Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

25 November 2021 *

(Reference for a preliminary ruling – Articles 34 and 36 TFUE – Free movement of goods – Measure having equivalent effect to a quantitative restriction – Medicinal products for human use – Parallel import of medicinal products – Legislation of a Member State under which a parallel import licence is to expire automatically after one year from the expiry of the marketing authorisation for the reference medicinal product – Protection of the health and life of humans – Proportionality – Directive 2001/83/EC – Pharmacovigilance)

In Case C-488/20,

REQUEST for a preliminary ruling under Article 267 TFEU from the Wojewódzki Sąd Administracyjny w Warszawie (Regional Administrative Court, Warsaw, Poland), made by decision of 9 September 2020, received at the Court on 2 October 2020, in the proceedings

Delfarma sp. z o.o.

v

Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych,

THE COURT (Third Chamber),

composed of A. Prechal, President of the Second Chamber, acting as President of the Third Chamber, J. Passer, F. Biltgen, L.S. Rossi and N. Wahl (Rapporteur), Judges,

Advocate General: E. Tanchev,

Registrar: A. Calot Escobar,

having regard to the written procedure and further to the hearing on 7 July 2021,

after considering the observations submitted on behalf of:

– Delfarma sp. z o.o., by J. Dudzik, radca prawny,

– the Polish Government, by B. Majczyna, T. Lisiewski and M. Wiącek, acting as Agents,

– the German Government, by D. Klebs, acting as Agent,

* Language of the case: Polish.

– the European Commission, by K. Herrmann and L. Haasbeek, and by A. Sipos, F. Thiran and Ł. Habiak, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Articles 34 and 36 TFEU.

2 The request has been made in proceedings between Delfarma sp. z o.o. and Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Poland) ('the President of the Office') concerning a decision declaring that a parallel import licence for a medicinal product has expired.

Legal context

EU law

Directive 2001/83/EC

3 Under Article 1(28d) 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 (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) ('Directive 2001/83'), 'pharmacovigilance system' is defined as 'a system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities listed in Title IX and designed to monitor the safety of authorised medicinal products and detect any change to their risk-benefit balance'.

4 Title IX of Directive 2001/83, entitled 'Pharmacovigilance', comprises Articles 101 to 108 thereof.

5 Article 101 of that directive is worded as follows:

'1. Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in Union pharmacovigilance activities.

The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards patients' or public health. That information shall in particular refer to adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, and to adverse reactions associated with occupational exposure.

2. Member States shall, by means of the pharmacovigilance system referred to in paragraph 1, evaluate all information scientifically, consider options for risk minimisation and prevention and take regulatory action concerning the marketing authorisation as necessary. …'

6 Article 104 of that directive states:

‘1. The marketing authorisation holder shall operate a pharmacovigilance system for the fulfilment of his pharmacovigilance tasks equivalent to the relevant Member State’s pharmacovigilance system provided for under Article 101(1).

2. The marketing authorisation holder shall by means of the pharmacovigilance system referred to in paragraph 1 evaluate all information scientifically, consider options for risk minimisation and prevention and take appropriate measures as necessary.

…

3. As part of the pharmacovigilance system, the marketing authorisation holder shall:

(a) have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance;

(b) maintain and make available on request a pharmacovigilance system master file;

(c) operate a risk management system for each medicinal product;

(d) monitor the outcome of risk minimisation measures which are contained in the risk management plan or which are laid down as conditions of the marketing authorisation pursuant to Articles 21a, 22 or 22a;

(e) update the risk management system and monitor pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products.

…’

7 The first and second subparagraphs of Article 107(3) of Directive 2001/83 state:

‘Marketing authorisation holders shall submit electronically to the database and data-processing network referred to in 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 referred to as the “Eudravigilance database”) information on all serious suspected adverse reactions that occur in the Union and in third countries within 15 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.

Marketing authorisation holders shall submit electronically to the Eudravigilance database information on all non-serious suspected adverse reactions that occur in the Union, within 90 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.’

8 Article 107a(1) and (4) of that directive states:

‘1. Each Member State shall record all suspected adverse reactions that occur in its territory which are brought to its attention from healthcare professionals and patients. Member States

shall involve patients and healthcare professionals, as appropriate, in the follow-up of any reports they receive in order to comply with Article 102(c) and (e).

Member States shall ensure that reports of such reactions may be submitted by means of the national medicines web-portals or by other means.

…

4. Member States shall, within 15 days following the receipt of the reports of serious suspected adverse reactions referred to in paragraph 1, submit the reports electronically to the Eudravigilance database.

