ACTION PLAN OF THE NATIONAL COORDINATING BODY FOR 2024 and 2025 TRADE FACILITATION

II EXPERT WORKING GROUP FOR TECHNICAL OBSTACLES AND MEASURES WITH EQUAL EFFECTS IN TRADE

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The Expert Working Group for Technical Obstacles and Measures with Equal Effect in Trade considers issues and proposes initiatives that contribute to the promotion and facilitation of foreign trade exchange in industrial (non-food) products (including, among other things, cosmetic products and other items of general use, medicines, medical devices, chemicals, toys, etc.). In the issues and initiatives that it considers and proposes, the expert working group makes sure that technical regulations, standards and procedures for assessing compliance with them are adopted and applied in such a way as not to introduce unnecessary obstacles to trade.

	Planned activity	Measures for the implementation of activities	Competent institutions	Outcome indicator
1.	**Improvement of the system of risk analysis during the control of goods by all inspection services in order to facilitate the international traffic of shipments**	• Introduction and further improvement of models for risk analysis when importing goods. • Drafting and/or revision of internal procedures for risk management and the acting of inspectors • Improvement of IT tools for analysis and risk management used for the implementation of control of goods during importation.	MH (Sector for Inspection Affairs)	Prepared methodological instructions for the application of risk analysis. Adopted official control and monitoring plans based on risk assessment. Developed internal procedures for risk management. Use of IT tools for risk analysis and risk management
2.	**Further harmonisation**	• Application of the complete list of Serbian standards (EU list) in the field of construction	Ministry of Construction,	Full application as of 1

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	of technical regulations with EU regulations	products, i.e. the list of standards that accompanies the legal act on construction products	Transport and Infrastructure	January, 2025.
		• In the domain of general use items - adoption and regular updating of regulations in accordance with changes in EU regulations, in particular: - Drafting of by-laws for materials and objects in contact with food, in accordance with EU regulations - Drafting of by-laws that regulate the regime of import of detergents, biocides, etc. in accordance with EU regulations	Sanitary Inspection Service, Ministry of Health	Rulebooks adopted based on the Law on Items of General Use
		• Transposition of the new EU Regulation on machine safety.	Ministry of Economy	Published Decree on Machine Safety.
		• Transposition of the new EU directive on radio devices (RED), up-to-date publication of the list of Serbian standards in the field of radio equipment, consideration of the validity period of the certificate of conformity and its cancellation.	Ministry of Information and Telecommunications, MDFT - Market Inspection Service	Amended regulations - publication of the Rulebook on Radio Equipment, Published list of Serbian standards in the field of radio equipment.
		• Continuous cooperation with market inspection authorities regarding the application of new technical regulations and compliance documents that accompany them when they are placed on the market.	Ministry of Information and Telecommunications, Ministry of Economy, MDFT – Market Inspection Service.	Reports and minutes from held meetings, round tables, etc.

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	Negotiations on the signing of the Agreement on Conformity Assessment and Acceptance of Industrial Products between the EU and Serbia (ACAA)	• Initiating and starting negotiations for the signing of the "ACAA" agreement between the EU and the Republic of Serbia, for selected groups of industrial products, namely electrical/electronic equipment and machinery. • Review and plan with the competent Ministries the extension of the "ASAA" agreement to other product groups from the competent Ministries.	Ministry of Economy, Ministry of Construction, Transport and Infrastructure, Ministry of Energy, Ministry of Health.	Finalisation of the process of signing the Agreement on Conformity Assessment and Acceptance of Industrial Products between the EU and Serbia
4.	**Cancellation of licences for the activity of trading in dangerous chemicals, as well as licences for the use of dangerous chemicals for natural entities** Amendments to the Law on Chemicals (*The Official Gazette of the Republic of Serbia*, Nos. 36/09, 88/10, 92/11, 93/12 and 25/15)	• **Repeal of the provisions of Articles 63 -72.** The provisions stipulate that the marketing of certain dangerous chemicals can only be carried out by legal entities or entrepreneurs who have a licence to carry out the activity of marketing those chemicals; further on, the procedure for submitting an application for obtaining a permit and the conditions that must be met in order to obtain the permit has been prescribed. In addition, the obligation to submit an application for obtaining a permit for the use of certain hazardous chemicals for natural entities has been prescribed. These provisions of the Law have been identified as an obstacle to the free movement of goods, and will be repealed by the adoption of the new Law on Chemicals. The deadline for the adoption of the new law is the last quarter of 2023.	Ministry of Environmental Protection	The Law on Amendments to the Law on Chemicals was adopted

