DECISION

19.3.2024

FIMEA/2023/001913

Biogen Netherlands B.V.

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MATTER A request for a prohibition on the release for consumption of medicinal products and/or for the withdrawal of marketing authorisations for medicinal products.

CLAIM

Biogen Netherlands B.V. (hereinafter referred to as "Biogen") has, through its representative, approached the Finnish Medicines Agency (hereinafter also "Fimea") by letters sent on 19.12.2023 and 22.12.2023. In the first letter, Biogen has demanded that Fimea take immediate action against the violation of the marketing protection of the company's medicinal product Tecfidera:

i) ordering generic pharmaceutical companies which continue to market products in Finland to cease immediately those activities,
ii) imposing penalties on companies that fail to comply with these provisions

In its latter letter, Biogen has demanded that Fimea completely revoke national marketing authorisations for Tecfidera's generic medicinal products that are based on applications submitted before 4 February 2022.

DECISION

Fimea will not take the measures required by Biogen Netherlands B.V. to prohibit the release of Tecfidera for consumption of generic medicinal products or to cancel national marketing authorisations for generic medicinal products. Fimea considers that it does not have the authority to implement these claims.

BACKGROUND OF THE MATTER

Procedure in the institutions of the European Union

Biogen is the marketing authorisation holder for the medicinal product Tecfidera containing the active substance dimethyl fumarate. Tecfidera is authorised by the European Commission for use in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 for human use on Union procedures for the authorisation and supervision of medicinal products and establishing a European Medicines Agency (hereinafter referred to as the "EU Medicines Regulation"). In other words, the authorisation has been granted under the so-called centralised marketing authorisation procedure, in which the granted marketing authorisation is directly valid throughout the European Union. The marketing authorisation was granted on 30.1.2014 and the decision was notified to

Biogen on 3.2.2014.

In its marketing authorisation decision, the Commission concluded that Tecfidera and Fumaderm, a medicinal product already authorised in Germany, do not fall within the same general marketing authorisation as described in Article 6(1) 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 (hereinafter referred to as the EU Medicinal Directive). This means that, according to the Commission's decision, Tecfidera has been entitled to the periods of protection referred to in Article 14(11) of the EU Medicines Regulation, which correspond to the periods of protection under Article 10(1) of the EU Medicinal Directive. The Commission has consistently interpreted those periods of protection as starting from the notification of its marketing authorisation decision.

In 2018, a competitor of Biogen brought an action before the General Court of the European Union (Case T-611/18) over the inadmissibility of the EMA's marketing authorisation application, which referred to Tecfidera's marketing authorisation application material. As a result of the action, the General Court ruled in its judgment of 5.5.2021 that the Commission had erred in granting the marketing authorisation for Tecfidera and that that marketing authorisation decision was not applicable in so far as the Commission held that Tecfidera did not fall under the same general marketing authorisation as Fumaderm.

Following the judgment, the European Medicines Agency and the national authorities of the Member States considered that the so-called abbreviated marketing authorisation applications referring to Tecfidera could no longer be dismissed and rejected on the basis of the protection periods provided for in pharmaceutical legislation, although the Commission, the EMA and Biogen appealed against the judgment of the General Court. Numerous generic pharmaceutical manufacturers applied for and received marketing authorisation with reference to Tecfidera both by Commission decision in the centralised procedure and by the national authorities of the Member States in the so-called decentralised marketing authorisation procedure under the EU Medicine Directive.

By its judgment of 16.3.2023 (Joined Cases C-438/21 P to C-440/21 P), the Court of Justice of the European Union (CJEU) set aside the judgment of the General Court and held that the Commission had not erred in granting the marketing authorisation for Tecfidera. The Commission's conclusion from this judgment is that the marketing authorisation decision for Tecfidera should be considered valid in its original form, despite the various scientific studies subsequently carried out regarding the similarity between Fumaderm and Tecfidera. Thus, the Commission has considered that Tecfidera is subject to the periods of protection referred to in the EU Medicines Regulation, a view which has nevertheless been disputed by numerous generic companies competing with Biogen.

However, prior to the judgment of the Court of Justice of the European Union of 16.3.2023, marketing authorisation applications submitted by numerous generic pharmaceutical companies had already had to be processed within the deadlines set by pharmaceutical legislation. Several of Biogen's competitors had also already launched their medicinal products in different Member States, including Finland, which had had an impact on the costs of pharmacotherapy and the market situation.

