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Gloss to the Judgment of the Court of Justice of the European Union (Third Chamber) of 25 November 2021 in Case C-488/20, Delfarma sp. z o.o. v. Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

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Abstract: Medicinal products are a special type of goods due to their importance for human health and life, and their trade is generally under the scope of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. The preamble to this act states that the essential aim of the rules governing the production, distribution and use of medicinal products must be to safeguard public health. Hence, in the above-mentioned directive, the rules related to the authorisation of medicinal products for marketing and *pharmacovigilance* are very important. At the same time, it should be noted that parallel import of medicinal products as a form of trade in an EU Member State in connection with their authorisation for marketing in another Member State, although it has a long tradition, has not had a clear normative pattern, and has not been subject to the scope of Directive 2001/83/EC. It is based on the achievements of the *acquis communautaire* developed in this area and the principle of free movement of goods (Article 34 TFEU) and its exceptions set out in Article 36 TFEU concerning the protection of human health and life. The commented judgment sets an example of one more verdict confirming the interpretation of Articles 34 and 36 TFEU, according to which national provisions

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of a Member State should be considered unacceptable, according to which the withdrawal of the marketing authorisation for the reference medicinal product in the country of import has the automatic effect of expiring the parallel import authorisation. At the same time, new circumstances affecting the safety of the medicinal product on the market were analysed to give the conclusion as declared in the sentence.

1. Theses

Articles 34 and 36 TFEU must be interpreted as precluding national legislation under which a parallel import licence for a medicinal product expires automatically after one year from the expiry of the marketing authorisation of reference, without examining whether there is any risk to the health and life of humans.

The fact that parallel importers are exempt from the obligation to submit periodic safety reports is not a ground which may per se justify the adoption of such a decision.

2. Selected Legal and Factual Ground

The commented judgment of the Court of Justice of the European Union (hereinafter CJEU or Court) was given following the request for a preliminary ruling under Article 267 TFEU. The request was filed by the referring court, namely Wojewódzki Sąd Administracyjny w Warszawie (Regional Administrative Court in Warsaw, Poland; hereinafter Administrative Court) in connection with case number Vl SA/Wa 235120 pending before that court between the applicant: Delfarma Sp. z o. o. (hereinafter "Delfarma") and the national authority – the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (hereinafter "President of the Office"). The court proceedings concerned a decision declaring that a parallel import licence for a medicinal product has expired automatically due to the expiry of the marketing authorisation (hereinafter MA) for the reference medicinal product on the ground of Article 21a (3a) of the Pharmaceutical Law.[1]

[1] Pharmaceutical Law of 6 September 2001 (Journal of Laws of 2020, item 944); hereinafter the Pharmaceutical Law.

The decision to request a preliminary ruling was taken in the factual circumstances described as follows. Delfarma Sp. z o.o. was an undertaking engaged in parallel imports of medicinal products into the Polish market. A Chech licence for the parallel import of the medicinal product Ribomunyl, granules for oral solution, 0.750 mg + 1.125 mg, was granted to Delfarma by decision of the Polish Minister for Health of January 27, 2011 and subsequently extended by decision of the President of the Office of January 15, 2016. That licence had been granted under a marketing authorisation for Ribomunyl, the reference medicinal product, in the territory of the Republic of Poland. Since that MA expired on September 25, 2018, the President of the Office, by decision of September 24, 2019, declared, pursuant to Article 21a(3a) of the Pharmaceutical Law, that the parallel import licence for the medicinal product Ribomunyl expired with effect from September 25, 2019.

