the Ministry of Health No. 1097/2019.

National Transplant Programme is a medium-term implementation document of the Republic of Moldova Government policies in the field of transplantation that includes the overall vision and the main principles of the development of transplantation in the Republic of Moldova for a period of 5 years.

Vigilance and traceability on tissue transplantation is organized and assured by an adequate staffing, in compliance with the Law No. 42/2008 On the transplant of human organs, tissues and cells (Chapter VII).

D. Patients' rights in cross-border healthcare & eHealth

30. Does Moldova have any legislation in place regarding the reimbursement of costs of healthcare received abroad by your citizens?

Reimbursement of the costs for healthcare received abroad by the citizens of the Republic of Moldova is regulated by the Order of the Ministry of Health No. 979/2016[232] and the Order of the Ministry of Health, Labor and Social Protection No. 902/2017[233]. Patients with diseases for which there is no capacity to perform

[230] Order of the Ministry of Health No. 773/2020 on the organization of the hemovigilance system, available in Romanian at: https://cnts.md/legislatie/Hemovigilenta%20Or.%20MSMPS%20nr%20773%20din%2024.08.2020.pdf

[231] Order of the Ministry of Health No. 644/2020 on the approval of Algorithms of conduct in the management of post-transfusion reactions, available in Romanian at: https://cnts.md/legislatie/Or%20MSMPS%20Algoritm%20reactii%20posttransfuzie%20nr.%20644%20din%2010.07.2020.pdf

[232] Order of the Ministry of Health No. 979/2016 on the selecting patients for expensive treatment, available in Romanian at: https://msmps.gov.md/sites/default/files/legislatie/ordin_privind_selectarea_pacientilor_pentru_tratament_si_sau_investigatii_costisitoare_in_redactie_noua.pdf

[233] Order of the Ministry of Health, Labor and Social Protection No. 902/2017 on the updating the Order of the MoH No. 979/2016, available in Romanian at: https://msmps.gov.md/wp-content/uploads/2022/04/Ordinul-nr.-902-din-24.11.2017-Cu-privire-la-modificarea-Ordinului-nr.-979-din-12.02.2016-„Privind-selectarea-pacienților-pentru-tratament-și-sau-investigații-costisitoare”.pdf

diagnostic procedures and/or treatment in the health care institutions in the country are eligible to receive these funds.

These orders regulate the activity of the Commission for selection of patients for treatment and/or costly investigations for the citizens of the Republic of Moldova, for treatment and/or costly investigations in the country and/or abroad of the Republic of Moldova.

The Commission decides on the reimbursement of healthcare costs provided abroad to the citizens of the Republic of Moldova in 2 steps:

- establishment of the preliminary amount, decided based on primary examination of the file by the Commission;
- establishment of the amount to be reimbursed to the patient/relatives decided based on the final examination by the Commission of the confirmatory financial documents regarding the treatment received abroad.

At the same time, the citizens of the Republic of Moldova who temporarily travel abroad, have the possibility to purchase their Travel Health Insurance Policy, regulated by the Law No. 407/2006[234], with subsequent amendments and the Civil Code of the Republic of Moldova[235]. Health insurance for travels abroad guarantees free access to health services in case of accident, medical emergencies, treatment in case of unforeseen illnesses or other situations that may affect a person's health, and for repatriation in case of death. If no health insurance was purchased, all health care expenses will be at the personal expense.

31. Does Moldova have any legislation in place regarding healthcare provided to nationals from EU Member States?

The provision of health care to foreign nationals in general is regulated by several normative acts in force. Thus, according to Law no. 1585/1998 on mandatory health insurance[236], the Government has the quality of insured for the beneficiaries of international protection included in an integration program, for its duration period.

Also, based on the provisions of Art. 2 para. (1) letter a)–c) of Law No. 274/2011 on the integration of foreigners in the Republic of Moldova[237], foreign nationals

[234] Law No. 407/2006 on the Health Insurance Policy for travel, available in Romanian at: https://www.legis.md/search/getResults?doc_id=129496&lang=en
[235] Civil Code of the Republic of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=112573&lang=ro
[236] Law no. 1585/1998 on mandatory health insurance, available in Romanian at:https://www.legis.md/cautare/getResults?doc_id=113243&lang=ro
[237] Law No. 274/2011 on the integration of foreigners in the Republic of Moldova, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=124776&lang=ro

have the same rights and obligations in the area of mandatory health insurance as the Moldovan citizens, unless the international treaties provide otherwise, if:

- they are employed in the Republic of Moldova on the basis of an individual employment contract, concluded according to the legislation of the Republic of Moldova,
- they are holders of a permanent residence permit in the Republic of Moldova,
- they are the beneficiaries of a temporary or humanitarian international protection.

Foreign citizens who have been granted the right of temporary residence on the territory of the Republic of Moldova for family reunification, for studies, for humanitarian, voluntary or religious activities have the obligation to insure themselves individually, paying the mandatory health insurance premium, similar to the citizens of the Republic of Moldova. In this way, they benefit from the entire package of health services from the Mandatory Health Insurance Funds.

Moreover, any person, regardless of their status on the territory of the Republic of Moldova, is offered emergency health care in case of danger to life (accidents, acute, serious illnesses, etc.). This aspect is stipulated in Art.24 Health Care in case of emergency and in extreme cases of the Law on Health Care No. 411/995[238], with subsequent amendments.

32. Does Moldova have a legal framework for health data protection? Who can have access to health data?

In the Republic of Moldova, health data denote:

- ***a special category of personal data***, as laid down in Law No. 133/2011 on personal data protection;
- ***medical secrecy/privacy***, as laid down in Law no. 263/2005 on patient's rights and responsibilities.

The processing (collection, storage, access and usage, etc.) of the special category of personal data takes place:

a) On the consent of the personal data subject, in line with the following provisions:

- Art. 6 para. (1) letter a) of Law No. 133/2011 on personal data protection[239] – the processing of special categories of personal data shall

[238] Law No. 411/1995 on Health Care, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=128014&lang=ro

[239] Law No. 133/2011 on personal data protection, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110544&lang=ro

be prohibited, except for cases where the personal data subject has given their consent.

- Art. 12 para. (3) Law no. 263/2005 on patient's rights and responsibilities[240] – the information which is deemed confidential may only be provided with the express consent of the patient or at the request of his or her legal representative (a close relative), under conditions consented to by the patient, to an extent appropriate to their capacity for understanding, and if a legal protection measure has been imposed on the patient or if expressly stated in the law.

Concerning medical facilities, health data can be accessed only by the staff providing the medical service and if the patient's consent was obtained before the medical examination.

b) Without personal data subject's consent:

- Art. 12 para. (4) letter c) of Law no. 263/2005 on patient's rights and responsibilities – transmission of the confidential information without patient or their legal representative's consent (a close relative) shall be allowed:
- to engage other specialists in the treatment process, including in case of emergency examination and treatment of a person deprived of the capacity to express their will because of their medical state, but only to the extent necessary to adopt a suitable decision;
- to inform the state public health surveillance authority of a real threat of a large-scale spread of infectious disease, intoxication, poisoning, and contamination;
- upon the reasoned request of the law enforcement agencies and courts of law in relation to the criminal prosecution or legal proceedings, as provided for in the legislation;
- upon the request of the Ombudsperson or, when needed, of the Ombudsperson for the Rights of the Child, to secure the protection of people against torture and other cruel, inhuman or degrading treatment or punishment;
- upon the request of the members of the Committee for the Prevention of Torture, during the visits they carry out and within the limits necessary to carry out these visits;
- upon the reasoned request of the Probation Inspectorate while performing their duties under the law;
- to inform the parents or the legal representatives of persons under 18 years of age if the latter are healthcare recipients;

[240] Law no. 263/2005 on patient's rights and responsibilities, available in Romanian at: https://www.legis.md/cautare/getResults?doc_id=110648&lang=ro

- if there is a ground to believe that the damage to a person's health is the result of some unlawful or criminal actions. Under such circumstances, the information shall be submitted to competent law enforcement agencies;
- Aggregate data that can no longer lead to patient identification are not covered by these legal provisions, and these data can be used for statistical purposes, for example.