As a result of the judgment, the Commission decided on 13.12.2023 to revoke marketing authorisations for generic medicinal products granted under the centralised marketing authorisation procedure that had used Tecfidera as a reference product and for which applications had been submitted before the end of Tecfidera's eight-year documentation protection period. In addition, the Commission amended Tecfidera's marketing authorisation by decision of 2.5.2023, by which the Commission granted Tecfidera an additional year for the so-called marketing protection period referred to in Article 14(11) of the EU Medicine Directive, stating that this protection period expires on 2.2.2025. Several generics companies have appealed against this decision to the General Court, which has not yet ruled on the matter.

Processing of the matter by Fimea

Following the judgment of the Court of Justice of the European Union on 16 March 2023, Biogen contacted Fimea through its agent by letter dated 17 March 2023, in which it demanded that Fimea initiate the cancellation or suspension of the validity of the marketing authorisations for Tecfidera's generic products applied for and granted immediately before 4 February 2022, considering them to be in breach of Tecfidera's documentation protection. In addition, Biogen demanded that Fimea take immediate measures to prevent Tecfidera's generic medicinal products from being placed on the market until the end of Tecfidera's marketing protection period. Fimea replied to this letter by stating that the national legislator had expressly excluded the sanction of breaches of marketing protection and, in general, binding interference outside Fimea's competence.

Biogen approached Fimea on 17.5.2023 with a new letter in which it highlighted the Commission's decision of 2.5.2023 concerning the extension of Tecfidera's marketing protection period and demanded that Fimea take the measures available to it under section 76 of the Medicines Act (395/1987) to comply with Tecfidera's marketing protection period. Fimea replied to this letter on 25.5.2023, stating that no action has been seen in the matter because, in Fimea's view, the legislation has not given Fimea the authority to intervene in such a situation in a binding manner, but based on the preparatory work for the Act, the legislator seems to have considered violations of marketing protection to be competition law matters between companies.

After the message sent by Fimea on 25 May 2023, Biogen next contacted Fimea in December 2023 after the Commission had cancelled the marketing authorisations for generic medicinal products granted in the centralised procedure. In that context, Biogen summarised the claims on the first page of that decision. Biogen considers that Fimea has an obligation under EU legislation to intervene in the market presence of generic medicinal products. As an appendix to its first letter dated 19.12.2023, Biogen has attached a justification in English according to which an authorised generic medicinal product must be treated as an unauthorised product during the marketing protection of the reference product.

In the appendix to the letter, views are expressed on the direct applicability and binding nature of Article 14(11) of the EU Medicines Regulation and the Commission's original marketing authorisation decision for Tecfidera and the decision of 2.5.2023 on the extension of Tecfidera's marketing protection period. Biogen states that the provisions of the EU Medicines Regulation and the EU Medicines Directive concerning the term of protection are intended to be equivalent and considers the provision on marketing protection to be

of a public law nature, in such a way that the authority must monitor compliance with it and ensure its enforcement, in relation to which Biogen has referred to the interpretation of the German court. In addition, Biogen has referred to Article 84 of the EU Medicines Regulation and Article 4(3) of the Treaty on European Union, as well as to the case-law relating to the principle of sincere cooperation.

In its second letter dated 22.12.2023, Biogen has demanded that Fimea completely withdraw national marketing authorisations for Tecfidera's generic medicinal products that are based on applications submitted before 4 February 2022. In that regard, Biogen relied, in particular, on the fact that, in its view, those marketing authorisation decisions have become unlawful and that marketing authorisations granted at national level should be treated in the same way as marketing authorisations granted by the Commission under the centralised procedure.

After the Commission revoked the marketing authorisations granted in the centralised procedure, Fimea has decided to reconsider the matter and consulted the holders of national marketing authorisations for generic medicinal products whose marketing authorisation applications were submitted before 4.2.2022 and who used Tecfidera as a reference product. These marketing authorisation holders are Stada Arzneimittel AG, Sandoz A/S, G.L. Pharma GmbH and Avansor Pharma Oy.

