EXPLANATORY MEMORANDUM

General part

Name

Draft Act amending Act No 375/2022 on medical devices and in vitro diagnostic medical devices, as amended (hereinafter the ‘draft Act’)

1. **Assessment of the existing provisions, including assessment of the current state in relation to the prohibition of discrimination and in relation to gender equality**

On 9 July 2024, Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices (hereinafter ‘Regulation (EU) 2024/1860’) was promulgated. However, the deadline for the Czech Republic to fulfil its implementation obligation already expired on 10 January 2025, whereas the draft Act had been placed on the agenda of the 9th parliamentary term of the Chamber of Deputies as Parliamentary Document 927, however it was not debated. In view of the above, the draft Act is therefore being resubmitted to the Government for further consideration and subsequent referral to the Chamber of Deputies for debate.

Compared to the version of the draft Act placed before the Chamber of Deputies in the last parliamentary term as Parliamentary Document 927, necessary legislative and technical changes have been made, reflecting the fact that, compared with the previous version, Act No 375/2022 on medical devices and in vitro diagnostic medical devices, as amended (hereinafter the ‘Medical Devices Act’), will not be amended by Parliamentary Document 918, which, in connection with the amendment of the Advertising Regulation Act, also amended the Medical Devices Act and provided for the adoption of a new provision in § 53a, which the original § 53b of the draft Act was to follow on in the sequence of the legislative process. As the order of the legislative process will change following the expiry of the Chamber of Deputies’ term of office, and the original Parliamentary Document 927 will take precedence over the original Parliamentary Document 918 in the proceedings, the designation of Section 53b is also changed, to Section 53a, including citations, in order that no technical legislative inaccuracies will arise following the adoption of the draft Act.

The provisions of § 61(4) of the draft Act are being reissued in accordance with the original draft, however, paragraph (4) is now worded to reflect the amendment to the Medical Devices Act implemented by Act No 236/2025 amending Act No. 325/2021 on the digitisation of healthcare, as amended, and other related acts, which has since been published in the Collection of Laws.

The Medical Devices Act adapts the Czech legal code to the regulation amended by Regulation (EU) 2024/1860, i.e., Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter the "Medical Devices Regulation") and

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (hereinafter the "IVDR").

Regulation (EU) 2024/1860, in amending Article 1(1) in relation to point 4(b) and the second indent of point 5, and Article 2(1) in relation to point 3(e), establishes a new Article 10a, which, in view of the impact that shortages of certain medical devices and in vitro diagnostic medical devices may have on patient safety and public health, stipulates a prior notice mechanism that would allow, in particular, competent authorities and health institutions to take mitigating measures where necessary to ensure patient health and safety. Consequently, if manufacturers, for whatever reason, anticipate an interruption or cessation of supplies of medical devices or in vitro diagnostic medical devices (hereinafter collectively referred to as ‘devices’) and it can reasonably be expected that such a disruption may cause serious harm or pose a risk of serious harm to patients or public health in one or more Member States, they are subject to a new obligation to inform the competent authorities and the economic operators to whom they directly supply such devices, and, where applicable, the healthcare providers to whom they supply them directly.

However, the fulfilment of this obligation alone is not sufficient to fulfil the purpose of Regulation (EU) 2024/1860, as expressed in paragraph (15) of the Preamble, i.e. to allow Member States to take measures in the event of an anticipated interruption or discontinuation of supply of devices. In view of this, it is also proposed to enable the Ministry of Health to regulate the handling of high-risk products on the basis of information assessed by the State Institute for Drug Control (hereinafter the ‘Institute’). To ensure that this obligation is based on factual knowledge, it is also essential that the Institute assesses not only the information obtained from the manufacturer pursuant to Regulation (EU) 2024/1860 or in the course of its official duties, but that it be able to specifically obtain and supplement this information from all relevant parties so as to make a qualified assessment of whether and to what extent public health may be at risk due to reduced availability or unavailability of the device. The draft also enables the Ministry of Health to respond flexibly and take measures also in the event of a risk of a shortage of a product caused by factors other than an anticipated interruption or discontinuation of supply by the manufacturer as defined by Regulation (EU) 2024/1860.

The present draft Act does not anticipate any impact in relation to the prohibition of discrimination or in relation to gender equality as defined in Act No 198/2009 on equal treatment and on legal remedies for protection against discrimination and amending certain acts (the Anti-Discrimination Act), as amended. The draft Act is indifferent from the point of view of the equality of men and women.

2. Justification of the main principles of the draft legislation, including the impacts of the proposed policy in relation to the prohibition of discrimination and in relation to the equality of men and women

The reason for drafting the present draft Act was the need to adapt Czech legislation accordingly following the introduction of amending Article 1(1) of Regulation (EU) 2024/1860, as the date of implementation of the Regulation was set for 10 January 2025. The primary objective is therefore to bring national legislation into line with European regulations and to put the system of reporting interruptions or discontinuations of supply of devices into practice.

The present draft Act does not anticipate any impact in relation to the prohibition of discrimination or in relation to gender equality as defined in Act No 198/2009 on equal treatment and on legal remedies for protection against discrimination and amending certain acts (the Anti-Discrimination Act), as amended. The draft Act is indifferent from the point of view of the equality of men and women.

3. Explanation of the need for the draft legislation as a whole

The draft legislation is necessary to ensure that national law is properly adapted to directly applicable EU legislation. The draft specifies the content of the obligations arising from Article 1(1) in relation to point 4(b) and point 5, second indent, and Article 2(1) in relation to point 3(e) of Regulation (EU) 2024/1860, and further specifies the national form of fulfilment of these obligations and the service channel for reporting on the interruption or discontinuation of the supply of the device. At the same time, the draft enables the Ministry of Health to monitor the situation and, where necessary, take measures also in the event of an impending shortage of a device for reasons other than a planned interruption or discontinuation of supply by the manufacturer pursuant to Regulation (EU) 2024/1860.