This decision was confirmed in response to Delfarma's request for re-examination by the decision of the President of the Office of November 18, 2019. Delfarma decided to bring an action against that decision before the Administrative Court, claiming, in essence, that that decision infringed Articles 34 and 36 TFEU.[2]

Legal grounds determining the request for the preliminary ruling concerned the disposition of Article 21a (3a) of the Pharmaceutical Law, according to which the licence for parallel import expires one year from the expiry of the MA in the territory of the Republic of Poland. It should be stressed that the main grounds for the MA expiration are determined by two factors: the marketing authorisation holder does not place the medicinal product on the market within three years from the date on which the authorisation was obtained, or the medicinal product is not marketed for three consecutive years.[3]

In the opinion of the Administrative Court, the interpretation of those provisions by the CJEU was necessary to determine whether the automatic expiry of a parallel import licence after one year from the expiry of the MA of reference on the basis of which that licence was granted is consistent

[2] Consolidated version of the Treaty on the Functioning of the European Union (hereinafter TFUE); Official Journal of the European Union, C 326, 26 October 2012, p. 47–390.

[3] Article 33a of the Pharmaceutical Law.

with EU law. The serious doubts of the referring court resulted, in particular, from two requirements set out by previous judgments. The first relates to the individual examination of the reasons for the end of validity of a parallel import licence, and the second relates to the consideration of the reasons which may justify maintaining the medicinal product on the market despite the end of validity of the MA of reference. Additionally, the referring court noted that since medicinal products are goods of a particular nature, the objective of the protection of the health and life of humans could justify such an automatic character. It refers in that regard to the argument of the President of the Office that maintaining a medicinal product on the market while no operator is required to update the data relating to the risks associated with the use of that product undermines that objective.

The circumstances outlined above gave the Administrative Court rise to the following questions which were asked to CJEU in the motion dated October 20, 2020:

> (1)Does Article 34 TFEU preclude national legislation under which a parallel import licence is to expire after one year from the expiry of the marketing authorisation for the reference medicinal product? (2) In the light of Articles 34 and 36 TFEU, may a national authority adopt a decision of a declaratory nature to the effect that a marketing authorisation for a medicinal product in connection with parallel import is to expire automatically, solely on the ground that the period laid down by law has expired, as from the date on which the marketing authorisation for the reference medicinal product expired, without examining the reasons for the expiry of [the marketing authorisation for] that product or other requirements referred to in Article 36 TFEU relating to the protection of the health and life of humans? (3) Is the fact that parallel importers are exempt from the obligation to submit periodic safety reports, and the authority consequently has no current data on the [risk-benefit balance] of pharmacotherapy, sufficient to adopt a decision of a declaratory nature to the effect that a marketing authorisation for a medicinal product in connection with parallel import is to expire?

The Court decided to examine together three of the asked questions for the reason that, in essence, all of them refer to one major issue: whether Articles 34 and 36 TFEU must be interpreted as precluding legislation of a Member State under which a parallel import licence for medicinal products is to expire automatically after one year from the expiry of the MA of

reference in that Member State, without examining whether there is any risk to the health and life of humans. During the main proceedings, the observations were submitted according to which the expiry of the MA of reference deprives the national authority responsible for *pharmacovigilance* of updated information on the quality, efficacy and safety of the medicinal product, which is the subject of a parallel import and, in particular, prevents that national authority from knowing the adverse reactions or from having access to the risk-benefit balance of that medicinal product. It was underlined that in the absence of an MA of reference, the updating of documents such as the package leaflet for the medicinal product is no longer guaranteed, and stated that the translation of those documents, updated by the MA holder in the exporting Member State by the parallel importer cannot remedy that shortcoming.

Taking into account the observation mentioned above, the legal framework for judicial considerations with respect to medicinal product safety was also set by relevant provisions of the Directive 2001/83/EC[4] related to the pharmacovigilance system. This system is used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities to monitor the safety of authorised medicinal products and detect any change to their risk-benefit balance. This is the main legal tool enabling continuous supervision over the safety of medicinal products used in the population, involving the cooperation of both public authorities and the marketing authorisation holder that have been assigned relevant tasks, among others, the obligation to submit electronically to the database and data-processing network – EudraVigilance[5] information on all serious suspected adverse reactions that occur in the UE and in third countries as well as information on all non-serious suspected adverse reactions that occur

4 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ 2012 L 299, p. 1) – hereinafter Directive 2001/83/EC.

