Crna Gora
Ministry of Health

Rimski trg br. 46
81000 Podgorica, Crna Gora
Tel: +382 20 482 133
Fax: +382 78 113 128
www.mzd.gov.me

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Podgorica, 30. 6. 2025.

MINISTRY OF HEALTH

(name of the ministry that conducted the public hearing)

REPORT ON THE PUBLIC HEARING
Draft Law on Medicines

(name of the draft law that was the subject of public hearing)

The duration of the public hearing: 20 days. The Ministry of Health announced a public hearing on the Draft Law on Medicines dated June 6. 2025 until June 26, 2025.
Method of conducting a public hearing:
The Ministry of Health has issued a public invitation to citizens, the professional community and all other interested parties to participate in the public hearing and contribute to the consideration of the Draft Law on Medicines by submitting comments, proposals and suggestions in written and/or electronic form, to the following e-mail addresses: milica.golubovic@mzd.gov.me and kabinet@mzd.gov.me, as well as by holding a roundtable in Podgorica at the Institute of Public Health of Montenegro, on June 17, 2025.
Authorized representatives of the Ministry who participated in the public hearing:
Dr Jovana Novaković, Director of the Directorate for Pharmacology, Precursors and Cosmetic Products; Milica Golubović, Head of the Directorate for Monitoring International Standards and National Regulations in the Field of Health Care; Dušanka Praščević, Head of the Directorate for Pharmacological Development and Regulation. Then representatives of the Institute of Medicines and Medical Devices: Dr sc. pharm Gordana Stanojević, Head of the Center for Drug Approval; Tatjana Babović, Head of the Department for Veterinary Medicines; Anđela Drašković, Head of the Center for Science, International Cooperation and Projects and Slađana Marsenić, Head of the Inspectorate.
Data on the number and structure of participants in the public hearing:
During the public hearing on the Draft Law on Medicines, the Pharmaceutical Chamber of Montenegro, "Farmega" DOO Podgorica, "American Chamber of Commerce", "Farmega" DOO Podgorica, "Evropa lek pharma" DOO Podgorica, and the "GENEZIS" association from Belgrade expressed interest.
At the round table held on June 17, 2025 at the Institute of Public Health of Montenegro, in addition to the representatives of the proposers, there were representatives of:

"MONTVET", "ANIMAVET"; VELTEKST DOO; Farmegra DOO Podgorica and "EVROPA LEK PHARMA" DOO Podgorica,

Summary of submitted comments, proposals and suggestions, with reasons for their acceptance or non-acceptance:

1. AMERICAN CHAMBER OF COMMERCE

Comment/proposal/suggestion 1:

It is proposed that Article 69 of this Draft Law enter into force only on the day of Montenegro's accession to the European Union.

The proposal is accepted.

***Explanation*:**

The revised version of the Draft provides that the provisions relating to the obligation to affix safety features to the packaging of medicines, in accordance with the principles of Directive 2001/83/EC and Delegated Regulation (EU) 2016/161, will enter into force only on the day of Montenegro's accession to the European Union.

Comment/proposal/suggestion 2:

It is proposed that the law clearly define the possibility of applying the reliance procedure for issuing marketing authorizations for medicines approved through the centralized procedure in the EU (CP medicines), including registrations, renewals and variations, with the obligation to submit the EU approved dossier, EMA Assessment Report and statement of identity of the documentation.

The proposal is not accepted.

***Explanation*:**

The legal basis for the application of the reliance approach already exists, both in the current Law on Medicines and in the text of the Draft New Law, through the provisions of Article 52. This article clearly stipulates the possibility for the competent authority to use relevant regulatory assessments of EU agencies when making a decision on issuing a marketing authorization for a medicinal product.

Additional standardization of this possibility at the legal level in the form of detailed procedural elaboration is not considered necessary, bearing in mind that the operational application of the reliance approach is carried out through secondary legislation, guidelines and regulatory practice, which allows for greater flexibility and timely alignment with changes in the international regulatory framework.

Comment/proposal/suggestion 3:

It is proposed to introduce shortened decision-making deadlines in licensing procedures under the reliance procedure, with a focus on the formal completeness of documentation, without additional substantive regulatory assessment.

The proposal is not accepted.

***Explanation*:**

The proposed approach is recognized in Article 52 of the Draft Law, which allows for an accelerated decision-making process in cases where the competent authority relies on previously conducted regulatory assessments by EU agencies. Specifically, the provision of that Article stipulates that in such cases the decision on issuing a permit shall be made within a period that cannot exceed 150 days from the date of establishing the formal completeness of the application.

This legal solution already takes into account the needs for efficiency and faster availability of therapies, while at the same time preserving regulatory accountability and procedural integrity.

However, it is important to note that the competent regulatory authority cannot be deprived of the right, nor the legal obligation, to conduct an appropriate regulatory assessment of the submitted documentation. Even under the reliance model, the national regulator remains responsible for the final decision and must confirm that the conditions for granting the permit are met, including checking the identity of the documentation, its relevance to the national context and compliance with applicable regulations..

2. PHARMACEUTICALS CHAMBER OF MONTENEGRO:

Comment/proposal/suggestion 1:

Article 18, paragraph 5, of the draft Law, which refers to the quantity of up to 100 finished individual packages per day, of galenic veterinary medicine. It is necessary to consider the specified quantity (which unlike the quantity for a galenic drug for human use) is not limited by batch size but by daily production, which is not usual.

It is proposed to include a new sentence in the same paragraph of this article, which reads: Active substances for which there is a withdrawal period cannot be used for the production of magistral and galenic medicinal products for veterinary use for the treatment of animals intended for human consumption or for the production of food for human consumption.

Explanation of comment/proposal/suggestion 1:

There is no experience in the production of exclusively galenic medicinal products for veterinary use in Montenegro, and the stated quantity (100 finished individual packages per day) is identical to that in the Law on Medicinal Products of the Republic of Serbia. It is suggested that fellow veterinarians consider the stated quantity and the provision on limiting production on a daily basis, in light of their experiences of the needs for this type of galenic medicinal products for use in animals.

The restriction on the use of active substances for which there is a waiting period is important from the aspect of protecting people's health.

The proposal is accepted.

Explanation:

A correction was made in the mentioned article.

Comment/proposal/suggestion 2:

It is proposed to delete paragraph 1 of Article 20 of the draft Law, which stipulates that the list of galenic medicines shall be adopted by the Ministry of Health. Paragraph 2 becomes paragraph 1 of the same Article.

Explanation of comment/proposal/suggestion 2:

Article 18, paragraph 1 of the draft Law states that galenic medicinal products shall be prepared according to the procedure for preparing valid pharmacopoeias, magistral formulas or according to standard recipes from professional pharmaceutical manuals. Considering that the publication of national, magistral formulas of Montenegro is in preparation (a representative of the Ministry of Health is included in the working group of the Pharmaceutical Chamber for the preparation of this manual), which will contain a list of magistral and galenic medicinal products with recipes for their preparation, it is not necessary to publish the list itself in the form of a by-law.

Considering the need to monitor constant changes and new formulations in professional literature, it would be necessary to amend such a by-law for the introduction of each new drug that is necessary for the treatment of a certain group of patients, which we believe may be a procedural prolongation to the detriment of the needs of patients who are then forced to order such therapies abroad. The publication of the list of Galenic drugs in the form of a by-law is not provided for in the comparative legislation (available to us) of EU member states - for example, the Republic of Croatia (Law on Pharmacy), but it is provided in the form of magistral formulas, pharmacopoeias and professional literature, as already provided for in the draft law.

The proposal is accepted.

Explanation:

A correction has been made to delete paragraph 1 of Article 20.

3. FARMEGRA DOO PODGORICA,

Comment/proposal/suggestion 1:

Article 31, paragraph 7, states that the person responsible for pharmacovigilance must have graduated from the faculty of pharmacy, medicine, dentistry or "another faculty of appropriate orientation".
We ask for a precise clarification of what is meant by the term "another faculty of appropriate specialization", that is, which educational profiles the legislator considers relevant for this responsibility.
Explanation of comment/proposal/suggestion 1: /

The proposal is accepted.
Explanation:
The clarification was made by deleting the words ""another faculty of appropriate specialization"" and adding "or the Faculty of Veterinary Medicine".