In connection with the new obligations laid down by both Regulation (EU) 2024/1860 and this draft, the definitions of infractions for failure to comply with the obligation to submit reports to the Institute or to economic operators receiving the devices are also laid down, including appropriate penalties, and a transitional arrangement is provided for in the event that, by the date of implementation of Regulation (EU) 2024/1860, the module for reporting the suspension or cessation of medical devices in the Medical Devices Information System is not yet fully operational.

As mentioned above, in addition to aligning the obligations set out in the substantive provisions of Regulation (EU) 2024/1860, this draft also sets out the powers of the Ministry of Health and the Institute, which will enable them to follow this Regulation and act on information provided by manufacturers, or to respond to any impending shortage of a device for other reasons. This legislative draft thus enables the Institute to use information from manufacturers regarding the interruption or discontinuation of supply, together with other information (obtained through the Institute's own official activities or from other economic operators via the mechanisms described in this draft) in the course of an investigation to identify any shortages of medical devices and, subsequently, where there is a justified conclusion that such a shortage exists, enables the Ministry of Health to adopt measures of a general nature to temporarily adjust the conditions for the handling of such devices. This procedure is in line with the premise set out in the preamble to Regulation (EU) 2024/1860, point (15) of which states: *'Having regard to the impact that shortages of certain medical devices and in vitro diagnostic medical devices can have on patient safety and public health, a prior notice mechanism should be introduced to enable competent authorities and health institutions, in particular, to take mitigating measures where necessary to ensure patient health and safety.'.* However, up to now the Czech Republic legal code has not contained instruments to adopt such *'mitigating measures to ensure patient health and safety'*; this draft therefore anticipates them in the form of instruments for monitoring and assessing the availability of medical devices and for issuing measures of a general nature, so as to enable the identification of a risk of a shortage of a medical device essential for the provision of healthcare, regardless of whether this risk is caused by a planned interruption or discontinuation of supply by a manufacturer, the reporting of which is provided for in

Regulation (EU) 2024/1860, or by some other cause. In practice, it can be assumed that shortages may arise not only on the part of the manufacturer, but also, for various reasons, on the part of other entities in the distribution chain or healthcare providers. The Institute should be able to investigate such situations in response to a report from any entity, but also to proactively investigate potential risks of a shortage of a product essential for the provision of healthcare, even where such a risk has not resulted in a planned interruption or discontinuation of supply by the manufacturer. The grounds for such proactive investigations include, for example, findings arising from the Institute's own official activities, communications with the legal and natural persons concerned, market monitoring, previously identified shortcomings, etc. Given that this is an entirely new concept, it is proposed that a minimalist regulatory framework be adopted, i.e. the Institute's power to obtain information from manufacturers, distributors, and healthcare providers, and the power of the Ministry of Health to issue, on the basis of information collected and analysed by the Institute, measures of a general nature in necessary and exceptional cases where there is a threat of a shortage of supplies essential for the provision of healthcare services that would jeopardise the availability and effectiveness of patient care in the Czech Republic.

4. Assessment of compliance of the draft legislation with the constitutional order of the Czech Republic

The draft legislation is in line with the constitutional order, especially with

- Article 2(3) of Constitutional Act No 1/1993, the Constitution of the Czech Republic, as amended (hereinafter the 'Constitution'), according to which state power may be exercised only in the cases, within the limits, and in the manner prescribed by law;
- Article 41(2) of the Constitution, under which the Government has the right of legislative initiative, and also in accordance with § 24 of Act No 2/1969 on the establishment of ministries and other central bodies of the state administration of the Czech Republic, as amended, which states, inter alia, that ministries shall prepare drafts of laws and other legal regulations concerning matters falling within their remit, as well as drafts which the Government has instructed them to prepare;
- Article 79(1) of the Constitution, according to which the powers of the administrative authorities may be established only by law.

The proposed legislation is also in line with the Charter of Fundamental Rights and Freedoms, promulgated by Resolution No 2/1993 of the Praesidium of the Czech National Council, as part of the constitutional order of the Czech Republic (hereinafter the 'Charter'), in particular with

- Article 2(2) of the Charter, pursuant to which State power may be exercised only in the cases and within the limits laid down by law, in the manner provided for by the law;
- Article 4(1) of the Charter, pursuant to which obligations may be imposed only on the basis of and within the limits of the law, and only in a manner that respects human rights and freedoms;
- Article 2(3) of the Charter, pursuant to which everyone is free to do anything that is not prohibited by law, and no one may be compelled to do anything that is not required by law.

The proposed legislation therefore meets the constitutional requirement that obligations be laid down by statute and is also consistent with the principles governing the limitation of fundamental rights and freedoms under Article 4 of the Charter. The draft Act also respects the principle of '*nullum crimen sine lege, nulla poena sine lege*' pursuant to Article 39 of the Charter.

The proposed legislation does not in any way curtail the rights of the parties concerned, nor does it discriminate against any specific groups of persons to whom the legal provisions apply. It respects the general principles of the constitutional order of the Czech Republic and does not contradict the judgements of the Constitutional Court.

5. Evaluation of the consistency of the draft legislation with EU legislation, EU case law, and the general principles of EU law

The draft Act is in accordance with EU legislation, EU case law, and the general principles of EU law. In particular, the draft Act improves the enforcement of obligations stemming from selected provisions of the following EU legislation:

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

The level of implementation of these regulations remains unchanged, nor shall the draft Act result in their re-implementation. The draft Act merely clarifies the content and form of the obligations laid down in Regulation (EU) 2024/1860 (e.g. the requirements and method of providing information, including the communication channel), and further introduces the elements of infractions and penalties for failure to comply with these obligations, as the Regulation itself does not set out any infractions or penalties for those subject to the rules.

Regulation (EU) 2024/1860 does not specify the competent authority responsible for supervising the obligations it introduces. The Institute's powers in the area of supervision of devices are already established by the Medical Devices Act, as part of the transposition of the above regulations amended by Regulation (EU) 2024/1860, specifically in § 5(1) and (2) (h). The bill therefore simply builds on what has already been stipulated.