5 Article 24 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1) – hereinafter Regulation 726/2004.

in the UE.[6] The EudraVigilance database is fully accessible, particularly to the competent authorities of the Member States.[7]

It was evident to the Court that observations raised show two objectives determining the legal construction of licence expiry. First, it seeks to reduce the administrative and economic burden of searching for and analysing updated information relating to the medicinal products at issue that is borne by the national authority responsible for pharmacovigilance. Second, it intends to protect the health and life of humans by preventing the importation of a medicinal product, the package leaflet of which is not updated and for which there is no such information.

In its judgment of 25 November 2021, the Court recalled that a situation such as that at issue in the main proceedings falls under TFUE provisions on the free movement of goods, and, in particular, Articles 34 and 36, which, in essence, prohibit the Member States from imposing quantitative restrictions on imports and measures having an equivalent effect which may, however, be justified, inter alalia, on grounds of the protection of health and life of humans.

The Court concluded, in the first place, that a provision which seeks to protect the health and life of humans, according to Article 36 TFEU, has to respect the settled case law, which requires fulfilment of two conditions: that measure must be appropriate for securing the achievement of the objective pursued and does not go beyond what is necessary in order to attain it.[8] However, it also should respect the principle of proportionality, which is the basis of the last sentence of Article 36 TFEU, which requires that the power of the Member States to prohibit imports of products from other Member States be restricted to what is necessary in order to achieve the aims concerning the protection of health legitimately pursued.[9]

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6 Article 104 of Directive 2001/83/EC.

7 Article 24 of Regulation 726/2004.

8 CJEU Judgment of 3 July 2019, Delfarma Sp. z o.o. v. Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Case C-387/18, EU:C:2019:556.

9 CJEU Judgment of 8 October 2020, kohlpharma GmbH v. Bundesrepublik Deutschland, Case C-602/19, EU:C:2020:804.

In the second place, the Court recalled that, according to the case law of the Court, national legislation which provides for the automatic cessation of the validity of a parallel import licence due to the withdrawal of the MA of reference constitutes a restriction on the free movement of goods contrary to that provision.[10] Since Artice 21a(3a) of the Pharmaceutical Law automatically prevents the import of medicinal products in parallel into Poland, it constitutes a restriction on the free movement of goods within the meaning of Article 34 TFEU. As regards the justification for such a restriction, the Court stressed that a parallel import licence for medicinal products might, for reasons of a general nature or, in specific cases, for reasons relating to the protection of public health, be linked to an MA of reference, so that the withdrawal of that MA may justify the withdrawal of the parallel import licence,[11] but in the case in question, the test of proportionality was not fulfilled.

The Court stressed that the MA of reference expires, pursuant to Article 33a of the Pharmaceutical Law, where the responsible operator does not place the medicinal product on the market within three years from the date on which the authorisation was obtained or where the medicinal product was not placed on the market for three consecutive years; the fact that the medicinal product poses no risk to the health and life of humans is irrelevant in that regard. In addition, the parallel import licence expires automatically following the expiry of the MA of reference and Article 21a(3a) of that Pharmaceutical Law does not require the competent Polish authority to carry out an individual and specific examination of the health risks which the medicinal product that is the subject of the parallel import might pose. It follows that the expiry of the MA of reference is not based on examining the specific risks to the health and life of humans arising from maintaining the medicinal product on the market.

In light of the above, the Court ruled that Articles 34 and 36 TFEU must be interpreted as precluding national legislation under which a parallel import licence for a medicinal product expires automatically after

10 CJEU Judgment of 10 September 2002, Ferring Arzneimittel GmbH v. Eurim-Pharm Arzneimittel GmbH, Case C-172/00, EU:C:2002:474.

11 CJEU Judgment of 8 May 2003, Paranova Läkemedel AB and Others v. Läkemedelsverket, Case C-15/01, EU:C:2003:256.

one year from the expiry of the marketing authorisation of reference without examining whether there is any risk to the health and life of humans. The fact that parallel importers are exempt from the obligation to submit periodic safety reports is not a ground which may per se justify the adoption of such a decision.