Comment/proposal/suggestion 2:

Article 71, paragraph 1: We propose that the wording "written in the Montenegrin language" be supplemented with "or in the language in official use in Montenegro", in order to allow greater flexibility in practice, while preserving the right of patients to understandable information.
Explanation of remarks/proposals/suggestions 2:
This amendment aims to allow for greater flexibility and practical application of the law, bearing in mind that other languages are also in official use in Montenegro (Constitution of Montenegro, Article 13, paragraph 3: "Serbian, Bosnian, Albanian and Croatian languages are also in official use"). This formulation protects the right of patients to receive instructions in a language they understand, while at the same time not making it more difficult for drug license holders to align instructions with official standards and legislation.

The proposal is not accepted.
Explanation:
Montenegro is, as part of the process of accession to the European Union, obliged to align its national legislation in the field of medicinal products with the legislation of the European Union, specifically with Directive 2001/83/EC. In accordance with Article 63 of the aforementioned Directive, the text of the Instructions for Use for a medicinal product must be clear, understandable and legible, and in the official language of the Member State on whose market the medicinal product is placed on the market. In the case of Montenegro, this is the Montenegrin language, which is defined as an official language by the Constitution.
The Institute for Medicines and Medical Devices, as the competent authority for approving the content of the Instructions for Use for a Medicine, approves exclusively the version in the Montenegrin language. Providing a version of the Instructions for Use in one of the languages in official use in Montenegro (Serbian, Bosnian, Albanian, Croatian), which are not the official language but languages that may be used in certain procedures in accordance with the Law on the Use of Languages and Scripts, does not guarantee that patients will receive information that has been approved by the Institute and has passed regulatory assessment.
Additionally, the Directive allows for multiple language versions of the Instructions, but only on the condition that the same information is provided in all languages, without any difference in content.
Therefore, in order to ensure the availability of verified, accurate and approved information about the medicine to end users, it is necessary that the Instructions for Use for the medicine be in the Montenegrin language.

Comment/proposal/suggestion 3:

Article 71, paragraph 2: We suggest deleting the wording "for a certain batch and quantity of medicine".
Explanation of the remark/proposal/suggestion 3:
This amendment would allow, in line with previous regulatory practice, that medicines intended exclusively for inpatient use do not have to be additionally labelled with a package leaflet in Montenegrin. This would avoid administrative burdens and enable timely supply to healthcare institutions, without compromising patient safety, given that these medicines are administered exclusively under the supervision of healthcare professionals.
The proposal is not accepted.

Explanation:
Article 71 of the draft law is formulated in accordance with Article 63 of Directive 2001/83/EC, which stipulates that the package leaflet for a medicinal product must be clear, understandable and available in the official language of the Member State in which the medicinal product is placed on the market. In Montenegro, this is Montenegrin.
The obligation to provide an approved Package Leaflet in the Montenegrin language applies to all medicines, regardless of the method of administration and the end user, as EU regulations do not differentiate between the presence of a leaflet in the language of the Member State when it comes to medicines that are used exclusively in hospital settings. Supervision by a healthcare professional cannot be a substitute for a regulatory approved leaflet in the language of the patient or the country.
The proposed wording "for a certain batch and quantity of the drug" makes it possible to exceptionally, and only in extraordinary circumstances (e.g. serious problems in the availability of the drug), allow a temporary deviation from this requirement, which has already met the needs of health institutions while preserving regulatory control and insight into the specific batch and quantity of the drug.
Further liberalisation of this exception, as proposed, would be contrary to the EU acquis and would jeopardise the consistent application of the law.

Comment/proposal/suggestion 4:

Article 71: We propose to add a new paragraph after paragraph 3: "In the event of systemic off-label use of a medicinal product within a healthcare institution, or when serious adverse reactions are observed during such use, the medical doctor or healthcare institution is obliged to notify the license holder and the Institute, in order to assess the safety and efficacy of the use."
Explanation of the remark/proposal/suggestion 4:
In this way, it is possible to: better protect patients, identify potential risks, collect additional data that can be the basis for future changes to indications or licenses.

The proposal is not accepted.
Explanation:
The Institute does not have documentation for off-label use of a drug (by definition, use outside of the approved indication) to conduct an assessment. In addition, the law clearly stipulates the obligation of medical doctors, or healthcare institutions, to report any observed serious adverse reactions to a drug.

Comment/proposal/suggestion 5:

Article 118, paragraph 2: Please provide an explanation, taking into account that the distributor (wholesale marketing authorization holder) does not receive a marketing authorization for a specific medicinal product, but a license to carry out the activity of wholesale marketing of medicinal products in general. Only the marketing authorization holder (MAH) has a license for a specific medicinal product.
Suggested wording:
"In order to protect the health and life of patients, the holder of a license for the wholesale sale of medicines is obliged, within the framework of his regular activity and the availability of the medicine on the market, to enable the delivery of the medicine to health institutions in the shortest possible time."
Explanation of the remark/proposal/suggestion 5:
The above paragraph is not clearly defined, taking into account that the distributor does not receive a license to distribute a specific medicine, but a license to carry out the activity of wholesale distribution of medicines in general.

The proposal is accepted.
Explanation:
The position will be reformulated:
"The holder of the license for the sale of drugs in bulk is obliged, in order to protect the health and life of patients, to enable the delivery of the drug to health institutions in the shortest possible time, at their request, and depending on the availability of the drug in accordance with their responsibilities."

Comment/proposal/suggestion 6:

Article 118, paragraph 4: We propose to further define obligations, responsibilities and delivery deadlines in the case of intervention imports, in order to avoid legal and procedural ambiguities.

Explanation of remark/proposal/suggestion 6: n/a

The proposal is not accepted.

Explanation:

The Ministry, in each specific case, determines the delivery deadline, which is conditioned by the need to protect public health.

Comment/proposal/suggestion 7:

Article 126, paragraph 2, item 4: The proposal is to more precisely define which medicines this item refers to, because the wholesale license does not cover individual medicines, but rather implies a license to carry out the activity of wholesale trade in medicines in general.

Explanation of remark/proposal/suggestion 7: n/a

The proposal is accepted.

Explanation:

It will be reformulated to read:

4) fails to fulfill the obligation of continuous supply of medicines to the market in accordance with its responsibilities;

Comment/proposal/suggestion 8:

Article 195, paragraph 1: We propose to exempt medicines that are imported under emergency conditions and are not on the List of Medicines.

Explanation of remark/proposal/suggestion 8:

In practice, medicines that are not registered in the country are imported, often for the treatment of individual patients in situations where there is no alternative. For such drugs, it is not always possible to establish a maximum wholesale price in an efficient way, especially if they are imported in small quantities and for emergencies. In these cases, it is important that the legal regulation does not hinder the availability of the drug due to formal obstacles such as the prior determination of the price.

The proposal is not accepted.

Explanation:

In practice, medicines that are not registered or on the List of Medicines are often imported, and are approved through the Commission for the Approval of Medicines Outside the List of Medicines. These are additional costs that significantly burden the budget, which has the consequence that the prices of these medicines are regulated.

Remark/proposal/suggestion 9:

Article 336: We propose to delete the 23-month period, but that valid licenses and certificates are valid until the moment of expiration (the same solution as the drug license in Article 337).

Explanation of the remark/proposal/suggestion 9:

We believe that the harmonisation relates to business operations, which is specified in Article 335 (12-month deadline). The obligation to submit applications for a licence to carry out the activity of manufacturing, or wholesale distribution of medicinal products, within 23 months from the date of application of the law will create an unnecessary administrative burden, especially considering the fact that valid licences and certificates are harmonised on standardised forms established by the acts of the European Union and the EMA.

Additionally, the wholesaler is obliged to submit a request to the Institute for amendment or amendment of the license in the event of a change in the conditions of the wholesale distribution license, so the obligation to submit a new request is burdensome for wholesalers.