The present draft is in accordance with Article 34 et seq. of the Treaty on the Functioning of the European Union (hereinafter 'TFEU'), as under Article 36 TFEU, the free movement of goods may be restricted for reasons such as the protection of public health, public security, or the prevention of crime, provided that such restrictions are not manifestly discriminatory, are proportionate (i.e., necessary to achieve a legitimate objective), and are implemented in a way that does not violate the principle of proportionality.

The proposed measure, which would take the form of a measure of a general nature allowing for the temporary adjustment of the conditions governing the placing on the market, supply to the market, and putting into service, prescribing, dispensing, or use of a device in the provision of healthcare services, could constitute interference with a legitimate interest, specifically the free movement of goods. However, a measure of a general nature will only be

adopted in order to protect public health and, in exceptional circumstances where the availability of specific devices is at risk. Without the adoption of this legislation, the administrative authorities responsible for regulating the handling of medical devices would have no means of responding to exceptional situations where such devices are unavailable, unless a state of emergency were declared pursuant to Constitutional Act No 110/1998 on the security of the Czech Republic, as amended, which the submitter, in light of the experience gained during the COVID-19 pandemic, considers to be a significant shortcoming of the Czech legal system and a substantial discrepancy compared to the legal framework governing shortages of pharmaceuticals. It can be assumed that measures of a general nature will be applied primarily to devices in higher risk categories.

Of all the possible solutions, the concept of measures of a general nature appears to be the most suitable tool for addressing shortcomings or a lack of devices, as it allows specific situations to be resolved swiftly, in a targeted manner, yet comprehensively; at the same time, however, it is possible to challenge such measures, for example through the administrative courts. Other legal instruments provided for in the Code of Administrative Procedure, i.e., that are available to the state in such situations, are unsuitable for the situations in question for various reasons.

In urgent cases of product shortages, it is anticipated that the Ministry of Health will use measures of a general nature primarily to restrict the range of entities to which the product may be supplied, e.g. limiting supply to hospitals only, restricting the range of patients or diagnoses for the treatment of which the product may be prescribed, etc. This may, among other things, involve interventions in the prescribing and dispensing of the product under Part Six and the rights and obligations imposed on healthcare providers under Part Seven of the Medical Devices Act. This will primarily consist of prioritising persons to whom resources can be delivered in the event of shortages or unavailability, or to whom healthcare can be provided through devices with reduced accessibility. Measures of a general nature will therefore always be used to address exceptional or urgent situations for which the administrative authorities have no other means at their disposal.

The protection of public health is recognised as a legitimate reason under Article 36 TFEU to restrict the free market, specifically the free movement of goods, provided that it is ensured that the measures do not discriminate against products from other EU Member States and that they comply with the principle of proportionality. An obligation imposed by a measure of a general nature will not discriminate against products from other Member States, because the origin of the product will not play any role in its adoption. The focus will be on the therapeutic properties of the product in question, its current availability, and an assessment of whether it is suitable for addressing the exceptional or urgent situation; consequently, the country of origin will not influence the final form of the general measure. When drafting and adopting measures of a general nature, it is also necessary to minimise interference with the free movement of goods and to preserve to the greatest possible extent the legitimate rights of entities whose goods are affected by a measure of a general nature such that the outcome is in accordance with the basic principles of administrative law that follow from § 2(3) of the Code of Administrative Procedure, i.e. in accordance with the principle of protecting rights acquired in good faith, the legitimate interests of persons affected by the activities of the administrative authority in an individual case, interference with these rights only to the necessary extent, and from § 2(4) of the Code of Administrative Procedure, i.e. the adoption of a solution that is in line with the public interest.

In relation to the protection of personal data, the submitter states that the draft is in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC. In this regard, we also refer to the assessment of the impacts of the proposed solution in relation to the protection of privacy and personal data in point 9 below.

6. Assessment of the compatibility of the proposed legislation with international treaties by which the Czech Republic is bound

The draft Act is fully in line with the international treaties by which the Czech Republic is bound, including the Treaty on the Functioning of the European Union and the Treaty on European Union, as well as with generally accepted principles of international law.

The draft legislation is in accordance with the Convention for the Protection of Human Rights and Fundamental Freedoms, in particular the principle of the right to a fair trial (Article 6 of the Convention), the imposition of punishment only in accordance with the law (Article 7 of the Convention) and the right not to be tried or punished twice (Article 4 of Protocol No. 7 to the Convention), as well as with the relevant case law.

7. Expected economic and financial impacts of the proposed legislation on the state budget, other public budgets and the business environment in the Czech Republic

The draft legislation will have an impact on the budget of the Institute. In order to adapt Article 1(1) in relation to point 4(b) and the second indent of point 5, and Article 2(1) in relation to point 3(e) of Regulation (EU) 2024/1860, it will be necessary to establish an interface at the national level through which manufacturers of devices will be able to report to the Institute the interruption or discontinuation of supply of devices. To achieve this objective, the least costly option was chosen, namely the creation of a new module within the existing Medical Devices Information System, which is the latest operational self-service portal under the purview of the relevant authority and, in practical terms, is directly relevant to the regulation of medical devices. It will also be necessary to expand the functionality of the Medical Devices Information System so that it can also accept reports from manufacturers regarding the interruption or discontinuation of supply. The estimated cost of implementing this change to the Medical Devices Information System is CZK 1 100 000 (to be funded from the state budget). All planned expenditures will be covered within the limits of Chapter 335 without any additional demands on the state budget. The implications for salaries and staffing will be managed as part of the existing staffing levels and the budget ceiling for salaries.

The draft legislation has no impact on other public budgets.

The draft Act will not have an impact on the environment. The primary obligation for producers and economic operators to report interruption or discontinuation of supply of devices has already been brought about by the text of Regulation (EU) 2024/1860 itself, applicable from 10 January 2025, regardless of whether this draft Act will be in effect by then. The draft Act as such does not therefore establish this obligation, but merely specifies it in such a way as to minimise the burden on businesses, by stipulating that reports must be submitted electronically via a self-service portal that the entities concerned already use.