	Planned activity	Measures for the implementation of activities	Competent institutions	Outcome indicator
5.	**Eliminate delays in issuing registrations, renewals of registrations, approval of variations and promotional materials for medicines** in accordance with the legal deadline	• Introduction of an electronic platform for submitting and processing documentation for medicines by mid 2024 (according to all the abovementioned procedures) • Meeting the action plan[1] for establishing the processing of requests for registrations, renewals and variations of the drug licence within the legal deadlines • MMDAS semi-annual progress report	MMDAS Ministry of Health	Issuance of registration for medicines, renewal of registration, approval of variations and promotional materials within the legal deadline of 2025 Established electronic platform for submitting documentation for medicines Semi-annual progress report
	Creation of prerequisites for the export of dietary products to the People's Republic of China	Special conditions for exporting food to the territory of the People's Republic of China apply to 18 types of food products, including dietary products that are classified as food. In order for a food product to be exported to the territory of the People`s Republic of China, it must be registered by competent national institutions recognised by the General Administration of Customs of China (GACC). The Ministry of Health of the Republic of Serbia should submit a request to open an account on the CIFER portal, where Serbian business entities wishing to export their dietary products to the People's Republic of China could be registered.	Ministry of Health	Enabled export of dietary products produced in the Republic of Serbia to the People's Republic of China

[1] Addendum 1 - Medicines and Medical Devices Agency of Serbia (MMDAS) need analysis for establishing the regular processing of requests for registrations, renewals and variations of the drug licence within the legal deadlines

	Planned activity	Measures for the implementation of activities	Competent institutions	Outcome indicator
	Creation of prerequisites for the export of dietary products to the Arab Republic of Egypt	The prerequisite for placing this group of products on the market of the Arab Republic of Egypt is product registration according to the requirements prescribed by the National Food Safety Authority of Egypt (hereinafter referred to as: the NFSA). One of the certificates enclosed during the registration process is the Free sale certificate (FSC) for a specific product from the exporter's country. For an FSC to be recognised by the NFSA, it must be issued by a country on the NFSA reference country list. Currently, 36 countries are on the NFSA list of reference countries, but the Republic of Serbia is not among them	Ministry of Health	Placement of dietary products produced in the Republic of Serbia on the market of the Arab Republic of Egypt

ADDENDUM 1 The MMDAS need analysis for establishing the regular processing of requests for registrations, renewals and variations of the drug licence within the legal deadlines

Projection of entry into legal deadlines for issuing registration, renewal and amendment of drug licences of the Centre for Human Medicines (CHM)

Based on the current pace of resolving requests with available human capacities, with the launch of an electronic platform that fully digitises the submission of documents and processes pertaining to the drug licence, the projection of full compliance with legal deadlines for certain administrative procedures is as follows:

- Registrations - end of 2026
- Renewals - end of 2025
- Variations - mid-2025

Bearing in mind that every year, the Centre for Human Medicines (CHM) increases the number of requests for registration and variations compared to the previous year, as well as that there is a significant backlog of cases from previous years, which makes it impossible for the CHM to issue drug licences/ notification of variations in legal deadlines, the CHM needs significant reinforcements in terms of personnel. What represents an additional problem is the space, since there would not have been space to accommodate the potentially newly hired personnel.

The needs for additional capacities, which would enable the execution of administrative procedures within the deadlines, within one year from the moment of securing these capacities, are as follows:

1. 18 employees for an indefinite period of time, who would enable cases to be completed within the legally stipulated deadlines in the future, namely:

    - National Centre for Pharmacovigilance: 5 employees (doctors or pharmacists) - tasks: establishment of a new team for solving C variations, speeding up work on registration and renewal cases and entering legal deadlines for assessment, as well as engaging in assessment and processing of reports on adverse drug reactions.
    - Efficiency and safety: 5 employees (doctors or pharmacists) - speeding up work on registration, renewal and variation cases, as well as entering the legal deadlines for assessment.
    - Pharmaceutical sector: 7 employees (5 pharmacists and 2 molecular biologists) - speeding up work on registration, renewal and variation cases, as well as entering legal deadlines for assessment

- CHM: 1 employee (doctor or pharmacist), assistant to the head of the CHM to whom a part of the activities currently performed by the head of the CHM would be delegated (answering inquiries about the status of requests, drafting a letter about the clock-stop, making various analyses on the efficiency of the Centre`s work, etc.)

2. 16 temporarily employed employees, who would enable the completion of backlog cases, namely:

- National Centre for Pharmacovigilance: 4 employees (doctors or pharmacists)
- Efficiency and safety: 5 employees (doctors or pharmacists)
- Pharmaceutical sector: 6 employees (pharmacists)
- Licencing Department: 1 employee (pharmacist)

3. Provision of spatial capacities for performing regular activities for all newly hired employees, as well as for some of the existing ones.