During the hearing, authorisation holders have objected to the withdrawal of their marketing authorisations. First, some of them stated that the actual examination of their applications for authorisation began only after the expiry of the eight-year period of documentation protection allegedly vested in Tecfidera, even though the applications themselves were submitted earlier. Furthermore, the companies consider that, in any event, between the judgments of the General Court and the Court of Justice, Tecfidera could not be regarded as benefiting from documentation protection. The companies consider that they acted in good faith when submitting their applications for authorisations and that they must therefore be able to rely on the permanence of the authorisations.

Secondly, the companies have taken the view that Fimea cannot revoke marketing authorisations in a situation such as the present one, which is not alleged to involve a public health risk. In the view of the companies, the judgment of the Court of Justice of the European Union in Case C-557/16 (Astellas) also constitutes an obstacle to the revocation of marketing authorisations on the grounds of documentation protection and that withdrawal of authorisations on this basis would be a disproportionate measure, since in any event Tecfidera's alleged eight-year period of documentation protection has already expired and applications for authorisation of the products concerned should be re-examined with the same content after withdrawal. A German court's ruling on documentation protection was also raised during the hearing.

The holders of authorisations have also argued that the Commission misinterpreted the judgment of the Court of Justice of 16.3.2023, erred in revocating the marketing authorisations of generic pharmaceutical companies granted under the centralised procedure and that the case should take into account a scientific study which, in the view of generic pharmaceutical companies, argues that Tecfidera could not be considered to have had any period of protection despite the judgment of the Court of Justice of 16.3.2023, but Tecfidera should be considered as belonging to the same general marketing authorisation together with a previously authorised product called Fumaderm. In connection with the consultation, it has been suggested that the decision made by the Commission does not require Fimea to act in the same way with regard to national permits. The companies have also indicated that the withdrawal of licences will cause them

economic damage and considered that the revocation of authorisations would be detrimental to the health system as a whole. The generic pharmaceutical company Sandoz A/S, whose product is available on the Finnish market, has also commented in its defence on the implementation of marketing protection, considering that Fimea does not have the right to do so.

Biogen has requested to see the pleadings of the generic pharmaceutical companies and, after reviewing them, reiterated its demand for the revocation of marketing authorisations by letter of 22.2.2024. In this context, Biogen took the view, inter alia, that the specific nature of the situation was recognised at the time the authorisations were processed and that, on the basis of reservations made to generic assessment reports, marketing authorisations should be withdrawn. In addition, Biogen has addressed certain other claims made by generic pharmaceutical companies.

GROUNDS FOR THE DECISION

Legislation

In accordance with Article 14(11) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Regulation (“EU Medicines Regulation”), medicinal products for human use authorised in accordance with the provisions of this Regulation are subject to the provisions of legislation relating to the protection of industrial and commercial property , eight years for data protection and ten years for marketing, which may be extended up to a maximum of 11 years if, during the first eight years of that ten-year period, the marketing authorisation holder obtains authorisation for one or more new therapeutic indications which, on the basis of the scientific evaluation carried out in order to obtain the authorisation, may have been considered to bring significant clinical benefits compared to existing treatments.

According to Article 10 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 (EU Medicinal Products Directive), an authorised generic may not be placed on the market until ten years have elapsed since the initial authorisation of the reference medicinal product has been granted. Furthermore, under Article 10, the 10-year period referred to in the second subparagraph is to be extended to a maximum of 11 years if, during the first eight years of that 10-year period, the marketing authorisation holder obtains authorisation for one or more new therapeutic indications which, following the scientific evaluation carried out in order to obtain the authorisation, have been found to bring significant clinical benefit compared to existing treatments.

According to section 1 of the Act on the Finnish Medicines Agency (593/2009), hereinafter referred to as the "Fimea Act"), the Finnish Medicines Agency is a central agency under the Ministry of Social Affairs and Health that promotes the health and safety of the population by supervising medicines, medical devices and the use of materials of human origin and by developing the pharmaceutical sector.

According to section 20 a of the Medicines Act (773/2009), the sale of a medicinal product to the general public or other release for consumption requires that the Finnish Medicines Agency has granted an authorisation for the product or registered it in accordance with this Act or that it has a marketing authorisation granted by an institution of the European Union.