They shall, within 90 days from the receipt of reports referred to in paragraph 1, submit reports of non-serious suspected adverse reactions electronically to the Eudravigilance database.

Marketing authorisation holders shall access those reports through the Eudravigilance database.'

9 Article 107b(1) and (2) of that directive reads as follows:

'1. Marketing authorisation holders shall submit to the [European Medicines Agency (EMA)] periodic safety update reports containing:

(a) summaries of data relevant to the benefits and risks of the medicinal product, including results of all studies with a consideration of their potential impact on the marketing authorisation;

(b) a scientific evaluation of the risk-benefit balance of the medicinal product;

(c) all data relating to the volume of sales of the medicinal product and any data in possession of the marketing authorisation holder relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal product.

The evaluation referred to in point (b) shall be based on all available data, including data from clinical trials in unauthorised indications and populations.

The periodic safety update reports shall be submitted electronically.

2. The [EMA] shall make available the reports referred to in paragraph 1 to the national competent authorities, the members of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use and the coordination group by means of the repository referred to in Article 25a of Regulation (EC) No 726/2004.'

10 Article 107h(1) of Directive 2001/83 sets out:

'Regarding medicinal products authorised in accordance with this Directive, national competent authorities in collaboration with the [EMA], shall take the following measures:

…

(c) monitor the data in the Eudravigilance database to determine whether there are new risks or whether risks have changed and whether those risks impact on the risk-benefit balance.'

11 Articles 107i, 107j and 107k of that directive establish an urgent procedure within the European Union. That procedure must be initiated when a Member State or the European Commission plans to adopt measures relating to a marketing authorisation ('MA') on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities. The other Member States, the EMA and, where appropriate, the Commission must be informed of the proposed measures.

Regulation No 726/2004

12 Article 24 of Regulation No 726/2004, as amended by Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 (OJ 2010 L 348, p. 1) ('Regulation No 726/2004') provides:

'1. The [EMA] shall, in collaboration with the Member States and the Commission, set up and maintain a database and data processing network (hereinafter the "Eudravigilance database") to collate pharmacovigilance information regarding medicinal products authorised in the Union and to allow competent authorities to access that information simultaneously and to share it.

The Eudravigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation as well as from uses outside the terms of the marketing authorisation, and on those occurring in the course of post-authorisation studies with the medicinal product or associated with occupational exposure.

2. The [EMA] shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the Eudravigilance database, together with a timeframe for their implementation.

…

The Eudravigilance database shall be fully accessible to the competent authorities of the Member States and to the [EMA] and the Commission. It shall also be accessible to marketing authorisation holders to the extent necessary for them to comply with their pharmacovigilance obligations.

The [EMA] shall ensure that healthcare professionals and the public have appropriate levels of access to the Eudravigilance database, while guaranteeing personal data protection. The [EMA] shall work together with all stakeholders, including research institutions, healthcare professionals, and patient and consumer organisations, in order to define the "appropriate level of access" for healthcare professionals and the public to the Eudravigilance database.

The data held on the Eudravigilance database shall be made publicly accessible in an aggregated format together with an explanation of how to interpret the data.

3. The [EMA] shall, in collaboration either with the marketing authorisation holder or with the Member State that submitted an individual suspected adverse reaction report to the Eudravigilance database, be responsible for operating procedures that ensure the quality and integrity of the information collected in the Eudravigilance database.

4. Individual suspected adverse reaction reports and follow-ups submitted to the Eudravigilance database by marketing authorisation holders shall be transmitted electronically upon receipt to the competent authority of the Member State where the reaction occurred.'

13 The first paragraph of Article 25a of that regulation sets out:

'The [EMA] shall, in collaboration with the national competent authorities and the Commission, set up and maintain a repository for periodic safety update reports (hereinafter the "repository") and the corresponding assessment reports so that they are fully and permanently accessible to the Commission, the national competent authorities, the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use and the coordination group referred to in Article 27 of Directive 2001/83/EC (hereinafter the "coordination group").'

14 Article 28a(3) of that regulation reads as follows:

The [EMA] and national competent authorities and the marketing authorisation holder shall inform each other in the event of new risks or risks that have changed or changes to the risk-benefit balance being detected.'

Implementing Regulation (EU) No 520/2012

15 Article 25 of Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation No 726/2004 and Directive 2001/83 (OJ 2012 L 159, p. 5) provides that, for the classification, retrieval, presentation, risk-benefit evaluation and assessment, electronic exchange and communication of pharmacovigilance and medicinal product information, the Member States, the MA holders and the EMA are to apply internationally agreed terminology.