Any measures of a general nature that would allow the Ministry of Health, in justified cases where there is a shortage of medical devices, to amend the conditions for the marketing, distribution, putting into service, prescribing, dispensing, or use of such devices in the

provision of healthcare services would constitute an encroachment on the autonomy of medical device handling. The measures listed may then, if adopted, generate costs for entrepreneurs and restrict their rights to freely handle such devices, including effects on the free movement of goods.

The adoption a measure of a general nature will be preceded by monitoring and subsequent analysis carried out by the Institute, through which it will assess information received regarding the interruption or discontinuation of supply of devices from the field and from other Member States; should the Institute suspect a threat to the availability of a product, it will call upon manufacturers, distributors, and healthcare providers to supply further information necessary to assess the impact of the impending shortage.

8. Assessment of social impacts, including impacts on specific groups of the population, in particular socially disadvantaged persons, persons with disabilities and national minorities, impacts on the protection of children's rights and environmental impacts

The draft legislation has no social impacts.

The area that this draft concerns does not establish any differences which could, as a result, be perceived as discriminatory from the point of view of specific population groups.

The draft legislation has no impacts on the environment.

9. Assessment of the impacts of the proposed policy in relation to the protection of privacy and personal data

The draft legislation is in compliance with the protection of privacy and personal data. Their standard protection is ensured in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). The Institute has implemented a data protection system in accordance with the cited regulation.

The draft Act is not at odds with the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (promulgated under No 115/2001 of the Collection of International Treaties) or with Act No 110/2019 on the processing of personal data, as amended.

The protection of privacy and personal data is not compromised by the establishment of new powers for the supervisory authority, as the exercise of such powers in the performance of supervisory activities must comply with the principle of proportionality, to an extent that is appropriate to the subject matter, purpose of the measure, and nature of the inspection, including the applicable procedural safeguards and principles set out in the Charter of Fundamental Rights of the European Union. Enforcement and coercive measures must be proportionate to the nature of the infringement of the legal provisions laying down product requirements or safety requirements, and to the actual or potential harm caused by non-compliance with those provisions.

The present draft Act anticipates the processing of personal data; however, such processing is already taking place within the Medical Devices Information System, in accordance with the principles set out in Article 5 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the

processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) and on a legal basis, specifically for the purpose of complying with a legal obligation to which the relevant supervisory authority, as the data controller, is subject (Article 6 of Regulation (EU) 2016/679), including the principles set out in Commission Implementing Decision (EU) 2023/975.

The supervisory authorities have appointed data protection officers who carry out the tasks stipulated in Article 39 of Regulation (EU) 2016/679 and have established internal mechanisms for the control, protection, and handling of classified information and sensitive data, as well as procedures for their recording, storage, destruction and handling, and guidelines for working with such information. The proposed legislation is therefore consistent with the protection of privacy and personal data and ensures their protection by default in accordance with Regulation (EU) 2016/679.

The processing of personal data will be carried out in a manner that ensures appropriate security and confidentiality of the data. Unauthorised access to personal data will be ruled out. The supervisory authorities will make use of the technical and software resources already at their disposal. All information relating to the processing of personal data is available on the websites of the relevant supervisory authorities. Data subjects will thus be informed of the identity of the controller or the purpose of the processing of personal data.

10. Assessment of corruption risks

The submitter has checked the obligation to carry out a corruption risk assessment, as laid down in the Government's Legislative Rules, according to the Corruption Impact Assessment (CIA) methodology published on the website of the Office of Conflict of Interest and Anti-Corruption of the Ministry of Justice's Anti-Corruption Department (https://korupce.cz/protikorupcni-agenda/metodika-cia).

The main – and essentially the only – risk of corruption in relation to this bill concerns the supervision of compliance with the obligation to report any interruption or discontinuation of the supply of devices. The supervisory authority for this area is the Institute, which, however, has sophisticated internal oversight mechanisms in place, including the appointment of a specific responsible person. The supervisory authority has drawn up an internal anti-corruption strategy and an internal anti-corruption programme, both of which are available on its website. Lists of advisory bodies and other bodies or persons providing legal services or legal advice to the supervisory authority, where used, are also published. The supervisory authority has also drawn up codes of ethics for its staff, which are based on Civil Service Regulation No 3 of 3 October 2023 of the Deputy Minister of the Interior on the ethical rules for civil servants, which lays down the ethical rules for civil servants.

The proposed legislation draws on existing concepts and processes that are already part of the Czech legal system, have proven their worth, and present a level of corruption risk that is within acceptable limits. The scope of the set of entities covered by the draft Act is commensurate with the purpose of the proposed legislation, there is no increase in the number of supervisory authorities. The Institute is already vested with supervisory powers by law. These are being extended only minimally.

The draft Act does not affect the availability of information under Act No 106/1999 on free access to information, as amended, and does not conflict with the requirements for transparency and open data.

11. Assessment of impact on state security or defence

The present draft Act has no implications for national security or defence, as it does not in any way materially relate to these areas.

12. Assessment of the impact on families, in particular with regard to the fulfilment of the functions of the family, the number of dependent members, the possible presence of disabled members, single-parent families, families with three or more children, and other specific life situations, as well as strengthening family integrity and stability, enhancing family harmony, achieving a better work-family balance, and strengthening intergenerational and wider family relationships

The draft Act has no impact on the security or functioning of families, nor on any other criterion assessed in this regard, as it does not in any way materially affect this area.

13. Assessment of territorial impacts, including impacts on territorial self-governing units

The presented draft has no territorial implications or implications for territorial self-governing units, as it does not materially affect this area in any way.

14. Evaluation of the compliance of the draft legislation with the principles of digitally friendly legislation

The draft promotes compliance with the principles of digitally friendly legislation. The draft anticipates the use of the services of public administration information systems (ISVS) through the expansion of the already functioning Medical Devices Information System, as the proposed legislation introduces obligations for the fulfilment of which new digital services should necessarily be built.

This draft anticipates the communication of economic operators with the Institute exclusively in electronic form, in particular through the Medical Devices Information System.

The draft legislative amendments is therefore subject to the principles of ‘Developing services that are accessible and usable by all, including people with disabilities’, ‘Shared public administration services’ and ‘Consolidation and interconnection of public administration information systems’.