Moreover, the institutions processing health personal data are obliged

- to develop a personal data protection policy that will stipulate the necessary technical and organisational measures to ensure that the data are processed correctly and in line with the law, and to focus on strictly necessary, relevant data categories which do not exceed the purpose for which they are processed (art. 29 and 30 of Law no. 133/2011 on personal data protection);
- to have a person in charge of personal data protection that will advise on and check that measures to secure the data are in place (art. 25 – 25^2 of Law no. 133/2011 on personal data protection).

In the performance of their duties, persons who received confidential data, along with the medical and pharmaceutical staff, bear liability for disclosure of the medical secrecy, as laid down in the law. In this case, the damages arising from health record information disclosure shall be considered.

33. Does Moldova have a national authority responsible for eHealth?

The national authority responsible for the policy making in the area of eHealth is the Ministry of Health[241]. However, there is not yet an entity for implementation and development for e-health. In this context, action plan of government for 2021-2022[242], envisages the creation of the governance body for eHealth, by end of 2022. The Republic of Moldova is one of the beneficiaries of EU4Digital initiative (2019-2022), funded by European Commission[243]. One of the thematic areas of the EU4Digital initiative is the development of harmonized national frameworks for eHealth, both among EaP partner countries and with the EU. During the first phase of the project, a set of individual recommendations for the Republic of Moldova was developed, which will inform the future decisions in the area of eHealth. Support is also being provided by WHO for development of a new national digital health strategy for Moldova by the end of 2022.

[241] Government Decision No.148/2021 on organization and functioning of Ministry of Health, available in Romanian at: HG148/2021 (legis.md)
[242] Government Decision 235/2021 on the approval of the Action Plan of the Government for 2021-2022, available in English at: hg_nr.235_13.10.2021-engl.pdf (gov.md)
[243] EU4Digital Initiative,available in English at: https://eufordigital.eu/thematic-area/ehealth/

34. Does Moldova have a legal framework on electronic health records?

Republic of Moldova is in the process of the development of legal framework on electronic patient health record[244]. In this context, some elements of the national or regional IT infrastructure for eHealth services and eHealth IT solutions, including eGovernment services will be re-used, such as Mcloud, MCabinet, etc.

35. Does Moldova have a legal framework on digital health?

Republic of Moldova is in the process of development of the legal framework on digital health. Key elements and strategic principles of the digital health are included in the draft Health system development strategy 2022-2031. Some basic principles of the future digital health are set by the Government Decision No.586/2017 on the keeping of medical register[245]. Medical register represents public information resource about patients, medical services providers, donors, blood transfusion. It includes several subsystems:

- SIAAMP (Automatic Information System on Primary Care),
- SIAAMS (Automatic Information System on Hospital Care),
- SIERUSS (Automatic Information system on human resources for health),
- SIATransplant (Automatic Information System on Transplant),
- SIASS (Automatic Information System on Blood Service),
- Portal of sick-leave certificates
- Medical Vaccination Certificate Portal, SIARVC-19 (Automatic Information System on COVID-19 Vaccine Record)
- Allied disease-specific systems developed by WHO, UNFPA, UNDP, and other international governmental organizations and donors operating in Moldova.

35. Does Moldova have a strategy in place to provide rare disease specific health services?

The Ministry of Health is currently finalising the drafting of the 2022-2030 National Programme on rare diseases and the List of rare disease in the Republic of Moldova. The 2022-2030 National Programme on rare disease control is a medium-term document encompassing the state's priority commitments to rare disease control and response measures with a view of reducing the medical and socio-economic burden of these disorders. Its goal is to improve the quality of life

[244]Analysis of the current state of eHealth in the Eastern partner countries, EU4Digital, 2020, available in English at: https://eufordigital.eu/wp-content/uploads/2021/02/Analysis-of-the-current-state-of-eHealth-in-the-Eastern-partner-countries.pdf

[245]Government Decision No.586/2017 on the keeping of medical register, available in Romanian at: HG586/2017 (legis.md)

and the degree of autonomy of the people affected by rare diseases by providing fair access to diagnosis, treatment and high-quality healthcare.

Patients with rare diseases benefit from the volume of services provided in the mandatory health insurance system included in the benefit package, as well reimbursed medicines. The diagnosis of patients with rare diseases is the responsibility of the Reproductive Health and Medical Genetics Centre under the Institute of Mother and Child Care, as well as other republican specialised institutions from Moldova. Then, a multidisciplinary commission is created to evaluate the patient and decide on treatment tactics.

Currently, 12 national clinical guidelines are implemented and they approach the subject of immunodeficiency diseases and rare disorders.[246]

The list of reimbursed medicines comprises the medicines for rare diseases (Epidermolysis bullosa, Mucoviscidosis, Myasthenia gravis, Duchenne muscular dystrophy), and patients with such disorders benefit from a 100% reimbursement from the mandatory healthcare insurance funds.

At the same time, a series of rare disease are identified in children (Mucopolysaccharidosis, Gaucher disease, Pompe disease, Fabry disease, Eizenmenger syndrome, severe heart malformations and heart rhythm disorders), and the access to treatment is a real challenge because of the tremendous costs. There are cases when the costs are bore by the parents or international charity and donor organisations, that cover the expenses for the medical care provided abroad.

E. Medicinal products for human use [& questions with * also should also be answered for medicinal products for veterinary use]

36. To what extent is national legislation in Moldova aligned with the EU acquis in these areas?

The authorization procedure of medicines for human use approved by the Order of the Ministry of Health of the Republic of Moldova No. 739/2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments[247] partially transposes the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use in Titles I - V, Titles VIII- IX.

[246] National clinical protocols, available in Romanian at: https://ms.gov.md/imunodeficiente-si-boli-rare/
[247] Order of the Ministry of Health of the Republic of Moldova No. 739/2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments, available in Romanian at: OMS739/2012 (legis.md)

Ethical promotion of medicines approved by Government Decision no. 944/2018 for the approval of the Regulation on the ethical promotion of medicines[248] partially transposes the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use in Art. 1, Titles VIII and VIIIa.

State control of drug quality is approved by Order of the Ministry of Health of the Republic of Moldova No. 521/2012 on state quality control of medicinal products[249] partially transposes the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use in Title VI.

Pharmacovigilance activities are regulated by the Order of the Ministry of Health of the Republic of Moldova No. 358/2017[250] on the approval of the Regulation on the performance of pharmacovigilance activities which transpune transposes Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.

The draft of the new Law of medicines is currently being drafted and will fully transpose Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. The approval of this law is included in the Government Action Plan for 2022.

The placing on the market and surveillance of medical devices is approved by:

- Law no. 102/2017 on medical devices[251];
- Government Decision no. 702/2018 on the approval of the Regulation on the conditions of placing medical devices on the market[252];

[248] Government Decision no. 944/2018 for the approval of the Regulation on the ethical promotion of medicines, available in Romanian at: HG944/2018
[249] Order of the Ministry of Health of the Republic of Moldova No. 521/2012 on state quality control of medicinal products, available in Romanian at: OMS521/2012
[250] Order of the Ministry of Health of the Republic of Moldova No. 358/2017, available in Romanian at:OMS358/2017
[251] Law no. 102/2017 on medical devices, available in Romanian at: LP102/2017 (legis.md)
[252] Government Decision No. 702/2018 on the approval of the Regulation on the conditions of placing medical devices on the market, available in Romanian at: HG702/2018

- Government Decision no. 703/2018 he approval of the Regulation on the conditions for the placing on the market of in vitro diagnostic medical devices[253];
- Government Decision no. 704/2018 on the approval of the Regulation on the conditions of placing active implantable medical devices on the market[254];
- Order of the Ministry of Health, Labor and Social Protection No. 211/2018 on the surveillance system of medical devices[255].