The proposal is accepted.

Explanation:

The article in question has been corrected, the 23-month period has been deleted and the provision reads: "The medicinal product manufacturing license and wholesale distribution license, as well as the certificate of conformity issued by the Institute in accordance with the regulations that were in force until the date of application of this law, are valid until the expiration of the period for which they were issued."

IV. EVROPA LEK PHARMA DOO PODGORICA, Kritskog odreda 4/1. 81000 Podgorica, Montenegro,

Remark/proposal/suggestion 1:

Article 7, paragraph 1, item 67 defines the Licensee Representativefor a medicinal product as a natural or legal person authorized by the holder of the medicinal product authorisation to represent it in Montenegro;

Article 31, paragraph 2, point 3 defines who can be an applicant for a medicinal product license... for a medicinal product license holder, or for a person who has registered a medicinal product in the European Union.

We propose to further define the term Marketing Authorization Holder in the context of the Global Marketing Authorization Holder, or the EU Marketing Authorization Holder, in accordance with Directive 2001/83/EC and Regulation (EC) No 726/2004.

Explanation of the remark/proposal/suggestions1:Bearing in mind that the proposal of the new law, and in accordance with the EU legislation, changes the meaning of the term "license holder" through several articles, and in order to avoid a double interpretation, we consider it useful to add the definition as stated above, because certain articles can be interpreted differently depending on the definition of the term "license holder for medicine".

See*Notice to Applicants, Vol 2A, Procedures for marketing authorisation. Chapter 1, Marketing Authorization*: point 2.8.

The terms "applicant" and "marketing authorisation holder" (MAH) are essential for the understanding and application of the definition of a global medicinal product authorisation, as well as in other contexts, such as: submission of an application under Directive 2001/83/EC, submission of variations, work-sharing or submission of an application for multiple marketing authorisations in accordance with Article 82(1) of Regulation (EC) No 726/2004.

In the case where the "applicant" and the "marketing authorisation holder" are different legal entities: For the purposes of applying the medicinal products regulation, the fact that certain entities have a special legal status, i.e. that they are different legal entities, does not necessarily mean that each of these entities can be viewed separately.

The "applicant" and the "marketing authorisation holder" are considered to be one legal entity, i.e. one applicant/authorisation holder, if:

- are part of the same corporation or group of companies, or are controlled by the same natural or legal person,
- do not belong to the same group of companies and are not controlled by the same natural or legal person, but have entered into a tacit or explicit agreement regarding the marketing of the same medicinal product, for the purposes of applying the medicinal product regulations relating to that medicinal product. This includes cases of joint marketing of a medicinal product, but also situations where one party licenses to another the right to market the same medicinal product, for a fee or other forms of compensation.

Applicant / Licensee	Are they considered one applicant/license holder?
Entities within the same corporate group	Yes
Under the control of the same natural or legal person	Yes
Independent, but have an (explicit or tacit) agreement to market the drug	Yes
Completely independent and unaffiliated, without any agreement	No

The local representative of the license holder in Montenegro is responsible for communication and documentation, i.e. ensuring that the MAH in the EU and/or the manufacturer's QP knows what has been approved in Montenegro, so that they can release the batch of the drug into the market in accordance with the Drug License.

The proposal is partially accepted.

Explanation:

The definition of the license holder was added in Article 7 of the draft Law, in the following form: "the license holder for a medicinal product is a natural or legal person with a registered office in Montenegro who has a license for a medicinal product issued by the Institute." This clearly defines that the license holder for a medicinal product in Montenegro is a person with a registered office in Montenegro, and cannot be viewed

in the context of a global license holder for a medicinal product.

Remark/proposal/suggestion 2:

Article 7, paragraph 1, item 95) defines a batch of a medicinal productthat is, the batch must correspond to the production phase characterized by the intended homogeneity;

Consider the GMP relevance of the local compliance of packaging with the permit (additional label and package leaflet). Provide a basis for local packaging harmonization through bylaws to be carried out by distributors for foreign packaging and/or packaging that cannot be opened without violating anti-counterfeiting protection.

Explanation of the remark/proposal/suggestions 2:

- If the additional labeling is considered GMP-relevant, it will mean that the additionally labeled quantity of the drug is released by the QP from the place where the additional labeling is performed.
- Such a place of additional marking should be reported as an additional place of secondary packaging and an additional place of release of the drug batch.
- When releasing a batch of a drug into the market, the QP must state in the batch certificate (BRC) that that specific batch was manufactured in a specific quantity in accordance with GMP guidelines and in accordance with the drug license in the country for which it is being released.
- All of the above implies that the part of the initial series that is additionally labeled and released into circulation is considered a new series of medicine released into circulation for Montenegro.
- Additional local GMP activities for Montenegro increase business costs, the time it takes for the drug to reach the patient, which can potentially jeopardize the availability of drugs to patients.

The proposal is not accepted.

Explanation:

The definition of a batch of medicinal products is aligned with the definition in the EU GMP guidelines. Additionally, in accordance with Article 40, paragraph 2 of Directive 2001/83, which is transposed into Article 89, paragraph 2 of the draft of this Law, it is prescribed that a manufacturing permit is issued for the entire manufacturing process of a medicinal product or individual parts of that process, as well as for various processes of division, packaging and equipping. The process of additional equipping of medicinal products is a GMP relevant process in the European Union and a long-standing practice applied in several EU member states.

Remark/proposal/suggestion 3:

Article 7 Defines the concept of placing a human drug on the market.

Explanation of the remark/proposal/Suggestions 3:

Article 7, paragraph 1, item 160 defines the term "placing a veterinary medicinal product on the market". As the law mentions placing, as well as the actual placing of a medicinal product on the market, in several articles, it is necessary to define this term in more detail.

A medicinal product is considered "placed on the market" on the date of release into the distribution chain. This is the date on which the product leaves the jurisdiction of the marketing authorisation holder.*

*See Notice to Applicant, Volume 2a, Procedures for marketing authorization, Chapter 1, Marketing Authorization, point 2.4.2.

The proposal is accepted.

Explanation:

The wording of the definition of placing a medicine on the market has been changed in such a way that it covers both human and veterinary medicines, and it provides that the placing on the market of a medicine represents the first making available of the medicine on the market of Montenegro or the European Union (the part that refers to the EU will be applied upon accession). Thus, putting into circulation means exactly the date of release of the drug into the distribution chain, which makes it available for further delivery.

Remark/proposal/suggestion 4:

Article 28defines the cases when the Institute can give consent for the import of a drug for which a drug license has not been issued, and paragraphs 2 and 3 describe the responsibilities for possible damage caused by the use of a drug that does not have a drug license or the use in unapproved indications of a drug that has a drug license, when such use is recommended or required by the Ministry.

We suggest that the mention of the Marketing Authorization Holder in paragraphs 2 and 3 be omitted, or that it be

further clarified who is being referred to.

Explanation of the remark/proposal/suggestion 4:

There is no Marketing Authorization Holder in Montenegro for medicinal products placed on the market pursuant to Article 28. The quality of these medicinal products is influenced by the manufacturers, importers and distributors, as well as the conditions under which they were issued an import permit by the Institute.

The proposal is not accepted.

Explanation:

It follows from the context of Article 28 that these are cases where the Institute may approveimport of a drug that does not have a license for a drug in Montenegro, i.e. import for the needs of individual treatment, emergency medical intervention or in situations of public health threat.

Accordingly, it is clear that the term"license holder for medicine" in paragraphs 2 and 3 does not refer to a person who has a license issued in Montenegro, because in such cases that person does not exist. Instead, the term "holder of the medicinal product's authorization" in this context means the holder of the authorization in the country of origin of the medicinal product, as the entity responsible for the medicinal product in the regulatory sense of the market from which it originates.

The purpose of the provision from paragraph 2 is to clearly prescribewho is not liable for any potential damage in the event that the Ministry of Health recommends or requires the use of such a medicine – specifically, these are healthcare professionals, manufacturers and license holders (in the country of origin), who are not participating in regulatory processes in Montenegro at that moment.