The draft Act respects the principle of ‘Maximum repeatability and reusability of data and services’. Where necessary, supervisory authorities make use of existing databases and IT tools, in particular the Trade Register, the Insolvency Register, the Administrative Register of Economic Entities, the Commercial Register, and the VAT Payers’ Register.

15. Regulatory impact assessment and waiver of the interdepartmental consultation procedure

No Regulatory Impact Assessment (RIA) was prepared for the draft Act on the basis of an exemption, as the draft Act is being submitted in accordance with the Government's Legislative Plan for 2025.

During the previous parliamentary term, the draft Act was submitted for interdepartmental consultation; it was subsequently presented without objection to the Government for consideration, which approved it on 5 March 2025, and was then submitted to the Chamber of Deputies of the Parliament of the Czech Republic for debate, where it was registered as Parliamentary Document No 927. However, as the parliamentary term was coming to an end, the draft Act was not passed.

In view of the above, the Chair of the Government Legislative Council stated in a letter dated 16 October 2025, Ref. No 44265-2025-UVCR, File No SPIS-2025-8231, that no consultation process on the draft Act would be conducted during this parliamentary term and that the draft Act would be submitted directly to the Government for consideration.

16. Justification of the need to adopt the draft in accordance with § 90(2) of the Code of Rules of Procedure of the Chamber of Deputies

It is proposed that the draft Act be debated during the first reading, as this is an implementing draft that has already been discussed by the Government and submitted to the Chamber of Deputies (as Parliamentary Document No. 927), but has not yet been debated. Given that the implementation period for compliance with Regulation (EU) 2024/1860 of the European Parliament and of the Council (EU) 2024/1860 expired on 10 January 2025, it is therefore proposed that the draft be debated as soon as possible so that the Czech Republic can fulfil its obligations arising from its membership of the European Union.

EXPLANATORY MEMORANDUM

Special part

Regarding § 4(j) and § 5(2)(x) to (z)

The Ministry of Health is now granted the power to issue measures of a general nature, enabling it, in justified cases relating to devices whose reduced availability or unavailability may jeopardise the provision of healthcare services, to amend the conditions for the marketing, distribution, commissioning, prescribing, dispensing, or use of such devices in the provision of healthcare services.

The adoption of a measure of a general nature will be preceded by monitoring and subsequent analytical work by the Institute, through which it will assess information regarding the interruption or discontinuation of supply of devices provided by manufacturers pursuant to Article 10a of the Medical Devices Regulation and Article 10a of the IVDR, as well as information obtained from other Member States, and, where necessary to verify or supplement the information identified, or where there is a suspicion that the shortfall in question is likely to jeopardise the availability and effectiveness of patient treatment in the Czech Republic, to obtain further information from the entities concerned on the basis of orders imposed by this Act. The Institute receives and collect information on the interruption or discontinuation of the supply of a device pursuant to Article 10a(1) of the Medical Devices Regulation or Article 10a(1) of the In Vitro Diagnostic Medical Devices Regulation and the data necessary to investigate and evaluate the impending unavailability of the device provided by manufacturers pursuant to § 8a or § 8b, distributors and importers pursuant to § 27a, and providers of health services pursuant to § 39a at the order of the Institute. In addition to the current availability of supplies, economic operators may be asked, for example, about current stock levels, sales of a particular device during a given period, estimated supply trends, and other information of a similar nature. The investigation itself on the part of the Institute will be carried out ex officio and will not be formalised, with the exception of the imposing of orders pursuant to § 8b, 27a, and 39a. The initiation of proceedings will generally follow on from the manufacturers' reports under § 8a; however, the Institute may become aware of the facts relevant to the initiation of proceedings through its official activities from any source. If, on the basis of an analysis of this information, the Institute concludes that a shortage of a particular device is likely to jeopardise the availability of healthcare services, it shall propose that the Ministry of Health issue a general measure and shall provide the Ministry with all the supporting documentation on which it based its conclusion.

By analogy with the ability to propose the adoption of a measure of a general nature, in the case of the Institute, and of to issue a measure of a general nature, in the case of the Ministry of Health, provision is also made for the negative competence of those administrative bodies, i.e. that the Institute may propose the cancellation of a measure of a general nature pursuant to § 53a and that the Ministry of Health is then authorised to cancel the measure of a general nature.

These provisions enshrine those essential powers within the sphere of competence of those two administrative authorities.

Furthermore, pursuant to Article 10a(2) of the Medical Devices Regulation and Article 10a(2) of the IVDR, the Institute is granted the power to notify the competent authorities of other Member States and the Commission of any anticipated interruption or discontinuation of the supply of a device.

Regarding § 8a

Following the addition of the new Article 10a to the Medical Devices Regulation and Article 10a to the IVDR, the form and method of providing this information are stipulated, namely that, at the national level, manufacturers shall notify the Institute of any interruption or discontinuation of supply of devices exclusively in electronic form via the Medical Devices Information System, which was established under the Medical Devices Act.

Although the Act foresees the submission of notifications via the Medical Devices Information System, it is likely that the technical solution of the module for reporting interruption or discontinuation of the supply of devices will not be completed in this system by the effective date of this Act. For this reason, the procedure for notifying the subjects of the legislation of the commissioning of the relevant part of the system is also set out. The Ministry of Health will publish a notice regarding this matter in the Collection of Laws and International Treaties.

As there is an ongoing debate within the Medical Devices Coordination Group regarding the scope of information to be provided by manufacturers concerning the interruption or discontinuation of the supply of devices, a legislative solution has been chosen whereby the scope of the requirements will be set out in implementing legislation, in line with the consensus reached at European level. This will ensure consistency of the national approach with that of other Member States.