The above-mentioned normative acts partially transpose the European Directives: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices; Council Directive 90/385 / EEC of 20 June 1990 on active implantable medical devices.

A new draft law on medical devices has been drafted to be finalized and approved in 2022 and will transpose the new EU Medical Devices Regulations, namely:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

37. How are medicines authorized in Moldova and on what basis?

In the Republic of Moldova, medicines, including vaccines are registered through five authorization procedures (regular turnaround - 210 days), including three accelerated procedures for emergency use (10 days), SRA registered products (10 days) and WHO prequalified medicines (45 days), which are regulated by the provisions of the following normative acts:

- Law No. 1456/1993 regarding the pharmaceutical activity[256];
- Law No. 1409/1997 regarding medicines[257];

[253] Government Decision No. 703/2018 he approval of the Regulation on the conditions for the placing on the market of in vitro diagnostic medical devices, available in Romanian at:HG703/2018 (legis.md)
[254] Government Decision No. 704/2018 on the approval of the Regulation on the conditions of placing active implantable medical devices on the market, available in Romanian at: HG704/2018 (legis.md)
[255]Order of the Ministry of Health, Labor and Social Protection No. 211/2018 on the surveillance system of medical devices, available in Romanian at: OMS211/2018 (legis.md)
[256] Law No. 1456 /1993 regarding the pharmaceutical activity, available in Romanian at: (LP1456/1993 (legis.md))
[257] Law No. 1409 /1997 regarding medicines, available in Romanian at: (LP1409/1997)

- Law No. 116/2016 for the accession of the Republic of Moldova to the Convention on the Development of a European Pharmacopoeia and to the Protocol to the Convention on the Development of a European Pharmacopoeia[258].

In this regards, the holder or his legal representative must submit to the Agency for Medicines and Medical Devices (AMMD) an application for authorization, with the following attachments:

- dossier for authorization consisting of five Modules, confirming the quality, safety and efficacy of the medicinal product in Common Technical Document (CTD) format, on electronic support;
- product samples in sufficient quantity to ensure 3 full analyzes in accordance with the quality parameters, provided by the finished product specification, according to the methods presented in the analytical-normative documentation (DAN);
- reference substances, impurities and degradation products according to DAN in sufficient quantity to ensure 3 full analyzes.

The following documents, which certify the quality of the product, are attached to the administrative data:

- Pharmaceutical Certificate according to WHO recommendations;
- Manufacturing Authorizations and the GMP Certificate for all manufacturers, including the active substance.

In order to initiate the procedure for authorizing the medicine, the applicant must pay the payment account according to the type of application indicated by the Holder and which is issued by AMMD, according to the provisions of Government Decision no. 348/2014 on tariffs for services provided by the Agency for Medicines and Medical Devices[259].

The expertise of the file is carried out by a group of experts, qualified in the field, in accordance with the provisions of:

- The Order of the Ministry of Health of the Republic of Moldova No. 739/2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments[260];

[258] Law No. 116 /2016 for the accession of the Republic of Moldova to the Convention on the Development of a European Pharmacopoeia and to the Protocol to the Convention on the Development of a European Pharmacopoeia, available in Romanian at: (LP116/2016 (legis.md))
[259] Government Decision No. 348/2014 on tariffs for services provided by the Agency for Medicines and Medical Devices, available in Romanian at: (HG348/2014)
[260] The Order of the Ministry of Health of the Republic of Moldova No. 739/2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments , available in Romanian at: (OMS739/2012 (legis.md))

- Order of the Ministry of Health, Labor and Social Protection of the Republic of Moldova No. 1490/2019 on the application of the European Pharmacopoeia [261];
- Order of the Ministry of Health of the Republic of Moldova No. 192/2013 on the requirements for quality specifications of medicines in the Republic of Moldova [262];
- Order of the Agency of Medicines and Medical Devices of the Republic of Moldova No. A07.PS-01.Rg04-111/2018 on the practical application of the ICH Guidelines in the field of medicines;
- Order of the Agency for Medicines and Medical Devices of the Republic of Moldova no. A07.PS-01.Rg04-309/2015 on the approval of the necessary Guidelines for the authorization of medicinal products for human use and the introduction of post-authorization amendments[263].

Following a positive opinion from the group of experts, the drug is proposed for approval to the Commission of Medicines under the AMMD, which operates according to the Regulation on the organization and functioning of the Commission of Medicines approved by the Order of the Agency for Medicines and Medical Devices no. Rg04-000006/2022. Following the decision of the Commission of Medicines, AMMD issues the order of authorization of the medicines and the Certificate of Registration of Medicines, together with the annexes (Summary of Product Characteristics; Patient leaflet: Information for the user; mock-ups), which is further placed in the State Nomenclature of Medicines, which is accessible online on the following link http://nomenclator.amdm.gov.md/

According to the Order of the Ministry of Health of the Republic of Moldova no. 739/2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization variations, If there are any objections and are not completely removed after 2 consecutive notifications on the same objections from the initial information note, within the established deadline and/or if the result of the laboratory analysis is negative, the authorization procedure is interrupted by the order of the Medicines and Medical Devices Agency, with the subsequent written information of the applicant within 20 days.

[261] Order of the Ministry of Health, Labor and Social Protection of the Republic of Moldova No. 1490/2019 on the application of the European Pharmacopoeia, available in Romanian at: (OMSMPS1490/2019)
[262] Order of the Ministry of Health of the Republic of Moldova No. 192/2013 on the requirements for quality specifications of medicines in the Republic of Moldova, available in Romanian at: (OMS192/2013)
[263] Order of the Agency for Medicines and Medical Devices of the Republic of Moldova No. A07.PS-01.Rg04-309/2015 on the approval of the necessary Guidelines for the authorization of medicinal products for human use and the introduction of post-authorization amendments, available in Romanian at: (https://amdm.gov.md/ro/page/ghiduri)

38. Is there any system in Moldova to take appropriate action, if emerging safety issues for authorised medicinal products are discovered?

According to the provisions of Article 11 paragraph (3) of Law No. 1456/1993 on pharmaceutical activity[264], in case of emergency (alerts of the World Health Organization and the European Medicines Agency, notifications regarding the quality, notifications of detection of counterfeit medicines, and communication of serious adverse reactions to the administration of medicines), to protect the health of the population, the Medicines and Medical Devices Agency (MMDA) suspends the use on the territory of the Republic of Moldova of an authorized drug and withdraws from the State Drug Register Database the authorized drug that turned out to be dangerous. In addition to the drug withdrawal mechanism from the pharmaceutical market, MMDA has the empowerment to restrict the indications, introduce special warnings and precautions or contraindications in the Patient leaflet and Summary of the Product Characteristics. It prepares communication on this subject which are placed on the MMDA website as well as in the quarterly MMDA newsletter. Also, elaborates Information letters for health care professionals.

MMDA monitors the safety signals declared by the Holder of Registration Certificates, those evaluated by the EMA Pharmacovigilance Risk Assessment Committee (PRAC), and validates its own signals. The mechanism for reporting and evaluating individual safety case reports is described in the standard operating procedure of the Pharmacovigilance section. MMDA performs pharmacovigilance activities using the passive (unsolicited) method, which is the reporting of adverse reactions by patients, healthcare professionals and the Marketing authorization holder. One of the aspects of their evaluation is the assessment of the impact on the risk-benefit ratio of the medicine and/or on patients or public health. In 2021, there were no cases of withdrawal from the safety reasons of the medicines from the market. In 2022, were withdrawn 2 drug products as a result of safety signals. Thus, the identified signals are prioritized, and those with the status of emerging safety issues are presented to the Medicines Commission, which decides on subsequent procedures (withdrawal/suspension/restrictions on use). The steps are described in the standard internal operating procedure MMDA: C02.SOP-01 Monitoring of adverse drug reactions.