On the other hand, paragraph 3 specifies that responsibility for any deficiencies in the quality of the medicine is not excluded and clearly remains with the manufacturer and the license holder (in the country of origin), which further emphasizes the importance of ensuring quality in the trade of such medicines, regardless of the specific import regime. Accordingly, we believe that the formulation is clear and fully justified, no change is necessary.

Remark/proposal/suggestion 5:

Article 31:Add a provision prescribing the obligation of the manufacturer, or the holder of the marketing authorization for a medicinal product, to define product liability insurance in a contract with a local representative.

Explanation of remark/proposal/suggestion 5:

A clearly prescribed provision in the Law requiring the existence of a contract defining the provision of insurance against liability for damage caused by the use of a product (product liability), makes it easier to explain the requirement to foreign partners.

The contract protects local legal entities that are representatives of the manufacturer and/or license holder for the drug from damage that did not occur due to their actions or inactions, but rather to the product, in terms of defects in design, production, or inadequate product information.

The proposal is not accepted.

Explanation:

The legal framework governing the field of medicines must clearly distinguish between regulatory obligations that are under the direct jurisdiction of the competent authority and commercial-legal relations between legal entities. The local representative, as an entity acting on behalf of the manufacturer or the holder of the marketing authorisation for a medicinal product, has a role defined by this law, while the mutual contractual relations between these parties are a matter of private law autonomy.

The competent authority cannot legally impose the content of the contract between the manufacturer/license holder and its local representative, as this would constitute an unjustified interference with the commercial freedom and contractual autonomy of the parties, which is not in line with fundamental legal principles, including the EU acquis.

Given the specifics of each business relationship, including the type of product and the role of the local representative, the responsibility for precisely regulating mutual rights and obligations lies with the contracting parties. If the protection of the interests of the local representative is to be ensured, this is achieved through contractual clauses and liability insurance that can be separately agreed, but this is not the subject of legal regulations in the field of medicines.

The Law on Medicines regulates obligations towards third parties, i.e. end users, through the institution of the marketing authorisation holder, who bears full responsibility for the safety, quality and efficacy of medicines on the Montenegrin market.

Remark/proposal/suggestion 6:

Article 31defines that the Marketing Authorization Holder is responsible for placing the medicinal product on the market and for the medicinal product on the market.

Explanation of remark/proposal/suggestion 6:

The product owner is responsible for placing the medicinal product on the market (Manufacturer, EU MAH). The local representative of the authorisation holder acts on behalf and for the account of the manufacturer or EU MAH. The local authorisation holder is the administrative representative and intermediary in communication between the regulatory authorities and the contract grantor. Placing on the market in the territory of Montenegro involves the procurement and import of the medicinal product from the manufacturer or an authorised distributor who enters into a contract with a local importer-distributor.

A medicinal product is considered "placed on the market" on the date of release into the distribution chain. This is the date on which the product leaves the jurisdiction of the marketing authorisation holder.*

*See Notice to Applicant, Volume 2a, Procedures for marketing authorisation, Chapter 1, Marketing Authorization point 2.4.2

See the explanation of the remark/proposal/suggestion no. 1

To understand this provision, it is also necessary to define the concept of license holder, as well as placing on the market, in accordance with the EU directive.

The proposal is not accepted.

Explanation:

The revised version of the draft Law clearly defines the concept of the marketing authorisation holder, which also clarifies its regulatory position in the system of supervision of the circulation of medicinal products in Montenegro. The provision of Article 31, paragraph 8 was introduced for the purpose of full harmonisation with Directive 2001/83/EC, which explicitly stipulates in Article 6, paragraph 1a:

"The marketing authorization holder shall be responsible for marketing the medicinal product."

Accordingly, the license holder bears full regulatory responsibility for the medicinal product placed on the market, including its quality, safety and efficacy, as well as compliance with the approved product information.

Remark/proposal/suggestion 7:

Article 32, paragraph 1, item 17 defines the obligation to submit copies of all drug licenses issued in a European Union member state or a third country, as well as copies of the decision to reject an application for a drug license in a European Union member state or a third country, with the justification for that decision.

We propose to consider deleting the obligation to submit copies of all permits along with the obligation to submit information on the registration status of the drug (WWRS), and copies of permits and decisions can be submitted upon request.

Explanation of remark/proposal/suggestion 7:

N/A

The proposal is not accepted.

Explanation:

The provision is fully taken from Directive 2001/83/EC, with the aim of full harmonisation with EU legislation.

Remark/proposal/suggestion 8:

Article 51, paragraph 5refers to the deadline from paragraph 1, it is necessary to correct the reference to the deadline from paragraph 2.

Explanation of remark/proposal/suggestion 8:

The deadline from paragraph 2 refers to the formal assessment, and the deadline from paragraph 1 refers to the deadlines after formal completion.

The proposal is not accepted.

Explanation:

For the purpose of clarification, a paragraph has been added stating that the time required to supplement the documentation, both during the formal assessment and after formal completeness, is not counted in the time referred to in paragraph 1.

Remark/proposal/suggestion 9:

Article 62 stipulates that, after the issuance of the drug license, the holder of the drug license is obliged to inform the Institute about the day of the actual placing of the drug on the market in Montenegro for each type and size of the drug package,

within 15 days.
We propose to define the term placing on the market (see suggestion no. 3), and to replace "for each type and size of packaging" with "for each strength, shape and size of packaging".
Explanation of remark/proposal/suggestion 9:
Harmonize the terminology so that it is unambiguous and clear that it refers to every medicine that has a special marketing authorization.

The proposal is accepted.
Explanation:
The definition of placing a medicine on the market was added, and the word "real" was removed from Article 62.

Remark/proposal/suggestion 10:

Article 63: When it comes to extraordinary circumstances in the production process that may lead to an interruption of supply, it is necessary to define in more detail what is meant by an interruption of market supply, i.e. to define the out of stock (OOS) period that needs to be reported and at what level (manufacturer/distributor).
Consider introducing an obligation for importers/distributors to notify the Institute directly or through the Licensee about shortages.
Explanation of remark/proposal/suggestion 10:
It is unclear whether market supply disruption means:

- Interruption deliveries by the manufacturer to the distributor (in which case, depending on the traffic dynamics, the distributor may have the drug available during the entire period of interruption of deliveries by the manufacturer). If the manufacturer reports an interruption in production, and the distributor has available quantities, it is potentially possible to import an unregistered drug, in addition to the registered drug that is still available at the distributor.
  or
- interruption of delivery by the distributor to health institutions.

In practice, it often happens that a medicine is not available for a short period of time from a distributor due to commercial reasons, e.g. poor planning, tenders, unexpectedly high demand... It is unclear whether there is an obligation to notify about this type of supply interruption and by whom.

The proposal is not accepted.
Explanation:
The provisions of this Article are fully aligned with the provisions of Article 23a of Directive 2001/83/EC.

Remark/proposal/suggestion 11:

Article 67defines that the parts of the summary of characteristics of the reference drug that refer to indications or pharmaceutical forms that are still under patent protection at the time of placing the generic drug on the market may not be included in the text of the summary of characteristics of the drug for which the license is issued.
Since the Institute is not competent for intellectual property matters, define whose responsibility it is if protected parts are found in the approved SmPC, or how it is determined in Montenegro what is protected in EU countries and under what conditions.
Explanation of remark/proposal/suggestion 11:
A local manufacturer's representative cannot know whether something is protected in other countries unless he receives information from the manufacturer, or the Institute.

The proposal is not accepted.
Explanation:
In accordance with the EU acquis, including Directive 2001/83/EC, it is clearly stipulated that the marketing authorisation holder is responsible for the content of the submitted documentation, including the content of the Summary of Product Characteristics (SmPC). The same applies in the legislation of Montenegro.
The Institute for Medicines and Medical Devices is not responsible for patent protection issues or for verifying the status of intellectual property in Montenegro or the EU. This includes the protection of indications, pharmaceutical forms and other aspects that may be covered by valid patents.
It is therefore the responsibility of the manufacturer and/or marketing authorisation holder to ensure that the submitted documentation and the proposed SmPC text do not contain elements that are still under valid patent protection. The manufacturer or marketing authorisation holder in the EU is obliged to inform the local representative in Montenegro and to provide him with all necessary information and instructions to ensure full compliance with applicable intellectual property rights.