Regarding § 8b, 27a, and 39a

§ 8b enshrines the power of the Institute to request from the manufacturer, if the Institute suspects a threat to the availability of a device or in order to clarify whether there is a suspicion of a threat to the availability of a device, all the data necessary to investigate and evaluate the threat of unavailability of a device and the obligation of those entities to provide that information by the deadline and to the extent specified in the notice. This may include any information that the Institute deems necessary for further analysis of the impact of an impending shortage of a device, such as information on the number of units intended for the market in the Czech Republic, the quantity of devices in circulation in the Czech Republic, planned supplies to distributors and/or healthcare providers, restrictions on such supplies, information on anticipated changes in the movement of goods or commodities required for the manufacture of the device, production or storage capacities, etc. Without this power, the Institute would have no means of investigating any suspected threat to the availability of a device, and it would therefore not be possible to take further measures to alleviate shortages; consequently, it would not be possible to fulfil the purpose of Regulation (EU) 2024/1860. In the area of medical devices, the Institute does not receive reports on stock levels and movements, as is the case with medicinal products, and therefore, in addition to the information obtained pursuant to Article 10a of the Medical Devices Regulation and Article 10a of the IVDR, it is necessary to establish the ability of the Institute to supplement this

information by other means, so that the Institute can make a qualified assessment of the significance and implications of an impending shortage of a device.

As is the case for manufacturers, the Institute's right to ask distributors, importers, and health service providers to provide the information necessary for the investigation and evaluation of a potential unavailability of a device is enshrined. Given that these entities will not be reporting data to the Institute via the Medical Devices Information System, the Institute will specify, in a formal notice addressed to the entity and served in accordance with the Code of Administrative Procedure, the manner and time limit for providing the required information.

The Institute may issue the aforementioned requests regardless of whether it has reasonable grounds to suspect that specific devices will be unavailable; indeed, the very response of the entity to which the request is addressed, as provided for in these provisions, may serve as the basis for initiating an investigation. The Institute will also have the power to issue such requests in order to clarify whether the duration of an already adopted measure of a general nature is justified or not, so that it can properly exercise its power under the proposed § 53a(5).

Regarding § 53a

A new obligation is being introduced for the Institute to assess the availability of resources essential for the provision of healthcare services and, should the availability and effectiveness of patient treatment in the Czech Republic be jeopardised, to propose that the Ministry of Health issue a measure of a general nature to regulate the matter.

A new power is also conferred on the Ministry of Health to adopt measures of a general nature to temporarily amend the conditions for the placing on the market, supply to the market, putting into service, prescribing, dispensing, or use of a device in the provision of healthcare services, taking into account the Institute's proposal and the information provided by the Institute. The Ministry of Health will thus be able to respond flexibly to any restrictions or disruptions in the supply of devices, regardless of the reason for the disruption – that is, regardless of whether the disruption is caused by the manufacturer or another entity in the supply chain. The regulation of the conditions for carrying out the aforementioned activities refers to the adoption of various restrictive or prohibitive measures, such as restricting the supply and use of a specific device with limited availability to healthcare services only, or to a specific type of procedure only, or prohibiting its export or distribution outside the Czech Republic. In all cases, this will be a measure of limited duration issued for the necessary period of time, and it will be possible to issue it if necessary, i.e. in the case of a device important for the provision of health services, where its shortage would jeopardise the availability and effectiveness of treatment of patients in the Czech Republic. This provision allows the Ministry of Health to adopt measures of a general nature even in the event of a risk of a shortage of a device caused by factors other than a planned interruption or discontinuation of supply by the manufacturer as defined in Regulation (EU) 2024/1860. At the same time, however, it is certain that the rules for placing and making available on the market or putting into service of a device under the Medical Devices Regulation or the In Vitro Diagnostic Medical Devices Regulation are not affected by these measures.

The terminology used in Regulation (EU) No 1860/2024 – specifically, the wording that it is ' *foreseeable that such interruption or discontinuation can result in serious harm or a risk of serious harm to patients or public health',* – is not used in the Czech legal system in the field

of healthcare. The terminology used in this amendment is therefore analogous to that used in the field of medicinal products, which are also a special category of goods closely linked to the protection of public health and the provision of healthcare services. The terminology used is therefore based on terms commonly employed in the healthcare sector and is thus adapted to the legal culture of the Czech Republic, albeit with some substantive overlap.

A measure of a general nature takes effect on the date specified therein and is notified in a manner allowing remote access. This deviation from the general legal provisions set out in § 172(1) in conjunction with § 173(1) of the Code of Administrative Procedure is primarily due to the nature of the interests to be protected, for the protection of which the measure of a general nature under the proposed § 53a is intended, namely the protection of the life and health of patients, which could be affected by a shortage or unavailability of specific medical devices. As mentioned above, it will be desirable to issue a measure of a general nature, for example, in a situation where one of the public interests described is at risk due to a shortage of a particular resource, and it will be necessary, for example, to restrict the range of entities to which the device may be supplied, (e.g. restricting the supply of the device to hospitals only – for the purpose of treating patients in acute conditions), or to narrow the range of patients or diagnoses for whose treatment the device may be prescribed, etc. In such situations, it is therefore necessary for the regulation of the use of such devices to take effect quickly, as in such circumstances delays in the issuance or approval of a measure of a general nature may in reality result in harm to the health of specific individuals, which might have been avoided had the measure of a general nature been issued in a timely manner.

The Institute will also regularly monitor the need for the continuation of adopted measures, at least once every three months. If there are grounds for concluding that the continued application of measures of a general nature is no longer necessary, it shall propose their cancellation to the Ministry of Health, which may cancel such measures on the basis of the facts thus established, or even without such a proposal. The Institute shall proceed similarly in the event of a change in the grounds for issuing a measure of a general nature. If, on the basis of its investigation and the available data, the Institute concludes that the grounds for the adoption of a measure of a general nature and the continued justification for its duration have changed, it shall again provide the Ministry of Health with all the information on which it based its conclusion. The Ministry of Health may then, on the basis of its own assessment and taking into account data from the Institute, cancel such a measure of a general nature. If it does so, it will take any change in the grounds into account in a newly issued measure of a general nature.

§ 55(2)(r) to (v) and (5)(d) and (e)

Definitions of infractions committed by manufacturers are being added.