In accordance with the Order of the Ministry of Health no. 358/2017 on the approval of the Regulation on the conduct of pharmacovigilance activities[265], the Marketing Authorisation Holder has the obligation to identify and prevent the risks related to the safety of medicines after a thorough assessment of the risk-benefit ratio. The updated risk management plan is submitted to MMDA. After evaluating

[264] Law No.1456/1993 on pharmaceutical activity, available in Romanian at: (LP1456/1993 (legis.md))
[265] Order of the Ministry of Health No. 358/2017 on the approval of the Regulation on the conduct of pharmacovigilance activities, available in Romanian at: (OMS358/2017)

the risk management report, MMDA decides on further procedures (withdrawal/suspension/restrictions on use) if necessary.

Order No. 358/2017 on the approval of the Regulation on the conduct of pharmacovigilance activities transposes Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and the Council.

The MMDA Quality Control Laboratory holds ISO 17025/2019 certification which transposes the ICH Q9 Guidelines on Risk Management Plan. These provide mandatory procedures for monitoring the pharmaceutical market.

39. Describe the pharmaceutical sector upon which the implementation of the EU acquis will have an impact?

The field of medicines and medical devices in the Republic of Moldova is regulated by Law no. 1456/1993 regarding the pharmaceutical activity[1], Law no. 1409/1997 on medicines[2], Law no. 102/2017 on medical devices[3].

National legislation in the field of medicinal products must continue to be harmonized with the provisions of **Directive 2001/83 / EC establishing a Community code relating to medicinal products for human use**, which regulates the production, distribution, and use of medicinal products in the context of public health protection, by means that do not impede the development of the pharmaceutical industry or the marketing of medicines on the pharmaceutical market of the Republic of Moldova, by applying the rules of free movement of goods with the European Union within the implementation of the Moldova / EU Association Agreement.

The impact of the subsequent implementation of the European acquis will boost the following areas:

Authorization of placing medicines on the market:

In order to better protect public health and to avoid unnecessary duplication of effort in examining applications for marketing authorization for medicinal products, the Republic of Moldova will have the opportunity to accept applications for marketing authorization for medicinal products which are being assessed at that time in an EU state. A positive impact will have some provisions for immunological medicines, homeopathic medicines, radiopharmaceuticals, and medicines based on human blood or human plasma and advanced therapy.

Manufacture of medicines:

Facilitating the circulation of medicines and excluding repeated controls on medicines from other EU countries, by adopting European regulations, will set minimum conditions for the manufacture of medicines in third countries and imports from them.

Drug distribution:

The adoption of European legislation also provides the need to exercise control over the entire distribution chain of medicines, from their manufacturing or import in the Republic of Moldova to their release to the population, so as to ensure the storage, transport, and handling of these products under appropriate conditions. The measures that will be taken in this regard will greatly facilitate the withdrawal of inappropriate products from the market and will allow more effective measures to be taken against counterfeit products. At the same time, the Republic of Moldova must impose certain public service obligations on distributors who supply medicines, in order to avoid the lack of essential and vital medicines on the market.

Advertising and promotion of medicines:

Provisions governing the information provided to users will need to provide for a high degree of consumer protection in order to enable the correct use of medicinal products on the basis of complete and clear information. Advertising to the general public, even for over-the-counter medicines, could affect public health if it is excessive and inappropriate.

Medicinal advertising for persons qualified to prescribe or release them contributes to informing this population target. However, such advertisement should be subject to strict conditions and effective supervision, drawing in particular on the activities of the European regulatory authorities.

Medical representatives play an important role in promoting medicines. Accordingly, certain obligations should be laid down for them, in particular the obligation to provide a summary of the product characteristics to the target population. The distribution of free samples of medicines to the general public for promotional purposes should also be prohibited.

Pharmacovigilance:

In order to ensure the safety of medicinal products even after they have been placed on the market, it is necessary to ensure the continuous adaptation of pharmacovigilance systems, taking into account scientific and technical progress. Marketing authorization holders are responsible for the ongoing pharmacovigilance of medicinal products which they place on the market. The impact of EU acquis will have on strengthening and rationalizing the EU pharmacovigilance system, with the overall objectives of better protecting public

health, ensuring proper functioning of the internal market and simplifying the current procedures. As well the harmonization of the legislation will provide clear roles and responsibilities for the key responsible parties and clear obligations, will strengthen transparency and communication on medicine's safety issues to increase the understanding and trust of patients and health professionals, will strengthen companies' pharmacovigilance systems, will introduce a risk management planning for each new medicinal product, will ensure the proactive and proportionate collection of high quality data relevant to the safety of medicines.

Clinical Trials

Harmonizing the EU regulatory environment for Clinical Trials with medicinal products means improving the protection of participants, optimizing the use of safety information, and ensuring the credibility of data through a strengthened responsibility of the sponsors. As well will have an impact on Competent Authorities, pharmacovigilance, monitoring, clinical trials infrastructure, and funding; Impact ethics committees in order of participant protection.

Regulation and Authorization of Medical Devices:

The transposition into national law of the **Medical Devices Regulation (2017/745 / EU) (MDR) and The In Vitro Diagnostic Medical Devices Regulation (2017/746 / EU) (IVDR),** adopted in May 2017, will replace the directives (93/42, 98/79, 90/385) and will have the following impact:

- increasing of the requirements for clinical investigations and risk management for better safety.
- improve surveillance and control, including in-vitro medical devices.
- increasing transparency and traceability.
- reducing ambiguity through clear definitions and classifications.
- adoption of the unique identification system of medical devices (UDI).
- integration into the database regarding medical devices (EUDAMED).
- use of the implant card with information about the medical device.
- use of more rigorous control for medical devices with higher risk classes.
- will impact the Intellectual property that are crucial for the EU's ability to stimulate innovation and to compete in the global economy. Counterfeit products can put at risk consumer safety and health, and can harm the environment. The EU supports strong IPR standards to tackle IPR infringements in the EU and abroad.

40. How many nationally authorised medicinal products (human and veterinary) are currently authorised to be placed on the market in Moldova?

As of April 2022, there are 4059 brand names of medicinal products authorized for human use included in State Register of human use medicines[266] and 865 brand names of medicinal products for veterinary use, included in the State Register of veterinary medicinal products[267].

41. Does Moldova have any legislation on the clinical trials on human subjects?

In the Republic of Moldova, clinical trials are regulated by Law No. 1409/1997 on medicines (chapter III art. Art. 11, 12, 13)[1], which describes the procedures for performing preclinical tests and clinical trials, how to submit files, defending the rights of patients and volunteers participating in studies. The authority that expertise and approves the way of conducting clinical trials is the National Committee for Ethical Expertise of Clinical Trial (NCEECT), a non-profit public institution with financial autonomy, in which the Ministry of Health has the quality of founder in accordance with Government Decision No. 5/2016 on the National Committee for Ethical Expertise of Clinical Trial[2].

NCEECT has the mission of protecting the rights, safety and well-being of all subjects, according to the provisions of the national legislation of the Republic of Moldova, international norms and standards recommended by the World Health Organization, the European Convention of April 4, 1997 for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, the Convention on Human Rights and Biomedicine, signed in Oviedo on April 4, 1997, compliance with the ethics rules in accordance with the Declaration of Helsinki on Human Rights and Good Clinical Practice (ICH – GCP), other conventions of the European Council. The clinical trials can be carried out only with the authorization of the Medicines and Medical Devices Agency (MMDA) after obtaining the approvals of the Medicines Commission and NCEECT.