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According to Section 21a(1)(1) (773/2009) of the Medicines Act (853/2005), by way of derogation from Section 21(1)(4) of the Medicines Act and without prejudice to legislation on the protection of industrial and commercial property, the applicant is not required to provide the results of pre-clinical tests and clinical trials, nor the results of safety and residue tests in respect of a veterinary medicinal product, if the applicant can demonstrate that authorisation is being sought for a generic medicinal product which corresponds to a reference product: holds or has had an authorisation in accordance with section 21 or a marketing authorisation granted by a State of the European Economic Area or the European Community for at least eight years.

According to Section 21 a (3) of the Medicines Act (853/2005), a marketing authorisation for a generic product shall enter into force no earlier than ten years after the original marketing authorisation of the reference product has been granted. If, within eight years following the granting of the marketing authorisation, the marketing authorisation holder of a reference medicinal product obtains authorisation for one or more new therapeutic indications which, following the scientific evaluation carried out in order to obtain the authorisation, have been found to bring significant clinical benefit compared to existing therapies, the marketing authorisation shall enter into force at the earliest 11 years after the original marketing authorisation of the reference product was granted.

According to Section 29.2 (773/2009) of the Medicines Act, the Finnish Medicines Agency may revoke a marketing authorisation and registration if it has been demonstrated through new studies or otherwise that the conditions for granting the authorisation or registration no longer exist. The marketing authorisation and registration may be suspended pending the necessary investigations if there is reason to believe that the conditions for granting or registering the marketing authorisation no longer exist.

According to section 76 (773/2009) of the Medicines Act, the general planning, steering and supervision of pharmaceutical services is the responsibility of the Finnish Medicines Agency under the Ministry of Social Affairs and Health.

According to Section 101(1) (773/2009) of the Medicines Act, the Finnish Medicines Agency has the right to prohibit the import, manufacture, distribution, sale and other release for consumption of a medicinal product if it appears or there is reason to suspect that the conditions for granting or registering a marketing authorisation no longer exist or if the requirements and obligations related to the manufacture or import of a medicinal product have not been met.

According to Section 101(2) (773/2009) of the Medicines Act (1200/2013), the Finnish Medicines Agency has the right to order the distribution, sale and other release for consumption of a medicinal product to be suspended and the medicinal product withdrawn from the market also if there is reason to suspect that the medicine is falsified or has a product defect. (30.12.2013/1200).

Prohibition of release for consumption

Biogen has demanded that Fimea order holders of generic authorisations to stop marketing their products. Section 101 of the Medicines Act applies to the prohibition on the sale and other release for consumption of medicinal products, according to which:

The Finnish Medicines Agency has the right to prohibit the import, manufacture, distribution, sale and other release for consumption of a medicinal product if:

it appears or there is reason to suspect that the conditions for granting or registering a marketing authorisation no longer exist or that the requirements and obligations relating to the manufacture or import of the medicinal product have not been fulfilled.

The Finnish Medicines Agency has the right to order the distribution, sale and other release for consumption of a medicinal product to be discontinued and the medicine removed from the market also if there is reason to suspect that the medicine is falsified or that the medicine contains a product defect (1200/2003)

In light of its wording, the provision in question does not give Fimea the power to intervene in the presence of a medicinal product on the market on the grounds that being on the market would violate the marketing protection period of the reference product. Fimea's competence in such a situation has not been laid down elsewhere in the Medicines Act either, nor does the EU Medicines Directive or EU Medicines Regulation contain a provision assigning the supervision of the marketing protection period to the supervision and enforcement of the national marketing authorisation authority. In general, those statutes do not specifically provide for measures taken by the authorities to prevent or sanction infringements of this protection period. Taking into account, in particular, the principle of statutory binding as set out in section 2.3 of the Constitution of Finland (731/1999), such powers to interfere in the conduct of business in a binding and significant manner cannot be derived from general provisions concerning Fimea's duties, such as section 76 of the Medicines Act.