An infraction under subparagraph (r) is committed if the manufacturer fails to inform the Institute without undue delay of any anticipated interruption or discontinuation of supply. The maximum fine for this infraction is CZK 15 000 000, given the potential consequences: if information is not provided, the opportunity to take timely measures to alleviate a shortage of a device will be lost, which may result in a significant threat to public health, including a direct threat to human life. The upper limit of the fine is determined in part by the manufacturer's position as the most important link in the distribution chain. If the manufacturer fails to notify the Institute, the Institute cannot in turn notify the other Member States and the European

Commission, which renders the entire system for reporting interruptions or terminations of supply ineffective, as the manufacturer is at the very start of the intended reporting chain. If the manufacturer does not inform their customers of a impending shortfall in the supply of devices, these customers are not only at risk of economic loss, but in particular patients' health may also be endangered.

The infraction under subparagraph (t), on the other hand, consists of a failure to provide information to the extent stipulated.

The definition of the infraction under subparagraph (s) consist of a breach of the manufacturer's obligation to inform its customers, including healthcare providers where they are direct customers, of any interruption or discontinuation of supply.

Subparagraph (u) lays down an infraction for manufacturers who do not comply with the Institute's request to provide the information necessary to assess the Institute's suspicion that the availability of a device is at risk. In the absence of this definition, it is not possible to ensure the enforceability of the manufacturer's obligation to provide the Institute with information to the extent and on the date specified in the letter of formal notice, nor, therefore, to ensure the public interest in the availability of the means necessary to protect public health.

The infraction under point (v) allows the enforceability of the new power of the Ministry of Health to adopt measures of a general nature laying down temporary conditions for restricted handling of a device.

The infraction under § 55(2)(r) therefore involves an infringement of legitimate interests that warrant a higher level of legal protection; consequently, the maximum fine for such infractions has been set at CZK 15 000 000. Other infractions involve infringements of a lesser degree of social harm, for which a lower maximum fine of CZK 5 000 000 is sufficient.

The amount of the fine is always specified with a view to the maximum foreseeable social hazard of the conduct exhibited by the stipulated constituent acts, including the possible consequences of such conduct. The amount of the fine is stipulated as a range and is capped by the maximum amount stipulated by the Act. The amount of the fine will be decided during the proceedings on the infraction, which are governed by separate legislation. The procedural rules for dealing with infractions and imposing penalties are governed by Act No 250/2016 on liability for and proceedings on infractions, as amended (hereinafter 'Act No 250/2016'). This Act regulates the conditions of liability for an infraction, the procedure prior to commencement of infraction proceedings and the procedure for infraction proceedings, plus the types of administrative penalties and protective measures and the principles for their imposition. At the same time, it is necessary to respect the relevant case-law, e.g. the judgment of the Constitutional Court, case No PI. ÚS 3/02, which prohibits destructive fines.

Act No 250/2016 stipulates, in a relatively detailed manner, for example, that in determining the type of administrative penalty and its amount, the following shall especially be taken into account:

- the nature and severity of the infraction;
- that an infraction among multiple infractions committed in one action or multiple actions were not decided on in joint proceedings;
- aggravating and mitigating circumstances;

- in the case of an attempted infraction, the extent to which the offender's conduct approached completion of the infraction, as well as to the circumstances and reasons for which it had not been completed;
- in the case of accomplices, the degree to which the actions of each of them contributed to the infraction;
- in the case of natural persons, their personal situation and whether and by what means proceedings before an administrative authority other than the proceedings on the infraction penalised the same illegal action;
- in the case of a corporate entity or sole trader, the nature of their activity;
- in the case of a legal successor, the extent to which they obtained benefits, profits or other advantages from the infraction, and in the case of multiple legal successors, whether any of them are continuing in the activity during which the infraction was committed;
- in the case of a continuous, persistent and collective infraction, whether the part of the conduct by which the infraction was committed took place under the efficacy of an act that stipulated a milder administrative penalty for the infraction.

In view of the above, and having assessed all aspects and the social harm caused by the misconduct, it was decided to stipulate an upper limit of CZK 15 000 000 for an infraction under § 55(2)(r). Other infractions involve infringements of a lesser degree of social harm, for which a lower maximum fine of CZK 5 000 000 is sufficient.

Regarding § 57(1)(u) to (w) and (2)(d), § 58(1)(o) to (q) and (2)(c)

Among the infractions that may be committed by an importer pursuant to § 57 or a distributor pursuant to § 58, the definitions of infractions pursuant to § 57(1)(u) and § 58(1)(o) are being added, consisting of a breach of the obligation under Article 10a(3) of the Medical Devices Regulation or Article 10a(3) of the IVDR, that is to say, the act of an importer or distributor failing to provide information without undue delay to other economic operators or health service providers to which it directly supplies the device information relating to the anticipated interruption or discontinuation of supply of devices of which the importer or distributor has become aware from the manufacturer or another economic operator in the supply chain.

However, unlike a manufacturer's infraction under § 55(2)(r), which to a certain extent could be regarded as comparable and for which, according to the proposal, a fine of up to CZK 15 000 000 may be imposed, these infractions concern an importer or distributor, i.e. entities that are minor links in the distribution chain, and therefore an upper limit of CZK 5 000 000 is proposed for the perpetrators of these infractions.

Similarly to the infraction under § 55(2)(u), the infractions under § 57(1)(v) and § 58(1)(p) constitute a failure to cooperate that prevents the Institute from exercising the powers conferred upon it for the protection of public health.

infractions under § 57(1)(w) and § 58(1)(q) are therefore similar to the infraction under § 55(2)(v) and constitute a significant threat to public health.

A maximum fine of CZK 5 000 000 is also proposed for the commission of these infractions. The amount of the fine is stipulated in the light of the maximum foreseeable social hazard of the conduct exhibited by the stipulated constituent acts, including the possible consequences of such conduct. The amount of the fine is stipulated as a range and is capped by the maximum amount stipulated by the Act. The amount of the fine will be decided during the

proceedings on the infraction, which are governed by separate legislation. The procedural rules for dealing with infractions and imposing penalties are governed by Act No 250/2016. This Act regulates the conditions of liability for an infraction, the procedure prior to commencement of infraction proceedings and the procedure for infraction proceedings, plus the types of administrative penalties and protective measures and the principles for their imposition. At the same time, it is necessary to respect the relevant case-law, e.g. the judgment of the Constitutional Court, case No PI. ÚS 3/02, which prohibits destructive fines.