Approximately 60 clinical trials are approved annually, predominantly phases 1-3. Therapeutic domain profile of approved clinical trials in 2021: Neurology - 9; Enterology - 6; Covid-19 - 6; Immunology - 5; Oncology - 5; Hepatology - 4; Rheumatology - 2; Urology - 2; Cardiology - 2; Hematology - 1; Psychiatry - 1; Pneumology - 1, Phthisiology - 1. Clinical trials approved in 2021, depending on the number and location of sites: unicentric international (foreign) - 13; multicenter international (foreign) - 32.

[266] State Register of Medicines, available in Romanian at: http://nomenclator.amdm.gov.md/
[267] State Register of veterinary medicinal products, available in Romanian at: http://registru.ansa.gov.md/

In 2021 national clinical trials were not submitted for approval. Usually, national clinical trials are phase IV clinical trials. The list of approved clinical trials is available on https://amdm.gov.md/ro/page/anunturi-importante-sc.

42. Does Moldova have any legislation to address the risk of falsified medicine in the legal supply chain?

The following actions shall be taken to carry out risk prevention measures, to verify a monitor the supply chain:

- State control of the quality of medicines at the stage of import and placing on the market, according to the provisions of the Order of the Ministry of Health No. 521/2012 on state control of drug quality[268].
- Monitoring of the pharmaceutical market by the MMDA Quality Control Laboratory, based on the ISO 17025/2019 certification that transposes the ICH Q9 Guidelines on Risk Management Plan. They provide mandatory procedures for monitoring the pharmaceutical market.
- Suspension of the use on the territory of the Republic of Moldova of an authorized drug and withdrawal from the State Drug Register, proved to be offensive, according to the provisions of Article 113 paragraph (3) of Law 1456/1993 on pharmaceutical activity, in case of emergency (World Health Organization and European Medicines Agency alerts), quality notifications, notifications for counterfeit medicines and reports of serious adverse drug reactions.
- State control in the field of pharmaceutical activity, through unannounced controls based on population complaints and planned controls based on risk analysis, performed by the Pharmaceutical Inspectorate.

According to the provisions of Article 27 of Law No. 1409/1997 on medicines[269], any natural or legal person who has committed, intentionally or negligently, violations of the provisions of this law, other laws and/or regulations regarding the production, circulation, marketing and use of medicines, lead to deterioration of the patient's health or death, mass drug poisoning, damage, falsification of medicinal products, failure to ensure the public or private medical institution with drugs according to the contractual commitments assumed or other similar acts, will be held disciplinary liability (including material), civil, contraventional or criminal, under the conditions of the law and of the clauses of the respective contract.

[268] Order of the Ministry of Health No. 521/2012 on state control of drug quality, available in Romanian at: OMS521/2012 (legis.md)
[269] Law No. 1409/1997 on medicines, available in Romanian at: LP1409/1997

At the same time, Article 77 paragraph (4), and paragraph (6) of the Contravention Code[270] of the Republic of Moldova provide sanctions for improper storage of medicines; storage, use, advertising, and marketing of medicines not authorized by the Medicines and Medical Devices Agency (MMDA) or after expiration date, as well as those without the document and/or information attesting the quality of the medicine and without the name and address of the manufacturer, with modification of the manufacturing formula, technological flow, labeling of medicines, other pharmaceuticals and para pharmaceuticals, also the technical-normative documentation, by the enterprises that produce medicines, other pharmaceutical and para pharmaceutical products without the respective authorization.

Also, in the light of Article 214[1] of the Criminal Code[271] of the Republic of Moldova, sanctions are provided for the production or sale of counterfeit medicines. There are no formal agreements between competent authorities. Any of the cases identified by a competent authority is communicated to other relevant authorities on a case-by-case basis.

According to the provisions set out in Order of the Ministry of Health No. 1400/2014 on the approval of the Rules of Good Distribution Practice of Medicines (GDP) for human use[272], wholesalers must immediately inform the competent authority and the marketing authorization holder of any medicinal products they identify as falsified or suspect to be falsified.

43. What is the level of expertise available in in Moldova on paediatric medicinal products, medicinal products for the diagnosis, prevention or treatment of rare conditions (covered in the EU by the definition of orphan medicinal products covered in the EU legislation on medicines for rare diseases), medical products based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering)?

The expertise of the files during the drug authorization process is performed by specialists approved through an order of the Medicines and Medical Devices Agency, based on their clinical qualification, professional experience, and training in the field of specialized regulatory expertise. Currently, 30 clinical experts are approved, two of whom are pediatricians.

The expertise of the files for the authorization of medicines, including pediatric ones, is made on the basis of the Order of the Ministry of Health No. 739/2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments[273]. In the Republic of Moldova, the

[270] Contravention Code No. 218/2008, available in Romanian at: CC218/2008 (legis.md)
[271] Criminal Code No. 985/2002, available in Romanian at: CP985/2002 (legis.md)
[272] Order of the Ministry of Health No. 1400/2014 on the approval of the Rules of Good Distribution Practice of Medicines (GDP) for human use, available in Romanian at: OMS1400/2014 (legis.md)
[273] Order of the Ministry of Health of the Republic of Moldova No. 739/2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments, available in Romanian at: OMS739/2012 (legis.md)

additional evaluation of medicines indicated for the pediatric population is not regulated by any legislative acts.

The evaluation of dossiers for medicinal products based on genes (gene therapy), cells (cell therapy), and tissues (tissue engineering) is performed according to the provisions of Chapter IV of Annex no. 3 to the Order of the Ministry of Health no. 739/2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments, Medicines for advanced therapy.

The dossiers for orphan medicinal products are evaluated under Section 6 of Annex no. 1 and section 5 of Annex no. 3 to the Order of the Ministry of Health of the Republic of Moldova no. 739 of 23.07.2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments.

Experts appointed to evaluate dossiers for the authorization of medicinal products for human use require further training in the evaluation of medicinal product dossiers based on genes (gene therapy), cells (cell therapy), and tissues (tissue engineering).

44. Describe the structure and the size of the competent institution(s) responsible for authorisation of human and veterinary medicines in Moldova, and their administrative capacity. Which ministry is supervising the veterinary and human medicinal products?

Competent authorities responsible for the authorization of human medicines is *Medicines and Medical Devices Agency*, according to the Law No.1409/1993 on medicines[274] and for the authorization of veterinary medicines is *National Food Safety Agency*, according to the Law no. 119/2018 on veterinary medicinal products[275]. Both authorities are directly subordinated to the Prime-Minister.

At the policy level, Ministry of Health is responsible for human medicines and Ministry of Agriculture and Food Industry is responsible for veterinary medicines.

Medicines and Medical Devices Agency, according to the Government Decision No.71/2013, on the approval of regulation, structure and staffing of Medicines and Medical Devices Agency[276], has 20 units with 110 staff positions, out of which 11 are main subdivisions and 9 support subdivisions. Main subdivisions include the following: Medicines authorization unit (19 staff); Pharmacovigilance and clinical studies unit (6 staff); Medical devices regulation and evaluation unit (5 staff); Medical devices management and surveillance unit (5 staff); Pharmaceutical activity licensing unit (4 staff); Pharmaceutical activity authorization unit (5 staff);

[274] Law No.1409/1997 on medicines, available in Romanian at: LP1409/1997
[275] Law No. 119/2018 on veterinary medicinal products, available in Romanian at: LP119/2018
[276] Government Decision No.71/2013, on the approval of regulation, structure and staffing of Medicines and Medical Devices Agency, available in Romanian at: HG71/2013 (legis.md)

Quality Control Laboratory (26,5 staff); Import/export permission unit (3 staff); Pricing unit (5 staff); Safe disposal of medicines unit (1 staff); Standing Committee on Drug Control (3 staff). Under the Agency of Medicines and Medical Devices, there is a Medicines Commission, consisting of 19 members (staff and non-staff), which is responsible for the decision making regarding medicines authorization.