3. Commentary on CJEU Decision

The trading of medicinal products is subject to special regulation due to the nature of these goods and their importance for human life and health, as defined in Directive 2001/83/EC. The legal provision requires prior authorisation to place a medicinal product on the market under the national or central procedure.[12] However, it is clear from the case law of the Court that Directive 2001/83/EC cannot apply to a medicinal product covered by an MA in one Member State which goes into another Member State as a parallel import already covered by a marketing authorisation in that other Member State, because the imported medicinal product cannot, in such a case, be regarded as being placed on the market for the first time in the Member State of importation. Such a situation, therefore, falls under TFEU provisions on the free movement of goods.[13] Therefore, the parallel import of medicines is a legally unquestionable form of trade in medicinal products authorized in a given EU Member State or a Member State of the European Free Trade Association (EFTA) within the single market. Its importance in terms of increasing access to medicinal products cannot be overestimated. The legal

[12] Article 6 of Directive 2001/83/EC. See: Katarzyna Miaskowska-Daszkiewicz, "Dopuszczanie do obrotu produktów leczniczych," in *Prawo farmaceutyczne. System Prawa medycznego*, vol. 2, ed. Joanna Haberko (Warsaw: C.H. Beck, 2019), 465–560; Rafał Stankiewicz, *Model racjonalizacji dostępu do produktu leczniczego. Zagadnienia publicznoprawne* (Warsaw: C.H. Beck, 2014), 217.

[13] See to that effect CJEU Judgment of 12 November 1996, The Queen v The Medicines Control Agency, ex parte Smith & Nephew Pharmaceuticals Ltd and Primecrown Ltd v. The Medicine Control Agency, Case C201/94, EU:C:1996:432, paragraph 21; and CJEU Judgment of 16 December 1999, The Queen, ex parte Rhône-Poulenc Rorer Ltd and May & Baker Ltd v The Licensing Authority established by the Medicines Act 1968 (represented by the Medicines Control Agency), Case C94/98, EU:C:1999:614, paragraph 27; see also, judgment of 3 July 2019, Delfarma sp. z o.o. and Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, C-OJ EU:C:2019:556.

framework at the level of EU law has been determined for over fifty years, in particular, based on decisions made in specific cases referred to the Court.[14]

As a consequence of the above, the institution of parallel trade has not been regulated in any EU act of a normative nature but is the result of the development of the institution in question, based on the case law of the Court deriving it from the fundamental freedoms of the internal market.[15]

The European Commission commented on this form of trade in medicinal products,[16] stating in its communication from 2003 that:

> Parallel importation of a medicinal product is a lawful form of trade within the Internal Market based on article 28 of the EC Treaty and subject to the derogations regarding the protection of human health and life and the protection of industrial and commercial property, provided by article 30 of the EC Treaty.[17]

A set of rules has been developed for granting parallel import licences to parallel distributors by the competent national authorities under a simplified procedure.[18] The free movement of goods means that an operator

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14 See: Michał Roszak, *Handel równoległy produktami leczniczymi w prawie unijnym. Granice swobody przepływu towarów na rynku farmaceutycznym* (Warsaw: Wolters Kluwer Polska, 2014), 62.

15 For more, see, for example, Claudia Desogus, *Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade* (Cambridge: Intersentia, 2011), 51; James S. Venit and Patrick Rey, "Parallel Trade and Pharmaceuticals: A Policy in Search of Itself," *European Law Review* 29, no. 2 (2004): 153–77; Roszak, *Handel równoległy produktami leczniczymi w prawie unijnym*, 62 et seq.; Maria Królikowska-Olczak, "Import równoległy produktów leczniczych a zasada swobodnego przepływu towarów," *Studia Prawno-Ekonomiczne* 100, (2016): 35–48.

16 In its Communication of 1998, the European Commission re-affirmed that pharmaceuticals are fully governed by the rules that oversee the functioning of the internal market – see Communication from the Commission on the single market in pharmaceuticals, COM(1998) 588, Brussels, November 25, 1988.

17 Subsequently, in 2003, it was stated that parallel trade was a legal form of trade among Members States. The Commission also underlined that these products are not identical but essentially similar to the products that have already received a marketing authorisation in the Member State; See Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, COM(2003) 839, Brussels, December 30, 2003.