It is expressly apparent from the provision-specific grounds in section 21 a of the Medicines Act concerning marketing authorisations for generic medicinal products (HE 853/2005 vp. p. 17) that the legislator did not wish to lay down sanctions within the scope of pharmaceutical legislation relating to violations of marketing protection:

"The law does not specifically provide for sanctions for breaching the deadlines for bringing goods into the store. If an authorised medicinal product is placed on the market before the marketing authorisation enters into force, the provisions of Chapter 44, Section 5 of the Criminal Code concerning pharmaceutical offences or Section 98 of the Medicines Act concerning pharmaceutical offences may be applied. In addition, the marketing authorisation holder of the reference product may have the possibility to seek damages from the holder of the marketing authorisation for the generic medicinal product.';

In the absence of specific prohibition measures in the event of such a situation, the national legislature apparently regarded the matter as a dispute between pharmaceutical companies and considered that the holder of the marketing authorisation for the reference medicinal product had access to justice in this way and/or through criminal sanctions. Such a situation also does not fall within Fimea's field of activity as described in section 1 of the Fimea Act, as it is not a matter related to health and safety. Biogen has argued that a medicinal product infringing marketing protection should be treated as an unauthorised product, but there is a significant difference between the two product categories in that the efficacy and safety of the medicinal product in question has been examined and established by the Medicines Authority and the application for authorisation of the product has already been processed.

Although the principle of bona fide under Article 4(3) of the Treaty on the Functioning of the European Union requires Member States and their authorities to safeguard the achievement of the objectives of Union law, Fimea cannot derive

powers that the legislator has not assigned to it on the basis of this principle either. On the other hand, even if it were considered possible to derive jurisdiction directly from EU law to intervene in breaches of marketing protection, we are now faced with a situation in which the Commission's decision of 2.5.2023 the extension of Tecfidera's protection period is manifestly contrary to the wording of Article 14(11) of the EU Medicines Regulation, Article 10 of the EU Medicinal Products Directive and Section 21a(3) of the Medicines Act. No decision has been made within eight years of Tecfidera's marketing authorisation being granted, and thus Fimea would make a decision contrary to the wording of both EU and national law if the market presence of generic medicinal products were to be interfered with on the basis of the Commission decision in question.

It is justifiable to consider that holders of marketing authorisations for generic medicinal products that are on the market before 3.2.2025 and that may intend to enter the market are perceived as taking a conscious risk of the possibility of liability.

Withdrawal of marketing authorisations

According to the 29.2 § of the Medicines Act, the Finnish Medicines Agency may revoke a marketing authorisation and registration if it has been demonstrated through new studies or otherwise that the conditions for granting the authorisation or registration no longer exist. The marketing authorisation and registration may be suspended pending the necessary investigations if there is reason to believe that the conditions for granting or registering the marketing authorisation no longer exist.

According to the grounds for that provision (HE 853/2005 vp. p. 23), this mainly refers to reasons related to safety of medicinal products and, in any event, it is obvious that, in the present situation, no circumstances have come to light that would even lead to a suspicion that the conditions for granting marketing authorisations no longer exist.

Furthermore, a decision by a national marketing authorisation authority to revoke a marketing authorisation on the grounds of documentation protection would be contrary to the judgment of the Court of Justice of the European Union in Case C-557/16 (Astellas Pharma). The revocation of authorisations would also be disproportionate, given that applications for authorisation should nevertheless be re-examined immediately with the same content, since the period of protection of documentation invoked has in any event already expired. The withdrawal of authorisations by the Commission does not oblige or entitle Fimea to do the same with regard to marketing authorisations granted nationally.

APPEAL

Anyone dissatisfied with this decision may appeal to the Helsinki Administrative Court in accordance with the appended notice of appeal.

LEGAL GUIDELINES APPLIED

Article 14(11) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency.

Article 10 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.

Act on the Finnish Medicines Agency (593/2009) 1 §.

Medicines Act 20 a §, 21 a §, 29 §, 76 § ja 101 §.

ATTACHMENTS

Annex 1: Instructions for appeal

FURTHER INFORMATION

If necessary, further information on the decision can be obtained from:

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This document is signed electronically and can be viewed on a separate signature page (attached).

Asiakirjan sähköinen allekirjoitus
Elektronisk underskrift av dokument
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Asia / Ärende / Case:
FIMEA/2023/001913
Marketing authorisations for generic dimethyl fumarate products - ruling of the Court of Justice of the European Union, 16.3.2023

Asiakirja / Dokument / Document:
FIMEA/2023/001913-32
Fimea's decision 19.3.2024

Allekirjoitukset / Underskrifter / Signatures:

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