Within the *National Food Safety Agency* there are two units responsible for the authorization and surveillance of veterinary medicinal products:

- The Control Department for veterinary medicinal products and feed - 2 staff positions,
- The Veterinary Medicinal Products Commission - 9 members.

The Commission, according to the Government Decision no. 157/2019 on the approval of the Regulation of the Commission on veterinary medicinal products[277] is responsible for scientific evaluation of authorization dossiers, and the Department is responsible for receiving applications for authorization, dossiers primary evaluation, interaction with applicants, issuing of registration certificates and updating the State Register, archiving of dossiers/other documentation etc.

45. How many inspections of pharmaceutical companies have there been in the previous three years in Moldova?

During previous three years, the total number of 406 inspections of pharmaceutical companies have been performed: the Good Pharmacovigilance Practice inspections (GVP) - 7; the Good Clinical Practice inspections (GCP) - 29; the Good Manufacturing Practice inspections (GMP) - 15, including 2 inspections abroad; the Good Distribution Practice inspections (GDP) – 20, and the state controls of pharmaceutical activity - 335. The GVP, GCP, GMP and GDP inspections are performed by National Regulatory Authority – Medicines and Medical Devices Agency, according to the following regulations:

- the Order of the Ministry of Health No. 309/2013 on the approval of the Good Manufacturing Practice of Medicinal Products for Human Use[278] which creates the necessary framework for the application of the Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of Good Manufacturing Practice in respect of medicinal products for human use and investigational medicinal products for human use and the Order of the Medicines and Medical Devices Agency No. 24/2013 on the approval of the Guide on the Good

[277] Government Decision No. 157/2019 on the approval of the Regulation of the Commission on veterinary medicinal products, available in Romanian at: HG157/2019 (legis.md)
[278] Order of the Ministry of Health No. 309/2013 on the approval of the Good Manufacturing Practice of Medicinal Products for Human Use, available in Romanian at: OMS309/2013 (legis.md)

Manufacturing Practice for medicinal products for human use[279], which at the time of approval was a transposition of the Volume 4 of "The rules governing medicinal products in the European Union" contains guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively;

- the Order of the Ministry of Health No. 1400/ 2014 on Good Distribution Practice of medicinal products for human use[280] transposing European Commission 2013/C 343/01 Guidelines of 5 November 2013
- the Order No. 648/2016 regarding the Regulation of the authorization to conduct clinical trials in the Republic of Moldova[281] and the Government Decision No. 5/2016 on the National Committee for Ethical Expertise of Clinical Trial[282]
- Law No. 1409/1997 on medicines[283];
- the Order of the Ministry of Health No. 358/2017 on the approval of the Regulation on the conduct of pharmacovigilance activities[284];
- the Order of the Ministry of Health No. 739/2012 on the Regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments[285].

State control on pharmaceutical activity is performed by the National Agency of Public Health to verify the compliance to the national legal framework: Law No. 1456/1997 on pharmaceutical activity, Law No.102/2017 on pharmaceutical devices, Law No.131/2012 on entrepreneurship, Law No.382/1999 on circulation of the Narcotic Drugs, Psychotropic Substances and their Precursors.

[279] Order of the Medicines and Medical Devices Agency No. 24/2013 on the approval of the Guide on the Good Manufacturing Practice for medicinal products for human use, available in Romanian at: OAMDM24/2013 (legis.md)

[280] Order of the Ministry of Health No. 1400/ 2014 on Good Distribution Practice of medicinal products for human use, available in Romanian at:OMS1400/2014

[281] Order No. 648/2016 regarding the Regulation of the authorization to conduct clinical trials in the Republic of Moldova, available in Romanian at:1._Ordinul_MS_nr._648.pdf (gov.md)

[282] Government Decision No. 5/2016 on the National Committee for Ethical Expertise of Clinical Trial, available in Romanian at: HG5/2016 (legis.md)

[283] Law No. 1409/1997 on medicines, available in Romanian at: LP1409/1997 (legis.md)

[284] Order of the Ministry of Health No. 358/2017 on the approval of the Regulation on the conduct of pharmacovigilance activities, available in Romanian at: OMS358/2017 (legis.md)

[285] Order of the Ministry of Health No. 739/2012 on the Regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments, available in Romanian at: OMS739/2012 (legis.md)

F. Cosmetics

46. Is there any national legislation in Moldova relating to cosmetics, and if so, is it aligned with Regulation (EC) No 1223/2009?

The regulatory framework in the field of cosmetics includes the Sanitary Regulation on cosmetics approved by Government Decision No.1207/2016[286], which partially transposed the Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products.

That decision provided for a transitional period of 24 months from the date of approval, in order to build national capacity in this field and to ensure compliance of the rules on market placing of cosmetic products within the provisions of the Regulation.

The Regulation lays down the requirements and responsibilities of economic operators for ensuring the safety of cosmetics for human health, lays down the safety assessment procedure, restrictions for certain substances, as well as labeling rules and product declarations for the purpose of informing the consumer.

The control over cosmetic products is carried out by the National Agency for Public Health, in accordance with Law No. 131/2012 on state control over entrepreneurial activity[287] and Law No. 10/2009 on state surveillance of public health[288]. Surveillance of compliance with the provisions of the Regulation shall be carried out through checks carried out on cosmetic products placed on the market, by means of a dossier with product information, physical and laboratory checks based on appropriate evidence.

In order to ensure the full implementation of the provisions of the Regulation, the regulatory and market surveillance authorities are to develop the notification platform on imported cosmetics and guidelines for importers regarding cosmetics notification portal.

[286] Sanitary Regulation on cosmetics approved by Government Decision No.1207/2016, available in Romanian at: HG1207/2016 (legis.md)
[287] Law No. 131/2012 on state control over entrepreneurial activity, available in Romanian at: LP131/2012
[288] Law No. 10/2009 on state surveillance of public health, available in Romanian at: LP10/2009 (legis.md)

Annex – EU acquis under Chapter 28

a) Consumers - Safety-related issues

- General Product Safety Directive (2001/95/EC)
- Commission implementing Decision laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' ((EU) 2019/417)
- Commission Implementing Decision on European standards for products drafted in support of Directive 2001/95/EC ((EU) 2019/1698)
- Food-imitating Products Directive (Directive 87/357/EEC)
- Liability for defective products (Directive 85/374/EEC)

b) Non-safety related measures (protection of economic interests of consumers)

- Certain aspects concerning contracts for the supply of digital content and digital services (Directive (EU) 2019/770)
- Sale of goods (Directive (EU) 2019/771)
- Unfair terms in consumer contracts (Directive 93/13/EEC)
- Indication of the prices of products offered to consumers (Directive 98/6/EC)
- Consumer rights (Directive 2011/83/EU)
- Distance marketing of consumer financial services (Directive 2002/65/EC)
- Credit agreements for consumers (Directive 2008/48/EEC)
- Misleading and comparative advertising (Directive 2006/114/EEC)
- Unfair commercial practices (Directive 2005/29/EC)
- Better enforcement and modernisation of consumer protection rules (Directive (EU) 2019/2161)
- Certain aspects of timeshare, long term holiday product, resale and exchange contracts (Directive 2008/122/EC)
- Package travel and linked travel arrangements (Directive (EU) 2015/2302)
- Representative actions for the protection of the collective interests of consumers (Directive 2020/1828)
- Consumer Protection Cooperation Regulation (Regulation 2017/2394)
- Alternative dispute resolution for consumer disputes (Directive 2013/11/EU)
- Online dispute resolution for consumer disputes (Regulation (EU) No 524/2013)
- Pre-contractual information to be given to consumers by lenders offering home loans (Commission Recommendation 2001/193/EC)
- Cooperation between national authorities responsible for the enforcement of consumer protection laws (Regulation (EU) 2017/2394)

c) Public Health

- Council conclusions on the "Reflection process on modern, responsive and sustainable health systems" (CON 2013/12)
- Social Investment Package - Commission Staff Working Paper Investing in Health accompanying the document Towards Social Investment for Growth and Cohesion - including implementing the European Social Fund 2014-2020 (2013)
- Conclusions of the 3053rd EPSCO Council meeting, Brussels, 7 December 2010, Investing in Europe's health workforce of tomorrow: Scope for innovation and collaboration.