Remark/proposal/suggestion 12:

Article 68 introduces the obligation of the license holder to make available the instructions for the drug in a form that is adapted to blind and partially sighted persons, at the request of the patient association.
We consider it appropriate to define in more detail the conditions under which this obligation would have to be implemented: deadlines for preparation, method of providing, checking and implementing such instructions.
Explanation of the remark/proposal/suggestion 12: N/A

The proposal is not accepted.
Explanation:
The standard prescribed by Article 68 aims to ensure access to information about medicines for blind and partially sighted persons, in accordance with the principles of non-discrimination and equal access to health information, which is also in the spirit of European regulations and EMA recommendations.
However, detailed elaboration of technical aspects, such as deadlines, formats, content verification and method of submission, is not subject to legal regulation, but can be regulated in more detail by a by-law adopted by the competent authority, in cooperation with relevant patient associations.

Remark/proposal/suggestion 13:

Article 69 introduces security marks, i.e. the possibility of checking the authenticity of a medicine and the possibility of identifying each individual package by persons engaged in wholesale and retail trade in medicines.
We request that the possibility of all participants in the supply chain be established to implement all necessary equipment and measures prescribed by this article in order to meet the prescribed requirements (from the possibility of implementing a security label that enables the identification of each individual package, to monitoring the movement of the drug through the supply chain by reading the security label by entities in the supply chain).
We propose that a transitional provision postpones its application at least until accession to the EU.
Explanation of remark/proposal/suggestion 13: The implementation of the FMD in the EU also required significant logistical interventions and investments and a transitional period allowed market participants to adjust their operations. Given the size of the market and the availability of resources, all impacts on the continuity of supply and availability of medicines should be considered before implementing these provisions.

The proposal is accepted.
***Explanation*:**
The revised version of the Draft provides that the provisions relating to the obligation to affix safety features to the packaging of medicines, in accordance with the principles of Directive 2001/83/EC and Delegated Regulation (EU) 2016/161, will enter into force only on the day of Montenegro's accession to the European Union.

Remark/proposal/suggestion 14:

Article 71, paragraph 2 introduces the possibility of omitting the PIL in the Montenegrin language for a medicine that is not intended for immediate dispensing to the patient or when there are serious problems with the availability of the medicine,
Clarify whether the PIL can be omitted in the case of packaging that is not in the languages in official use.
Consider the possibility of approving the omission of the additional attachment of the PIL in Montenegrin for all medicines that are not intended for direct dispensing to the patient, except in the case of significant substantive differences, in the case of approved packaging in languages in official use.
Explanation of comment/proposal/suggestion 14: Updated instructions in Montenegrin language are available in electronic form on the CInMED website. Healthcare professionals have access to the locally approved SmPC.

The proposal is not accepted.
***Explanation*:**
Montenegro is, as part of the process of accession to the European Union, obliged to align its national legislation in the field of medicinal products with the legislation of the European Union, specifically with Directive 2001/83/EC. In accordance with Article 63 of the aforementioned Directive, the text of the Instructions for Use for a medicinal product must be clear, understandable and legible, and in the official language of the Member State on whose market the medicinal product is placed on the market. In the case of Montenegro, this is the Montenegrin language, which is defined as an official language by the Constitution.
The Institute for Medicines and Medical Devices, as the competent authority for approving the content of the Instructions for Use for a Medicine, approves exclusively the version in the Montenegrin language. Providing

a version of the Instructions for Use in one of the languages in official use in Montenegro (Serbian, Bosnian, Albanian, Croatian), which are not the official language but languages that may be used in certain procedures in accordance with the Law on the Use of Languages and Scripts, does not guarantee that patients will receive information that has been approved by the Institute and has passed regulatory assessment.
Additionally, the Directive allows for multiple language versions of the Instructions, but only on the condition that the same information is provided in all languages, without any difference in content.
Therefore, in order to ensure the availability of verified, accurate and approved information about the medicine to end users, it is necessary that the Instructions for Use for the medicine be in the Montenegrin language.

Remark/proposal/suggestion 15:

Article 78: It does not provide for a deadline for the implementation of variations, nor for variations of type IA and IAin.
Please define the deadline for implementing variations, as well as take into account variations of type IA and IAin and define deadlines, methods of application, assessment and implementation.
We propose to maintain the 12-month deadline for implementing variations after approval, as stated in the currently applicable Law.
We also suggest recognizing the concept of "supply critical" variations and considering defining accelerated deadlines for them.
Explanation of remark/proposal/suggestion 15: N/A

The proposal is not accepted.
***Explanation*:**
Deadlines for implementing variations, as well as the classification and manner of dealing with certain types of variations (including IA, IAin, IB, II and so-called "supply critical" variations), are not defined by law, but are the subject of secondary legislation adopted by the competent authority, i.e. a rulebook that regulates this area in more detail, in accordance with the needs of regulatory practice and harmonization with EU regulations.
Even in the current legislative framework, the implementation deadlines are aligned with EU guidelines, and in that sense, no changes to the essence of regulatory practice are planned.
The proposal to maintain the 12-month deadline for the implementation of approved variations, as well as the consideration of "supply critical" variations, may be considered when adopting the rulebook, but is not subject to normative regulation at the level of law.

Remark/proposal/suggestion 16:

Article 79 paragraph 5 add "bulk" so that the paragraph reads:"A drug for which the drug license has been transferred to a new drug license holder can be in wholesale circulation until the expiration date, and no longer than 18 months from the date of the adoption of the decision approving the transfer of the license for that drug, in accordance with the data from the original drug license.
Explanation of remark/proposal/suggestion 16: Make a clear distinction between wholesale and retail trade in order to avoid the obligation to withdraw the medicine to the level of health institutions after the expiration of 18 months, if the medicine with old data is still available at health institutions.

The proposal is not accepted.
***Explanation*:**
The draft law subsequently stipulates the obligation of the license holder to keep records of all imported batches and quantities of the medicinal product placed on the market in Montenegro, and the obligation of the manufacturer to inform the license holder thereof. Based on this data, the license holder has the opportunity to plan and coordinate activities related to stocks in a timely manner, including the possible withdrawal of the medicinal product after the transfer of the license.
Adding restrictions solely on wholesale distribution is not justified, as it could lead to legal uncertainty and different interpretations of obligations. Instead, the responsibility lies with the current and new marketing authorisation holders to plan all aspects of distribution in a timely manner when implementing the transfer, in order to avoid operational problems and ensure an orderly supply without unnecessary risk to patients.

Remark/proposal/suggestion 17:

Article 196 provides for the establishment of maximum prices for medicines imported in accordance with Article 28.
Consider not introducing a maximum price for medicines imported in accordance with Article 28, especially in relation to points 1, 4 and 5 of paragraph 1 of Article 28.
Additionally, Article 196 does not clearly refer to Article 195, so it is not unambiguously clear that the obligations prescribed by Article 196 apply only to prescription-only medicines, as defined in Article 195.

Explanation of remark/proposal/suggestion 17: N/A

The proposal is not accepted.

Explanation:

In practice, medicines that are not registered or on the List of Medicines are often imported, and are approved through the Commission for the Approval of Medicines Outside the List of Medicines. These are additional costs that significantly burden the budget, which has the consequence that the prices of these medicines are regulated.

Article 195 stipulates that maximum prices are set for medicines that have been granted import approval in accordance with Article 28 and whose prescription regime is established, while Article 196 only defines the deadline for submitting a request for determining the maximum price for these medicines.

Remark/proposal/suggestion 18:

Article 309, paragraph 5 Delete or replace with the condition that the person could not have been in the ownership structure or connected to persons in the ownership structure of legal entities engaged in the production, wholesale trade and testing of medicines and medical devices and other legal entities that participated in the preparation of documentation submitted with the application for the issuance of a medicine license and registration of a medical device, as well as in other regulatory affairs in the field of medicines and medical devices, for the previous 3 years.