18 See ibid., 7.

who has bought a medicinal product lawfully marketed in one Member State under a marketing authorisation issued in that State can import that medicinal product into another Member State where it already has a marketing authorisation without having to obtain such authorisation under Directive 2001/83/EC and without having to provide all the particulars and documentation required by the Directive 2001/83/EC to determine whether the medicinal product is effective and safe. Therefore, a Member State must not obstruct parallel imports of a medicinal product by requiring parallel importers to satisfy the same requirements as those applicable to undertakings applying for the first time for a marketing authorisation for a medicinal product, subject to the condition, however, that the import of that medicinal product does not undermine the protection of public health.[19]

Consequently, the competent authorities of the Member State of importation must ensure, at the time of import and based on the information in their possession, that the medicinal product imported as a parallel product and the medicinal product which is the subject of an MA in the Member State of importation, even if not identical in all respects, has at least been manufactured according to the same formulation, has the same active ingredient and has the same therapeutic effect, and that the imported medicinal product does not pose a problem of quality, efficacy or safety. If all those criteria are satisfied, the medicinal product to be imported must be regarded as having already been placed on the market in that Member State and, consequently, must be entitled to benefit from the marketing authorisation issued for the medicinal product already on the market, unless there are countervailing considerations relating to the effective protection of the life and health of humans. Thus, the authority is required to authorise that medicinal product where it is convinced that that product, in spite of differences relating to the excipients, as the case may be, does not pose a problem of quality, efficacy or safety.[20]

However, particular cases and decisions based on them do not exhaust all doubts. Locating this institution in the internal market rules specified in

19 CJEU Judgment of 3 July 2019, Delfarma Sp. z o.o. v Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Case C387/18, EU:C:2019:556.

20 Ibid.

Article 34 TFEU can be used to justify their restriction based on Article 36 TFEU. It should be emphasised that the current situation does not guarantee legal certainty, both from the perspective of parallel importers and public authorities at the national level. The latter take actions aimed at protecting the values indicated in Article 36 TFEU, where the health and life of people are of primary importance when deciding on the level of protection and how this level will be achieved. It must also comply with the proportionality test, which involves the verification of two elements: whether a measure contrary to Article 34 is capable of achieving the objective pursued by the State and whether that objective could not be achieved by means which would have a lesser impact on trade between Member States.[21]

There is no doubt that in the light of the well-established case law of the CJEU, the provisions of Articles 34 and 36 TFEU exclude the application of national provisions of a Member State, according to which the withdrawal of the reference authorisation in the country of import automatically results in the expiry of the parallel import authorisation.[22] On the other hand, it follows from these judgments that in the event of withdrawal of the reference authorisation in the country of importation, this may impact the validity of the parallel import authorisation if the withdrawal was for reasons related to the protection of public health.[23]

In that regard, it should be stressed that a situation such as that at issue in the main proceedings before CJEU in case C-488/20 verify circumstances as to the possibility of justifying the expiry of the parallel import licence. The case broadly relates to the obligations imposed on the responsible entity (MA holder) in connection with the operation of the pharmacovigilance

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21 Dawid Miąsik and Ryszard Skubisz, "Commentary on Article 36," in *Traktat o funkcjonowaniu Unii Europejskiej. Komentarz. Tom I (art. 1–89)*, eds. Dawid Miąsik, Nina Półtorak, and Andrzej Wróbel, Warsaw 2012, LEX/el.

22 See: Jarosław Dudzik, "Limitations on Parallel Import of Medicinal Products: Comments in the Context of the Judgement of the Court of Justice of the European Union in Case C-602/19 Kohlpharma," *Studia Iuridica Lublinensia* 30, no. 4 (2021).