- The Commission Communication "Towards a job rich recovery" (Com 2012 173/3) sets out a range of measures to encourage employment and strengthen economic growth in Europe. It also identifies healthcare as one of three key sectors with a high employment potential and includes an Action Plan for the EU health workforce (SWD 2012 93 final).
- Council Recommendation 1999/519/EC of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)

d) Tobacco

- Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products and repealing Directive 2001/37/EC
- Commission Delegated Directive 2014/109/EU of 10 October 2014 amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products
- Commission Implementing Decision (EU) 2015/1735 of 24 September 2015 on the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches
- Commission Implementing Decision (EU) 2015/1842 of 9 October 2015 on the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking
- Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products
- Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers
- Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes
- Commission Implementing Decision (EU) 2016/787 of 18 May 2016 laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations
- Commission Implementing Regulation (EU) 2016/779 of 18 May 2016 laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour
- Commission Implementing Decision (EU) 2016/786 of 18 May 2016 laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determining whether tobacco products have a characterising flavour
- Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products
- Commission Delegated Regulation (EU) 2018/573 of 15 December 2017 on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products
- Commission Implementing Decision (EU) 2018/576 of 15 December 2017 on technical standards for security features applied to tobacco products

- Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products
- Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provisions of audio-visual media services (Audio-visual Media Services Directive)
- Council Recommendation 2003/54/EC of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco control
- Council Decision 2004/513/EC of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco Control
- Council Recommendation of 30 November 2009 on smoke-free environments (2009/C296/02)

e) Serious cross-border health threats including communicable diseases

Basic Act

 1082/2013/EU: Decision of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

f) Implementing Measures

g) Early Warning and Response System

- 2000/57/EC: Commission Decision of 22 December 1999 on the early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council. - Official Journal, L 21/32; 26.01.2000
- 2008/351/EC: Commission Decision of 28 April 2008 amending Decision 2000/57/EC as regards events to be reported within the early warning and response system for the prevention and control of communicable diseases (OJ, L 117, 01.05.2008, p. 44).
- 2009/547/EC: Commission Decision of 10 July 2009 amending Decision 2000/57/EC on early warning and response system for the prevention and control of communicable diseases under Decision No 2119/98/EC of the European Parliament and of the Council (OJ L 181, 11.07.2009, p.57)
- 2017/253/EU: Commission Implementing Decision of 13 February 2017 laying down procedures for the notification of alerts as part of the early warning and response system established in relation to serious cross-border threats to health and for the information exchange, consultation and coordination of responses to such threats pursuant to Decision No 1082/2013/EU of the European Parliament and of the Council (OJ L 37, 14.2.2017, p. 23–27)
- Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions.

h) List of communicable diseases

- 2000/96/EC: Commission Decision of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (OJ, L 28, 03.02.2000, p.50)
- 2003/534/EC: Commission Decision of 17 July 2003 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions for communicable diseases (OJ L 184, 23.7.2003, p. 35).
- 2003/542/EC: Commission Decision of 17 July 2003 amending Decision No 2000/96/EC as regards the operation of dedicated surveillance networks (OJ L 185, 24.7.2003, p. 55).
- 2007/875/EC: Commission Decision of 18 December 2007 amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards the operation of dedicated surveillance networks (OJ L 344, 18.12.2007, p. 48).
- 2009/312/EC: Commission Decision of 2 April 2009 as regards dedicated surveillance networks for communicable diseases (OJ L 91, 3.4.2009, p. 27).
- 2009/539/EC: Commission Decision of 10 July 2009 amending Decision 2000/96/EC on communicable diseases to be progressively covered by the Community network under Decision No 2119/98 of the European Parliament and of the Council (OJ L 180, 11.7.2009, p. 22).
- 2012/492/EU: Commission Decision of 3 September 2012 amending Decision 2000/96/EC as regards tick-born encephalitis and the category of vector-borne communicable diseases (OJ L 239, 5.9.2012, p. 3).
- 2018/945/EU: Commission Implementing Decision of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions.

i) Case definitions for reporting communicable diseases

- Commission Decision No 2002/253/EC: of 19 March 2002 laying down case definitions for reporting communicable diseases to the Community network under Decision N° 2119/98/EC of the European Parliament and of the Council - Official Journal, L 86/44; 03.04.2002
- Commission Decision No 2008/426/EC of 28 April 2008 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (OJ L 159, 18.6.2008, p. 46).
- Commission Decision No 2009/363/EC of 31 April 2009 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (OJ L 110, 1.5.2009, p. 58).
- Commission Decision No 2009/540/EC of 10 July 2009 amending Decision 2002/253/EC as regards case definitions for reporting Influenza A(H1N1) to the Community network (OJ L 180, 11.7.2009, p. 24).
- Commission Decision No 2012/506/EU of 8 August 2012 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (OJ L 262, 27.9.2012, p.1).

j) Basic Act

- Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April
2004 establishing a European Centre for Disease Prevention and Control- Official Journal L 142/1;30.04.2004
- Regulation (EU) No 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

k) Basic Act

 Regulation (EU) No 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), (OJ L 119, 4.5.2016, p.1)

l) Implementing Measures

 2012/73/EU: Commission Recommendation of 6 February 2012 on data protection guidelines for the Early Warning and Response System (EWRS), (OJ L 36, 9.2.2012, p. 31).

m) Basic Act

- 2000/54/EC: Directive of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC), (OJ L 262, 17.10.2000, p.21).
- Regulation (EU) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).
- 2003/99/EC: Directive of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 235, 12.12.2003, p. 31).

Blood, tissues, cells and organs

- Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC
- Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components
- Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life
- Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events

- Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments
- Commission Directive 2014/110/EU of 17 December 2014 amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations
- Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments
- Directive 2004/23/EC of the European Parliament and the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
- Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells
- Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells
- Commission Directive 2010/453/EU of the European Parliament and the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation
- Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells
- Commission Directive 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells
- Commission Directive 2015/566/EU of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells
- Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation
- Corrigendum to Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation
- Commission implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation
- Council conclusions on organ donation and transplantation
- Communication from the Commission Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States

n) Patients' rights in cross-border health care

- Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45–65)

- Commission Implementing Decision (2011/890/EU) of 22 December 2011 providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth.
- Commission Implementing Decision (2013/329/EU) of 26 June 2013 providing the rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment
- Commission Delegated Decision 2014/286/EU of 10.3.2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil
- Commission Implementing Decision 2014/287/EU of 10.3.2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks
- Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measure to facilitate the recognition of medical prescriptions issued in another Member State

o) Medicinal products (human and veterinary), cosmetics and medical devices

A complete list of EU medicinal products acquis is available on the DG Health and Food Safety website - EudraLex (europa.eu)

- Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.