Act No 250/2016 stipulates, in a relatively detailed manner, for example, that in determining the type of administrative penalty and its amount, the following shall especially be taken into account:

- the nature and severity of the infraction;
- that an infraction among multiple infractions committed in one action or multiple actions were not decided on in joint proceedings;
- aggravating and mitigating circumstances;
- in the case of an attempted infraction, the extent to which the offender's conduct approached completion of the infraction, as well as to the circumstances and reasons for which it had not been completed;
- in the case of accomplices, the degree to which the actions of each of them contributed to the infraction;
- in the case of natural persons, their personal situation and whether and by what means proceedings before an administrative authority other than the proceedings on the infraction penalised the same illegal action;
- in the case of a corporate entity or sole trader, the nature of their activity;
- in the case of a legal successor, the extent to which they obtained benefits, profits or other advantages from the infraction, and in the case of multiple legal successors, whether any of them are continuing in the activity during which the infraction was committed;
- in the case of a continuous, persistent and collective infraction, whether the part of the conduct by which the infraction was committed took place under the efficacy of an act that stipulated a milder administrative penalty for the infraction.

In view of the above, and having assessed all aspects and the social harm caused by the misconduct, it was decided to stipulate an upper limit of CZK 5 000 000.

Regarding § 59(1)(i) and (j) and (3)(c), § 60(1)(k) and (2)(c), and § 61(4)

Because the conditions for the use of the product laid down in a general measure issued by the Ministry of Health pursuant to § 53a may also be breached by healthcare providers acting as dispensers, prescribers, or persons using the product in the provision of healthcare services, it is necessary to establish appropriate infractions for such cases. However, based on a comparison with a similar infraction by a manufacturer, importer, or distributor, this infraction may be classified as socially less harmful. For this reason, the upper limit of the fine is lower, namely up to CZK 2 000 000. The upper limit of the fine for a similar infraction committed by a prescriber is then set at CZK 200 000, given that the offender is a natural person, in which case this lower penalty will suffice to prevent such a breach of duty.

An infraction is also added under § 59(1)(i), one committed by a healthcare provider who, upon request by the Institute, fails to provide the information pursuant to § 39a. This is therefore a similar failure to provide the cooperation needed to investigate and evaluate the impending unavailability of the device as in the case of a manufacturer, importer, and distributor. However, here too, the upper limit is set at a lower level than for infractions that may be committed by the latter entities, namely CZK 2 000 000.

The amount of the fine is stipulated in the light of the maximum foreseeable social hazard of the conduct exhibited by the stipulated constituent acts, including the possible consequences of such conduct. The amount of the fine is stipulated as a range and is capped by the maximum amount stipulated by the Act. The amount of the fine will be decided during the proceedings on the infraction, which are governed by separate legislation. The procedural rules for dealing with infractions and imposing penalties are governed by Act No 250/2016. This Act regulates the conditions of liability for an infraction, the procedure prior to commencement of infraction proceedings and the procedure for infraction proceedings, plus the types of administrative penalties and protective measures and the principles for their imposition. At the same time, it is necessary to respect the relevant case-law, e.g. the judgment of the Constitutional Court, case No PI. ÚS 3/02, which prohibits destructive fines.

Act No 250/2016 stipulates, in a relatively detailed manner, for example, that in determining the type of administrative penalty and its amount, the following shall especially be taken into account:

- the nature and severity of the infraction;
- that an infraction among multiple infractions committed in one action or multiple actions were not decided on in joint proceedings;
- aggravating and mitigating circumstances;
- in the case of an attempted infraction, the extent to which the offender's conduct approached completion of the infraction, as well as to the circumstances and reasons for which it had not been completed;
- in the case of accomplices, the degree to which the actions of each of them contributed to the infraction;
- in the case of natural persons, their personal situation and whether and by what means proceedings before an administrative authority other than the proceedings on the infraction penalised the same illegal action;
- in the case of a corporate entity or sole trader, the nature of their activity;
- in the case of a legal successor, the extent to which they obtained benefits, profits or other advantages from the infraction, and in the case of multiple legal successors, whether any of them are continuing in the activity during which the infraction was committed;
- in the case of a continuous, persistent and collective infraction, whether the part of the conduct by which the infraction was committed took place under the efficacy of an act that stipulated a milder administrative penalty for the infraction.

In view of the above, and having assessed all aspects and the social harm caused by the misconduct, it was decided to stipulate an upper limit of CZK 2 000 000.

Regarding § 68

In relation to the last sentence of § 8a(1), empowerment provisions are amended to include empowerment for the Ministry of Health to issue a decree setting out the scope of the information provided by the manufacturer in the notification of the anticipated interruption or discontinuation of supply of the device pursuant to Article 10a(1) of the Medical Devices Regulation or Article 10a(1) of the IVDR.

Regarding technical notification

This Act shall be notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, as amended.

Regarding the effective date

It is proposed that the draft Act take effect on the day following the date of its promulgation, as this is implementing legislation for Regulation (EU) 2024/1860, which has already been applicable since 10 January 2025. Given the need to comply with the obligations under EU law that arise for the Czech Republic as a Member State from its EU membership, it is therefore essential to ensure that the transposing legislation takes effect as soon as possible, thereby enabling the Czech Republic to fulfil its obligations. In view of the novelty of reporting by manufacturers and their authorised representatives, it is proposed to defer the effective date for reporting through the Medical Devices Information System by three calendar months. The deferred effect of Article I(6) is then linked to the publication of a communication on the commissioning of the Medical Devices Information System (or the relevant part thereof in respect of such notifications) pursuant to § 8a(3) in the Collection of Legislative Acts and International Agreements. A deferred effective date for reporting via the Medical Devices Information System is proposed in the interests of the entities concerned, so that they have sufficient time to familiarise themselves with the system, specifically the new module of the Medical Devices Information System.