Explanation of the remark/proposal/suggestion 18:

The wording of Article 309 limits the selection to employees of the Institute. There are no similar legal restrictions (paragraph 5) in comparable regulations (EU, HR, RS). Experience in areas relevant to the work of the Institute can only be acquired in positions in industry and wholesale trade, if the employee does not work at the Institute.

The proposal is not accepted.

***Explanation*:**

The provision of Article 309, paragraph 5, is formulated in accordance with the need to entrust the function of director of a regulatory authority, such as the Institute for Medicines and Medical Devices, to a person with direct regulatory experience and a deep understanding of the procedures, responsibilities and role of the Institute in protecting public health.

This solution does not exclude the possibility of persons working in industry or wholesale trade being employed by the Institute. On the contrary, by gaining work experience at the Institute, these persons may in the future meet the requirement for a director position. This does not restrict freedom of employment, but rather clearly sets an institutional standard that guarantees that a management position is entrusted to a person with specific regulatory experience, and not exclusively commercial or advisory experience.

Although similar restrictions are not explicitly prescribed in some comparative regulations, in the practice of European regulatory agencies, management positions are reserved for persons with previous regulatory experience, precisely due to the complexity of the tasks and the need to maintain independence and impartiality in decision-making.

This provision serves to strengthen the integrity of the institution and ensure that the director possesses the necessary experience and an impartial view, and does not come from structures that are subject to regulation.

V."GENESIS" ASSOCIATION, NOVA DALMATINSKA 2008, PODGORICA, MONTENEGRO

Remark/proposal/suggestion 1:

Article 7, paragraph 1, item 95 defines a batch of a medicinal productthat is, the batch must correspond to the production phase characterized by the intended homogeneity;

Consider the GMP relevance of the local compliance of packaging with the permit (additional label and package leaflet).Provide a basis for local packaging harmonization through bylaws to be carried out by distributors for foreign packaging and/or packaging that cannot be opened without violating anti-counterfeiting protection.

Explanation of the remark/proposal/suggestions 1: Additional local GMP activities for Montenegro increase business costs, the time it takes for the drug to reach the patient, which can potentially jeopardize the availability of drugs to patients.

The proposal is not accepted.

***Explanation*:**

The definition of a batch of medicinal products is aligned with the definition in the EU GMP guidelines. Additionally, in accordance with Article 40, paragraph 2 of Directive 2001/83, which is transposed into Article 89, paragraph 2 of the draft of this Law, it is prescribed that a manufacturing permit is issued for the entire manufacturing process of a medicinal product or individual parts of that process, as well as for various processes of division, packaging and equipping. The process of additional equipping of medicinal products is a GMP relevant process in the European Union and a long-standing practice applied in several EU member states.

Comment/proposal/suggestion 2:

Article 7, point 67 representative of the marketing authorisation holder is a natural or legal person authorized by the marketing authorisation holder to represent it in Montenegro;
Comment: We assume that this refers to the holder of the drug's license in the EU, or rather its representative in Montenegro, but I believe that additional clarification would be useful for everyone.
Explanation of the remark/proposal/Suggestions 2: N/A

Comment: The definition of the representative of the holder of the medicinal product license stipulated in Article 7 point 67) of the draft Law was amended in the draft Law after the public hearing and now reads "the representative of the medicinal product license holder is a natural or legal person designated by the medicinal product license holder to represent him in a certain member state of the European Union". In this way, the definition is fully harmonized with the definition from Directive 2001/83/EC and in the case of Montenegro it will be applicable upon EU accession.

Remark/proposal/suggestion 3:

Article 7 Defines the concept of placing a human drug on the market.
Explanation of the remark/proposal/Suggestions 3: Article 7, paragraph 1, item 160) defines the term "placing a veterinary medicinal product on the market". As the law mentions placing, as well as the actual placing of a medicinal product on the market, in several articles, it is necessary to define this term in more detail.
A medicinal product is considered "placed on the market" on the date of release into the distribution chain. This is the date on which the product leaves the jurisdiction of the marketing authorisation holder.*
*See Notice to Applicant, Volume 2a, Procedures for marketing authorization, Chapter 1, Marketing Authorization, point 2.4.2.

The proposal is partially accepted.
***Explanation*:**
The wording of the definition of placing a medicine on the market has been changed in such a way that it includes both human and veterinary medicines and it provides that the placing on the market of a medicine represents the first making available of the medicine on the market of Montenegro or the European Union (the part relating to the EU will be applied upon accession). Thus, putting into circulation means exactly the date of release of the drug into the distribution chain, which makes it available for further delivery.

Remark/proposal/suggestion 4:

Article 28 defines the cases when the Institute can give consent for the import of a drug for which a drug license has not been issued, and paragraphs 2 and 3 describe the responsibilities for possible damage caused by the use of a drug that does not have a drug license or the use in unapproved indications of a drug that has a drug license, when such use is recommended or required by the Ministry.
We suggest that the mention of the Marketing Authorization Holder in paragraphs 2 and 3 be omitted, or that it be further clarified who is being referred to.
Explanation of remark/proposal/suggestion 4: There is no Marketing Authorization Holder in Montenegro for medicinal products placed on the market pursuant to Article 28. The quality of these medicinal products is influenced by the manufacturers, importers and distributors, as well as the conditions under which they were issued an import permit by the Institute.

The proposal is not accepted.
Explanation:

It follows from the context of Article 28 that these are cases where the Institute may approveimport of a drug that does not have a license for a drug in Montenegro, i.e. import for the needs of individual treatment, emergency medical intervention or in situations of public health threat.
Accordingly, it is clear that the term"license holder for medicine" in paragraphs 2 and 3 does not refer to a person who has a license issued in Montenegro, because in such cases that person does not exist. Instead, the term "holder of the medicinal product's authorization" in this context means the holder of the authorization in the country of origin of the medicinal product, as the entity responsible for the medicinal product in the regulatory sense of the market from which it originates.
The purpose of the provision from paragraph 2 is to clearly prescribewho is not liable for any potential damage in the event that the Ministry of Health recommends or requires the use of such a medicine – specifically, these are healthcare professionals, manufacturers and license holders (in the country of origin), who are not participating in regulatory processes in Montenegro at that moment.
On the other hand, paragraph 3 specifies thatResponsibility for any deficiencies in the quality of the medicine is not excluded and clearly remains with the manufacturer and the license holder (in the country of origin), which further emphasizes the importance of ensuring quality in the trade of such medicines, regardless of the specific import regime. Accordingly, we believe that the formulation is clear and fully justified, no change is necessary.

Remark/proposal/suggestion 5:

Article 31: Add a provision prescribing the obligation of the manufacturer, or the holder of the marketing authorization for a medicinal product, to define product liability insurance in a contract with a local representative.
Explanation of remark/proposal/suggestion 5:A clearly prescribed provision in the Law requiring the existence of a contract defining the provision of insurance against liability for damage caused by the use of a product (product liability), makes it easier to explain the requirement to foreign partners.
The contract protects local legal entities that are representatives of the manufacturer and/or license holder for the drug from damage that did not occur due to their actions or inactions, but rather to the product, in terms of defects in design, production, or inadequate product information.

The proposal is not accepted.
***Explanation*:**
The legal framework governing the field of medicines must clearly distinguish between regulatory obligations that are under the direct jurisdiction of the competent authority and commercial-legal relations between legal entities. The local representative, as an entity acting on behalf of the manufacturer or the holder of the marketing authorisation for a medicinal product, has a role defined by this law, while the mutual contractual relations between these parties are a matter of private law autonomy.
The competent authority cannot legally impose the content of the contract between the manufacturer/license holder and its local representative, as this would constitute an unjustified interference with the commercial freedom and contractual autonomy of the parties, which is not in line with fundamental legal principles, including the EU acquis.
Given the specifics of each business relationship, including the type of product and the role of the local representative, the responsibility for precisely regulating mutual rights and obligations lies with the contracting parties. If the protection of the interests of the local representative is to be ensured, this is achieved through contractual clauses and liability insurance that can be separately agreed, but this is not the subject of legal regulations in the field of medicines.
The Law on Medicines regulates obligations towards third parties, i.e. end users, through the institution of the marketing authorisation holder, who bears full responsibility for the safety, quality and efficacy of medicines on the Montenegrin market.