p) Mental health, socio-economic determinants of health, health inequalities, drug abuse prevention, healthy lifestyle, nutrition, eHealth, alcohol abuse prevention, cancer screenings, and healthy environment including prevention of injury, promotion of safety and European action in the field of rare diseases

q) Mental health

- 2000/86/01/EC: Council Resolution of 18 November 1999 on the promotion of mental health
- Con. 02/6/01/EC: Council Conclusions of 15 November 2001 on combating stress and depression-related problems
- Con. 03/9688/1/EC: Council Conclusions of 2 June 2003 on combating stigma and discrimination in relation to mental illness
- Con. 05/9805/EC: Council Conclusions of 3 June 2005 on a Community Mental Health Action
- Communication from the Commission to the European Parliament and the Council Taking forward the Strategic Implementation Plan of the European Innovation Partnership on active and healthy ageing - COM (2012) 83 final
- Council conclusions on Healthy Ageing across the Lifecycle, 7 December 2012
- Communication from the Commission to the European Parliament and the Council on a European initiative on Alzheimer's disease and other dementias - COM(2009) 380 final
- Council conclusions on 'The European Pact for Mental Health and Well-being: results and future action' - Con. 11/3095/EC

- Council conclusions December 2015 - Living with dementia: improving care policies and practices

r) Health inequalities

- (2013) Commission Staff Working Document - Report on Health Inequalities in the European Union
- (2012) Commission Communication “National Roma Integration Strategies: a first step in the implementation of the EU Framework” - COM 2012/226 final
- (2011) Council Conclusions on closing health gaps within the EU through concerted action to promote healthy lifestyle behaviour
- (2011) Council conclusions on an EU Framework for National Roma Integration Strategies up to 2020
- (2010) Council Conclusions on equity in health of 8 June 2010
- (2010) Commission Communication on the economic and social integration of the Roma in Europe, April 2010 - COM/2010/0133 final
- (October 2009) Commission's plans to address health inequalities are set out in the Commission Communication - Solidarity in Health: Reducing Health Inequalities in the EU, published on 20 October 2009
- (2009) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Solidarity in health: reducing health inequalities in the EU {SEC(2009) 1396} {SEC(2009) 1397}

s) Drug abuse prevention and harm reduction

- Res. 00/C218/3/EC - Council Resolution of 29 June 2000 on action on health determinants Drugs abuse prevention and harm reduction
- 2003/488/EC: Council Recommendation of 18 June 2003 on the prevention and reduction of health-related harm associated with drug dependence
- Notice 2008/C 326/09: EU Drugs Action Plan for 2009-2012

t) Nutrition and physical activity

- (2016) Council conclusions of 17 June 2016 on food product improvement
- (2014) Council Conclusion on Nutrition and Physical Activity
- (2014) EU Action Plan on childhood obesity
- (2013) Council Recommendation on promoting health-enhancing physical activity across sectors (COM(2013) 603 final)
- (2011) Council Conclusions on closing health gaps within the EU through concerted action to promote healthy lifestyle behaviours, 1-2 December 2011
- (2010) Council Conclusions of 8 June 2010 on action to reduce population salt intake for better health
- (2007) WHITE PAPER A Strategy for Europe on Nutrition, Overweight and Obesity related health issues COM (2007) 279 final, 30.5.2007
- Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods
- Con. 05/9803/EC: Council Conclusions of 3 June 2005 on obesity, nutrition and physical activity

- Con. 04/C221/EC: Council Conclusions of 2 December 2003 on healthy lifestyles: education, information and communication

u) eHealth

- (June 2014) Council Conclusions on the economic crisis and healthcare
- (December 2013) Council Conclusions on the "Reflection process on modern, responsive and sustainable health systems"
- (December 2011) Commission Implementing Decision 2011/890/EU of 22 December 2011 providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth
- (December 2009) Council Conclusions on "Safe and efficient healthcare through eHealth", on how best to introduce and make use of information and communication technology to improve healthcare, aiming at moving from theoretical experience exchange to concrete cross-border cooperation and creating a structure for cooperation that can gather and pass on the outcomes of all ongoing initiatives and projects in the area of eHealth.
- (July 2008) Commission Recommendation on cross-border interoperability of electronic health record systems (lead by Directorate General Information Society), aiming to create a means whereby authorised health professionals can gain managed access to essential health information about patients (in respect of the fundamental right to the protection of personal data)
- (November 2008) Joint Communication on Telemedicine. The Joint Communication has launched a 4-year undertaking, aiming to facilitate patient access to secure and high quality healthcare, even in remote areas, through telemedicine services.
- (May 2007) 409 standardisation mandate to the European Standardisation bodies (CEN, CENELEC and ETSI) in the field of Information and Communication Technologies, aiming at listing, agree on and recommend on existing standards relevant to eHealth.

v) Alcohol abuse prevention

- EU Action Plan on youth drinking and on heavy episodic drinking (binge drinking) 20142016
- (2015) Council Conclusions on an EU strategy on the reduction of alcohol-related harm
- (2014) EU Action Plan on youth drinking and on heavy episodic drinking (binge drinking) 2014-2016
- (2009) Council Conclusions on Alcohol and health, 1 December 2009
- (2006) Council Conclusions on EU strategy to reduce alcohol-related harm, 30 November-1 December 2006 (Con. 16165/06)
- COM (2006) 265 final: Communication from the Commission of 24 October 2006: An EU Strategy to support Member States in reducing alcohol related harm
- Rec. 01/458/EC: Council Recommendation of 5 June 2001 on the drinking of alcohol by young people, in particular children and adolescents
- Con. 01/C175/EC: Council Conclusions of 5 June 2001 on a Community strategy to reduce alcohol-related harm

w) Cancer screening

- Rec. 03/878/EC: Council Recommendation of 2 December 2003 on cancer screening

- C0M(2008) 882: Report from the Commission to the Council, the European Parliament, the European Committee of the Regions - Implementation of the Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC)
- Con. 10/06/2008: Council Conclusions on reducing the burden of cancer (http://www.eu2008.si/en/News_and_Documents/Council_Conclusions/June/0609_EPSC 0- cancer.pdf)
- COM (2009) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Action against Cancer European Partnership
- Con. 13/09/2010: Council Conclusions on action against cancer (page 17 on: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/EN/genaff/116489.pdf and http://register.consilium.europa.eu/pdf/en/10/st12/st12667.en10.pdf)
- (2014) Commission Decision 2014/C 167/05 of 3 June 2014 establishing a Commission expert group on Cancer Control and repealing Decision 96/469/EC
- (2015) Cancer Control Joint Action (2015)
- (2015) European Guide for Quality National Cancer Control Programmes (2015) and other European Guidelines: ○ European guidelines for quality assurance in breast cancer screening and diagnosis ○ European guidelines for quality assurance in colorectal cancer screening and diagnosis

○ European guidelines for quality assurance in cervical cancer screening (2016) To improve the overall quality of care, the European Commission Initiative on Breast Cancer (ECIBC), coordinated by the JRC, is developing a voluntary European quality assurance scheme for breast cancer services. This will include a set of evidencebased requirements and indicators for good psychosocial care at the European level to ensure equal treatment for all patients and to increase confidence in the quality of breast cancer services.

x) Prevention against electromagnetic fields, injury and promotion of safety

- Rec. 99/519/EC: Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)
- Prevention of injury and promotion of safety
- Rec. 07/C164: Council Recommendation of 31 May 2007 on the prevention of injury and the promotion of safety
- European Parliament Resolution of 2 April 2009 on health concerns associated with electromagnetic fields (2008/2211)

y) Patient safety

- Council Recommendation of 15 November 2001 on prudent use of anti-microbial agents in human medicine
- Rec. 2009/C 151/01: Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of health care associated infections
- Report from the Commission to the Council on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare associated infections - COM(2012) 658 final
- Report from the Commission to the Council - The Commission’s Second Report to the Council on the implementation of Council Recommendation 2009/C 151/01 on patient

safety, including the prevention and control of healthcare associated infections COM(2014) 371

z) European Action in the field of Rare Diseases

- Implementation report on the Commission Communication and Council Recommendation on Rare Diseases – COM (2014)548
- Council Recommendation 2009/C 151/02 of 9 June 2009 on action in the field of rare diseases
- Commission Communication COM(2008) 679 final of 11 November 2008 on Rare Diseases: Europe's challenges