Polish law

16 Article 2(7b) of the Ustawa – Prawo farmaceutyczne (Pharmaceutical Law) of 6 September 2001 (Dz. U. of 2020, item 944) ('the Law on medicinal products') defines the concept of 'parallel import' as follows:

'Parallel import shall mean each action within the meaning of Article 72(4) involving import from European Union Member States or member states of the European Free Trade Agreement (EFTA) – parties to the Agreement on the European Economic Area – of a medicinal product that meets all of the following conditions:

(a) the imported medicinal product has the same active substance or active substances, at least the same indications up to level 3 of the ATC/ATCvet code (code of the international anatomical therapeutic chemical classification of medicinal products/code of the international anatomical therapeutic chemical classification of veterinary medicinal products), the same strength, the same route of administration and the same form as a medicinal product authorised for marketing in the territory of the Republic of Poland or has a similar form which does not result in any therapeutic differences compared to the medicinal product authorised for marketing in the territory of the Republic of Poland;

(b) the imported medicinal product and the medicinal product authorised for marketing in the territory of the Republic of Poland are both reference medicinal products or are both generic medicinal products in the country from which the product is imported and in the territory of the Republic of Poland, respectively.'

17 Article 21a(3a) of the Law on medicinal products sets out:

'The parallel import licence shall expire after one year from the expiry of the marketing authorisation in the territory of the Republic of Poland, and in the event of expiry of the marketing authorisation of a medicinal product in the European Union Member State or the member state of the European Free Trade Agreement (EFTA) – party to the Agreement on the European Economic Area from which the medicinal product has been the subject of a parallel import, it shall expire on the date of expiry of that authorisation.'

18 Article 33a of that law provides:

'1. The [marketing] authorisation shall expire when:

(1) the responsible operator does not place the medicinal product on the market within a period of three years from the date on which the authorisation was obtained;

(2) the medicinal product was not placed on the market for three consecutive years.

2. On grounds of the protection of public health and, in the case of a veterinary medicinal product, on grounds of the protection of human or animal health or the protection of the environment and in exceptional circumstances, in particular where a court issues an interim order prohibiting the placing of a medicinal product on the market, the President of the Office may, at the request of the responsible operator, decide to maintain the validity of the authorisation referred to in subparagraph 1.'

The dispute in the main proceedings and the questions referred for a preliminary ruling

19 Delfarma is an undertaking engaged in parallel imports of medicinal products into the Polish market.

20 A licence for the parallel import, from the Czech Republic, 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 27 January 2011, and subsequently extended by decision of the President of the Office of 15 January 2016. That licence had been granted on the basis of an MA for Ribomunyl, the reference medicinal product, in the territory of the Republic of Poland.

21 Since that MA expired on 25 September 2018, the President of the Office, by decision of 24 September 2019, declared, on the basis of Article 21a(3a) of the Law on medicinal products, that the parallel import licence for the medicinal product Ribomunyl expired with effect from 25 September 2019.

22 That decision was confirmed, in response to a request for re-examination made by Delfarma, by a decision of the President of the Office of 18 November 2019.

23 Delfarma brought an action against that decision before the referring court, claiming, in essence, that that decision infringed Articles 34 and 36 TFEU.

24 The referring court states that the interpretation of those provisions by the Court is necessary in order 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 with EU law.

25 That court states that it has serious doubts in that regard. The automatic nature of the expiry of a parallel import licence due to the expiry of the MA of reference, provided for in that law, may be regarded as inconsistent with two requirements set out by the judgments of 10 September 2002, *Ferring* (C-172/00, EU:C:2002:474), of 8 May 2003, *Paranova Läkemedel and Others* (C-15/01, EU:C:2003:256), and of 8 May 2003, *Paranova* (C-113/01, EU:C:2003:258), the first relating to the individual examination of the reasons for the end of validity of a parallel import licence, and the second relating 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.

26 Nonetheless, the referring court notes 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.

27 In those circumstances the Wojewódzki Sąd Administracyjny w Warszawie (Regional Administrative Court, Warsaw, Poland) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

‘(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?’

Consideration of the questions referred

28 By its three questions, which it is appropriate to examine together, the referring court asks, in essence, 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 carrying out an examination whether there is any risk to the health and life of humans. The referring court is also unsure whether the fact that parallel importers are exempt from the obligation to submit periodic safety reports is a ground which justifies per se the adoption of such a decision.