Remark/proposal/suggestion 6:

Article 31. One of the paragraphs reads "The person responsible for pharmacovigilance may be employed or otherwise engaged by the holder of the marketing authorisation for the medicinal product." Additionally, in this regard, Article 148 defines this area and introduces certain innovations.
Question: Are license holders in Montenegro given the opportunity to engage or outsource services in the field of PV?
Explanation of remark/proposal/suggestion 5: N/A

Comment: The provisions of the articles referred to provide license holders in Montenegro with the opportunity to engage or outsource services in the field of PV.

Remark/proposal/suggestion 7:

Article 32, paragraph 1, item 17 defines the obligation to submit copies of all drug licenses issued in a European Union member state or a third country, as well as copies of the decision to reject an application for a drug license in a European Union member state or a third country, with the justification for that decision.
We propose to consider deleting the obligation to submit copies of all permits along with the obligation to submit information on the registration status of the drug (WWRS), and copies of permits and decisions can be submitted upon request.
Explanation of remark/proposal/suggestion 6: N/A

The proposal is not accepted.
***Explanation*:**
The provision is fully taken from Directive 2001/83/EC, with the aim of full harmonisation with EU legislation.

Remark/proposal/suggestion 8:

Article 63: When it comes to extraordinary circumstances in the production process that may lead to an interruption of supply, it is necessary to define in more detail what is meant by an interruption of market supply, i.e. to define the out of stock (OOS) period that needs to be reported and at what level (manufacturer/distributor).
Consider introducing an obligation for importers/distributors to notify the Institute directly or through the Licensee about shortages.
Explanation of remark/proposal/suggestion 7:
It is unclear whether market supply disruption means:

- interruption of deliveries by the manufacturer to the distributor (in which case, depending on the traffic dynamics, the distributor may have the drug available during the entire period of interruption of deliveries by the manufacturer). If the manufacturer reports an interruption in production, and the distributor has available quantities, it is potentially possible to import an unregistered drug, in addition to the registered drug that is still available at the distributor.
  or
- interruption of delivery by the distributor to health institutions.

In practice, it often happens that a medicine is not available for a short period of time from a distributor due to commercial reasons, e.g. poor planning, tenders, unexpectedly high demand... It is unclear whether there is an obligation to notify about this type of supply interruption and by whom.

The proposal is not accepted.
Explanation:
The provisions of this Article are fully aligned with the provisions of Article 23a of Directive 2001/83/EC.

Remark/proposal/suggestion 9:

Article 67defines that the parts of the summary of characteristics of the reference drug that refer to indications or pharmaceutical forms that are still under patent protection at the time of placing the generic drug on the market may not be included in the text of the summary of characteristics of the drug for which the license is issued.
Since the Institute is not competent for intellectual property matters, define whose responsibility it is if protected parts are found in the approved SmPC, or how it is determined in Montenegro what is protected in EU countries and under what conditions.
Explanation of remark/proposal/suggestion 8:A local manufacturer's representative cannot know whether something is protected in other countries unless he receives information from the manufacturer, or the Institute.

The proposal is not accepted.
***Explanation*:**
In accordance with the EU acquis, including Directive 2001/83/EC, it is clearly stipulated that the marketing authorisation holder is responsible for the content of the submitted documentation, including the content of the Summary of Product Characteristics (SmPC). The same applies in the legislation of Montenegro.
The Institute for Medicines and Medical Devices is not responsible for patent protection issues or for verifying the status of intellectual property in Montenegro or the EU. This includes the protection of indications, pharmaceutical forms and other aspects that may be covered by valid patents.
It is therefore the responsibility of the manufacturer and/or marketing authorisation holder to ensure that the submitted documentation and the proposed SmPC text do not contain elements that are still under valid patent protection. The manufacturer or marketing authorisation holder in the EU is obliged to inform the local representative in Montenegro and to provide him with all necessary information and instructions to ensure full

compliance with applicable intellectual property rights.

Remark/proposal/suggestion 10:

Article 68 introduces the obligation of the license holder to make available the instructions for the drug in a form that is adapted to blind and partially sighted persons, at the request of the patient association.
We consider it appropriate to define in more detail the conditions under which this obligation would have to be implemented: deadlines for preparation, method of providing, checking and implementing such instructions.
Explanation of remark/proposal/suggestion 9: N/A

The proposal is not accepted.
***Explanation*:**
The standard prescribed by Article 68 aims to ensure access to information about medicines for blind and partially sighted persons, in accordance with the principles of non-discrimination and equal access to health information, which is also in the spirit of European regulations and EMA recommendations.
However, detailed elaboration of technical aspects, such as deadlines, formats, content verification and method of submission, is not subject to legal regulation, but can be regulated in more detail by a by-law adopted by the competent authority, in cooperation with relevant patient associations.

Remark/proposal/suggestion 11:

Article 69 introduces security marks, i.e. the possibility of checking the authenticity of a medicine and the possibility of identifying each individual package by persons engaged in wholesale and retail trade in medicines.
We propose that a transitional provision postpones its application at least until accession to the EU.
Explanation of remark/proposal/suggestion 10: The implementation of the FMD in the EU also required significant logistical interventions and investments and a transitional period allowed market participants to adjust their operations. Given the size of the market and the availability of resources, all impacts on the continuity of supply and availability of medicines should be considered before implementing these provisions.
Additional costs will be created for producers outside the EU (third countries). In Article 343, this article is not mentioned, but only the paragraphs of Article 97 that relate to this issue. Apart from paragraph 5 of Article 69, whose application is postponed until accession to the EU, it seems that all other paragraphs of this article should be applied after the adoption of the law

The proposal is accepted.
***Explanation*:**
The revised version of the Draft provides that the provisions relating to the obligation to affix safety features to the packaging of medicines, in accordance with the principles of Directive 2001/83/EC and Delegated Regulation (EU) 2016/161, will enter into force only on the day of Montenegro's accession to the European Union.

Remark/proposal/suggestion 12:

Article 71, paragraph 2 introduces the possibility of omitting the PIL in the Montenegrin language for a medicine that is not intended for immediate dispensing to the patient or when there are serious problems with the availability of the medicine,
Clarify whether the PIL can be omitted in the case of packaging that is not in the languages in official use.
Consider the possibility of approving the omission of the additional attachment of the PIL in Montenegrin for all medicines that are not intended for direct dispensing to the patient, except in the case of significant substantive differences, in the case of approved packaging in languages in official use.
Explanation of remark/proposal/suggestion 11: Updated instructions in Montenegrin language are available in electronic form on the CInMED website. Healthcare professionals have access to the locally approved SmPC.

The proposal is not accepted.
***Explanation*:**
Montenegro is, as part of the process of accession to the European Union, obliged to align its national legislation in the field of medicinal products with the legislation of the European Union, specifically with Directive 2001/83/EC. In accordance with Article 63 of the aforementioned Directive, the text of the Instructions for Use for a medicinal product must be clear, understandable and legible, and in the official language of the Member State on whose market the medicinal product is placed on the market. In the case of Montenegro, this is the Montenegrin language, which is defined as an official language by the Constitution.
The Institute for Medicines and Medical Devices, as the competent authority for approving the content of the

Instructions for Use for a Medicine, approves exclusively the version in the Montenegrin language. Providing a version of the Instructions for Use in one of the languages in official use in Montenegro (Serbian, Bosnian, Albanian, Croatian), which are not the official language but languages that may be used in certain procedures in accordance with the Law on the Use of Languages and Scripts, does not guarantee that patients will receive information that has been approved by the Institute and has passed regulatory assessment.
Additionally, the Directive allows for multiple language versions of the Instructions, but only on the condition that the same information is provided in all languages, without any difference in content.
Therefore, in order to ensure the availability of verified, accurate and approved information about the medicine to end users, it is necessary that the Instructions for Use for the medicine be in the Montenegrin language.