23 CJEU Judgment of 10 September 2002, Ferring Arzneimittel GmbH v Eurim-Pharm Arzneimittel GmbH, Case C172/00, EU:C:2002:474; CJEU Judgment of 4 May 2003, Paranova Läkemedel AB and Others v Läkemedelsverket, Case C15/01, EU:C:2003:256; CJEU Judgment of 8 October 2020, kohlpharma GmbH v Bundesrepublik Deutschland, Case C-602/19, EU:C:2020:804; Rafał Stankiewicz, "Import równoległy," in *Instytucje rynku farmaceutycznego*, ed. Rafał Stankiewicz (Warsaw: Wolters Kluwer Polska, 2016), 342.

system. According to Article 104 of Directive 2001/83/EC, the MA holder must implement a pharmacovigilance system. In that respect, it is responsible, inter alia, for updating the risk management system and monitoring pharmacovigilance data in order to determine whether there are new risks, whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products. Furthermore, the MA holder must, in accordance with Article 107b of Directive 2001/83/EC, submit to the EMA periodic safety update reports containing, inter alia, a scientific evaluation of the risk-benefit balance of the medicinal product.[24]

This was legitimately raised in the case as those obligations are imposed on the holder of the MA of reference and not on the parallel importer; in the absence of an MA of reference, the national authority responsible for pharmacovigilance in the Member State of importation does not have access to any updated documents or data relating, in particular, to the risk-benefit balance of pharmacotherapy in that Member State. However, it was also rightly stressed that even without an MA of reference, the national authority responsible for pharmacovigilance in the Member State of importation may effectively have access to the information necessary to carry out suitable pharmacovigilance. The Court considered that provisions of Directive 2001/83/EC can ordinarily be guaranteed for medicinal products that are the subject of parallel imports through cooperation with the national authorities of the other Member States by means of access to the documents and data produced by the manufacturer in the Member States in which those medicinal products are still marketed under an MA still in force.[25]

The updated information is accessible to the national authority responsible for pharmacovigilance in the Member State of importation in the context of cooperation between Member States. That authority may also have access to the periodic safety update reports, which are made available to the competent national authorities by means of a repository.[26] Moreover,

[24] Katarzyna Mełgieś, "Nadzór nad bezpieczeństwem produktów leczniczych," in *Prawo farmaceutyczne, System prawa medycznego*, ed. Joanna Haberko (Warsaw: C.H. Beck, 2019), 620.

[25] CJEU Judgment of 8 October 2020, kohlpharma GmbH v Bundesrepublik Deutschland, Case C-602/19, EU:C:2020:804.

[26] Article 107b(2) of Directive 2001/83/EC and the first paragraph of Article 25a of Regulation No 726/2004.

the adverse reactions to medicinal products reported by the MA holders, healthcare professionals or patients are listed in the EudraVigilance database, which is fully accessible to the competent authorities of the Member States.[27]

It should be pointed to the case that the national authority responsible for pharmacovigilance in the Member State of importation is informed where the medicinal product poses serious difficulties in the Member State of exportation or in the Member States, still marketed under a valid MA. An urgent procedure has been established enabling all Member States to be informed where a medicinal product poses such difficulties that measures relating to its MA are under consideration.[28]

All the above-mentioned arguments, in the light of the circumstances of the case, lead to the conclusion that the national authority responsible for pharmacovigilance in the Member State of importation has access to the updated information which is necessary for that authority to carry out its functions. Therefore, the conclusion that the automatic expiry of the parallel import licence for a medicinal product solely on the basis that the MA of reference has expired, without examining the risks arising from that product, goes beyond what is necessary to protect the health and life of humans.

It should be noted that due to a CJEU judgment resolving the issue of parallel import licence expiration, the legislator in Poland decided to change the provision of Article 21a(3a) of the Pharmaceutical Law.[29] In accordance with the current wording of this provision, the withdrawal of marketing authorisations of medicinal products does not constitute grounds for the automatic expiry of the parallel import licence for medicinal products.

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27 Article 107(3) and Article 107a(4) of Directive 2001/83/EC in connection with Article 24 of Regulation No. 726/2004.

28 Articles 107i, 107j and 107k of Directive 2001/83/EC.

29 Law of 17 August 2023 amending the Law on Reimbursement of Medicines, Foodstuffs for Special Dietary Purposes and Medical Devices and some other laws (Journal of Law of 2023, item 1938).

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