29 In that regard, it should be recalled that a situation such as that at issue in the main proceedings, where a medicinal product covered by an MA in one Member State is imported into another Member State in which an essentially similar medicinal product is already the subject of an MA, constitutes a parallel import of a medicinal product.

30 Since, in such a situation, the imported medicinal product cannot be regarded as being placed on the market for the first time in the Member State of importation, such a situation does not fall within the scope of Directive 2001/83. Such a situation, in contrast, falls under the provisions of the TFEU on the free movement of goods and, in particular, Articles 34 and 36 TFEU which, in essence, prohibit Member States from imposing quantitative restrictions on imports and measures having equivalent effect which may, however, be justified, inter alia, on grounds of the protection of health and life of humans (see, to that effect, judgment of 8 October 2020, *kohlpharma*, C-602/19, EU:C:2020:804, paragraph 25 and the case-law cited).

31 In order to determine whether Article 34 TFEU must be interpreted as precluding national legislation such as that at issue in the main proceedings, it should also be 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 (see, to that effect, judgment of 10 September 2002, *Ferring*, C-172/00, EU:C:2002:474, paragraph 33).

32 It follows from Article 21a(3a) of the Law on medicinal products that, in Poland, the parallel import licence for a medicinal product expires automatically after one year from the expiry of the MA of reference in that Member State.

33 Since that provision has the effect of automatically preventing the import of medicinal products imported in parallel into Poland, it constitutes a restriction on the free movement of goods within the meaning of Article 34 TFEU.

34 As regards the justification for such a restriction, it follows from the case-law of the Court that a parallel import licence for medicinal products may, 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 (see, to that effect, judgment of 8 May 2003, *Paranova Läkemedel and Others*, C-15/01, EU:C:2003:256, paragraphs 30 and 31).

35 In that regard, the Polish and German Governments submitted in their observations that 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 having knowledge of the adverse reactions or from having access to the risk-benefit balance of that medicinal product. The German Government added 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.

36 It is apparent from those observations that, according to those Member States, a provision such as that at issue in the main proceedings pursues two objectives. 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 is intended 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.

37 In that regard, in the first place, in so far as that provision seeks to protect the health and life of humans, it must be borne in mind that, among interests protected by Article 36 TFEU, the protection of health and life of humans is ranked in first position and that it is for the Member States, within the limits imposed by the FEU Treaty, to decide the level of protection they wish to afford. However, according to settled case-law, a measure having equivalent effect to a quantitative restriction on imports can be justified, for example, on grounds of the protection of the health and life of humans, within the meaning of that article, only if that measure is appropriate for securing the achievement of the objective pursued and does not go beyond what is necessary in order to attain it (judgment of 3 July 2019, *Delfarma*, C-387/18, EU:C:2019:556, paragraph 29 and the case-law cited).

38 It is also apparent from settled case-law that the principle of proportionality, which is the basis of the last sentence of Article 36 TFEU, 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 that are legitimately pursued (judgment of 8 October 2020, *kohlpharma*, C-602/19, EU:C:2020:804, paragraph 41 and the case-law cited).

39 In the present case, legislation such as that at issue in the main proceedings is capable of ensuring the protection of health and life of humans. That legislation prevents the parallel import of a medicinal product the safety of which is no longer necessarily established due to the fact that the expiry of the MA of reference deprives the national authority responsible for pharmacovigilance of a source of information on the safety of that medicinal product.

40 As to the proportionality of such legislation, first, it should be recalled that the MA of reference expires, pursuant to Article 33a of the Law on medicinal products, where the responsible operator does not place the medicinal product on the market within a period of 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 that 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 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.

41 It follows that the expiry of the MA of reference is not based on an examination of the specific risks to the health and life of humans arising from maintaining the medicinal product on the market of the Member State of importation or, a fortiori, on the existence of such risks, with the result that there is no specific reason relating to the protection of public health requiring that the parallel import licence for medicinal products automatically expire due to the expiry of the MA of reference.

42 Second, it is true that, in the case of expiry of the MA of reference, the national authority responsible for pharmacovigilance in the Member State of importation is deprived of a significant source of information and data on the safety of the medicinal product at issue. As the Republic of Poland points out, under the system established by Directive 2001/83, the supervision carried out by that authority is, in the case of parallel imports, dependent on the information provided by the holder of the MA of reference on the basis of which the parallel import licence was granted.

43 Thus, under Article 104 of that directive, 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 or 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 that directive, submit to the EMA periodic safety update reports containing, inter alia, a scientific evaluation of the risk-benefit balance of the medicinal product.

44 In so far 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.

45 Such a circumstance does not, however, constitute a reason of a general nature which may justify national legislation such as that at issue in the main proceedings, under which the parallel import licence expires automatically due to the expiry of the MA of reference.