Remark/proposal/suggestion 13:

Article 78: It does not provide for a deadline for the implementation of variations, nor for variations of type IA and IAin.
Please define the deadline for implementing variations, as well as take into account variations of type IA and IAin and define deadlines, methods of application, assessment and implementation.
We propose to maintain the 12-month deadline for implementing variations after approval, as stated in the currently applicable Law.
We also suggest recognizing the concept of "supply critical" variations and considering defining accelerated deadlines for them.
Explanation of remark/proposal/suggestion 12: N/A

The proposal is not accepted.
***Explanation*:**
Deadlines for implementing variations, as well as the classification and manner of dealing with certain types of variations (including IA, IAin, IB, II and so-called "supply critical" variations), are not defined by law, but are the subject of secondary legislation adopted by the competent authority, i.e. a rulebook that regulates this area in more detail, in accordance with the needs of regulatory practice and harmonization with EU regulations.
Even in the current legislative framework, the implementation deadlines are aligned with EU guidelines, and in that sense, no changes to the essence of regulatory practice are planned.
The proposal to maintain the 12-month deadline for the implementation of approved variations, as well as the consideration of "supply critical" variations, may be considered when adopting the rulebook, but is not subject to normative regulation at the level of law.

Remark/proposal/suggestion 14:

Article 79 paragraph 5 add "bulk" so that the paragraph reads: "A drug for which the drug license has been transferred to a new drug license holder can be in wholesale circulation until the expiration date, and no longer than 18 months from the date of the adoption of the decision approving the transfer of the license for that drug, in accordance with the data from the original drug license.
Explanation of remark/proposal/suggestion 13: Make a clear distinction between wholesale and retail trade in order to avoid the obligation to withdraw the drug to the level of health institutions after the expiration of 18 months, if the drug with old data is still available at health institutions.

The proposal is not accepted.
***Explanation*:**
The draft law subsequently stipulates the obligation of the license holder to keep records of all imported batches and quantities of the medicinal product placed on the market in Montenegro, and the obligation of the manufacturer to inform the license holder thereof. Based on this data, the license holder has the opportunity to plan and coordinate activities related to stocks in a timely manner, including the possible withdrawal of the medicinal product after the transfer of the license.
Adding restrictions solely on wholesale distribution is not justified, as it could lead to legal uncertainty and different interpretations of obligations. Instead, the responsibility lies with the current and new marketing authorisation holders to plan all aspects of distribution in a timely manner when implementing the transfer, in order to avoid operational problems and ensure an orderly supply without unnecessary risk to patients.

Remark/proposal/suggestion 15:

Article 82 states "Compliance with the conditions referred to in paragraph 1 of this Article shall be proven by submitting a document verifying compliance with the GMP guidelines issued by the competent authority of one of the EEA or EUMRA member states or by verifying compliance with the conditions stipulated in the GMP guidelines by the Institute." Does this mean that after Montenegro's accession, the Institute will continue to issue GMP certificates for manufacturers from third

countries, which will relate, as now, to the batch release process, which will enable them to continue to produce medicines intended for the Montenegrin market, without transferring the batch release process to another legal entity located in an EU member state?
Explanation of remark/proposal/suggestion 14: Additional analyses and procedures for releasing drug batches to the market that would be transferred from third countries to member states would significantly affect production costs and would question the profitability of drug production for Montenegro.

Comment: After Montenegro's accession to the European Union, Montenegro will issue EU GMP certificates, so the relevant evidence will still be EU or EUMRA GMP certificates or a certificate issued by CInMED. However, the activity of releasing a batch of a medicinal product from third countries for Montenegro after accession to the European Union will have to be carried out exclusively on the Montenegrin, or EU, market.

Remark/proposal/suggestion 16:

Article 97, paragraph 4 states: "In the case where a medicinal product is imported from a third country with which the European Union has concluded appropriate agreements that ensure that the manufacturer applies standards of good manufacturing practice at least equivalent to those in the European Union and that the quality control referred to in paragraph 1, point 2 of this Article is carried out in a third country, which is the country of export, the person responsible for the release of a batch of the medicinal product in Montenegro may be exempted from the responsibility for carrying out the control, in accordance with the concluded agreement. We believe that it is necessary to define more closely "third country with which the European Union has concluded appropriate agreements".
Explanation of remark/proposal/suggestion 15: In particular, third countries that are candidates for accession to the European Union should be considered as countries to which this paragraph applies. It should be more precisely defined in the law in order to avoid subsequent interpretations.

The proposal is not accepted.
***Explanation*:**
This applies to countries that have concluded agreements with the European Union, the so-called MRA (Mutual Recognition Agreement) or some other agreements on the recognition of GMP certificates or other acts that prove the application of good manufacturing practice standards.

Remark/proposal/suggestion 17:

Article 155 – Paragraph 3 refers to medicines registered before July 21, 2012.
Comment:In our assessment, the information missing here is that it refers to licenses issued in the EU before this date, as defined in paragraph 1 of Article 149.
Explanation of remark/proposal/suggestion 15: N/A

Comment: An identical article already exists in the current Law on Medicinal Products, the provision was taken from Directive 2001/83/EC and applies only to licenses issued in the European Union.

Remark/proposal/suggestion 18:

Article 196 provides for the establishment of maximum prices for medicines imported in accordance with Article 28.
Consider not introducing a maximum price for medicines imported in accordance with Article 28, especially in relation to points 1, 4 and 5 of paragraph 1 of Article 28.
Additionally, Article 196 does not clearly refer to Article 195, so it is not unambiguously clear that the obligations prescribed by Article 196 apply only to prescription-only medicines, as defined in Article 195.
Explanation of remark/proposal/suggestion 16: N/A

The proposal is not accepted.
Explanation:
In practice, medicines that are not registered or on the List of Medicines are often imported, and are approved through the Commission for the Approval of Medicines Outside the List of Medicines. These are additional costs that significantly burden the budget, which has the consequence that the prices of these medicines are regulated.
Article 195 stipulates that maximum prices are set for medicines that have been granted import approval in accordance with Article 28 and whose prescription regime is established, while Article 196 only defines the deadline for submitting a request for determining the maximum price for these medicines.

Remark/proposal/suggestion 19:

Article 309, paragraph 5 Delete or replace with the condition that the person could not have been in the ownership structure or connected to persons in the ownership structure of legal entities engaged in the production, wholesale trade and testing of medicines and medical devices and other legal entities that participated in the preparation of documentation submitted with the application for the issuance of a medicine license and registration of a medical device, as well as in other regulatory affairs in the field of medicines and medical devices, for the previous 3 years.

Explanation of remark/proposal/suggestion 17:

The wording of Article 309 limits the selection to employees of the Institute. There are no similar legal restrictions (paragraph 5) in comparable regulations (EU, HR, RS). Experience in areas relevant to the work of the Institute can only be acquired in positions in industry and wholesale trade, if the employee does not work at the Institute.

The proposal is not accepted.

Explanation:

The provision of Article 309, paragraph 5, is formulated in accordance with the need to entrust the function of director of a regulatory authority, such as the Institute for Medicines and Medical Devices, to a person with direct regulatory experience and a deep understanding of the procedures, responsibilities and role of the Institute in protecting public health.

This solution does not exclude the possibility of persons working in industry or wholesale trade being employed by the Institute. On the contrary, by gaining work experience at the Institute, these persons may in the future meet the requirement for a director position. This does not restrict freedom of employment, but rather clearly sets an institutional standard that guarantees that a management position is entrusted to a person with specific regulatory experience, and not exclusively commercial or advisory experience.

Although similar restrictions are not explicitly prescribed in some comparative regulations, in the practice of European regulatory agencies, management positions are reserved for persons with previous regulatory experience, precisely due to the complexity of the tasks and the need to maintain independence and impartiality in decision-making.

This provision serves to strengthen the integrity of the institution and ensure that the director possesses the necessary experience and an impartial view, and does not come from structures that are subject to regulation.