46 Even in the absence of an MA of reference and, consequently, of documents and data provided by the holder of that MA, 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.

47 In that regard, as the Court has previously held, pharmacovigilance satisfying the relevant requirements of Directive 2001/83 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 on the basis of an MA still in force (judgment of 8 October 2020, *kohlpharma*, C-602/19, EU:C:2020:804, paragraph 48 and the case-law cited).

48 Thus, the updated information referred to in paragraph 43 of the present judgment is accessible to the national authority responsible for pharmacovigilance in the Member State of importation in the context of cooperation between Member States. Specifically in respect of Poland, such a possibility is, according to the information supplied by the referring court, provided for by the applicable Polish law.

49 The national authority responsible for pharmacovigilance in the Member State of importation also has access to other information relating to the imported medicinal product.

50 Where the medicinal product at issue is still marketed in a Member State on the basis of an MA still in force, that authority may obtain from other national authorities information on whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of a medicinal product, in so far as Article 28a(3) of Regulation No 726/2004 requires the EMA, the national competent authorities and the MA holder to inform each other when new risks, changes to existing risks or changes to the benefit-risk balance are found.

51 That authority may also have access to the periodic safety update reports. Under Article 107b(2) of Directive 2001/83 and the first paragraph of Article 25a of Regulation No 726/2004, those reports are made available to the national competent authorities by means of a repository.

52 Furthermore, it follows from the combined provisions of Article 107(3) and Article 107a(4) of Directive 2001/83 that the adverse reactions to medicinal products reported by the MA holders, healthcare professionals or patients are listed in the Eudravigilance database which, under Article 24 of Regulation No 726/2004, is fully accessible to the competent authorities of the Member States.

53 In that context, it must be recalled, first, that Article 25 of Implementing Regulation No 520/2012 requires the EMA, the Member States and the MA holders to apply certain internationally recognised terminology for the classification, retrieval, presentation, risk-benefit evaluation and assessment, electronic exchange and communication of pharmacovigilance and medicinal product information.

54 Second, Article 107h(1)(c) of Directive 2001/83 requires Member States to monitor the data in the Eudravigilance database to determine whether there are new risks or whether risks have changed and whether those risks impact on the risk-benefit balance.

55 Next, it should be pointed out 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 in which it is still marketed on the basis of an MA that is still in force. Articles 107i, 107j and 107k of Directive 2001/83 established an urgent procedure enabling all Member States to be informed where a medicinal product poses such difficulties that measures relating to its MA are under consideration.

56 Lastly, contrary to what the German Government suggests, the absence of an MA of reference in the Member State of importation does not mean that the package leaflet of the medicinal product which is the subject of parallel imports cannot be updated. The holder of the MA in the Member State of exportation must ensure that that document is updated, the translation of which is facilitated by the use of the terminology referred to in paragraph 53 of the present judgment.

57 Therefore, provided that the medicinal product at issue is used in the Member State of importation for the same therapeutic indication or indications as in the exporting Member State, 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, notwithstanding the fact that parallel importers are not required to submit periodic safety reports.

58 It follows 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 carrying out an examination of the risks arising from that product, goes beyond what is necessary to protect the health and life of humans.

59 In the second place, in so far as that provision seeks to reduce the administrative and economic burden of searching for and analysing the updated information relating to the medicinal product at issue on the national authority responsible for pharmacovigilance, it is sufficient to recall that Article 36 TFEU cannot be relied on to justify rules or practices which, even though they are beneficial, contain restrictions which are explained primarily by a concern to lighten the administration's burden or reduce public expenditure, unless, in the absence of the said rules or practices, this burden or expenditure clearly exceeds the limits of what can reasonably be required (judgment of 3 July 2019, *Delfarma*, C-387/18, EU:C:2019:556, paragraph 30 and the case-law cited).

60 In the view of the accessibility of the information, highlighted in paragraphs 47 to 55 of the present judgment, that burden and the resulting expenditure do not exceed, even where several medicinal products are the subject of parallel imports, the limits of what can reasonably be required of those authorities, since those authorities are, as is apparent, inter alia, from Article 101 of Directive 2001/83, responsible for pharmacovigilance and monitoring of medicinal products.

61 It follows from all the foregoing considerations that the answer to the questions referred for a preliminary ruling is 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 one year from the expiry of the MA of reference, without carrying out an examination 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.

Costs

62 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Third Chamber) hereby rules:

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 carrying out an examination 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.

[Signatures]