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CASE NOTES

Decoding the Tecfidera Case: The Court of Justice of the European Union's Verdict on the "Same Global Marketing Authorisation"

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Headline: Determination of the "same global marketing authorisation" (area of discussion)

Reference: *Joined Cases C-438/21 P to C-440/21 P, European Commission and Others v Pharmaceutical Works Polpharma S.A. [2023] ECLI:EU:C:2023:213*

Headnote: Appeal – Public health – Medicinal products for human use – Directive 2001/83/EC – Regulation (EC) No 726/2004 – Application for marketing authorisation for a generic version of the medicinal product Tecfidera – Decision of the European Medicines Agency (EMA) not to validate the application for marketing authorisation – Earlier European Commission decision taking the view that Tecfidera was not covered by the same global marketing authorisation as Fumaderm – Previously authorised combination medicinal product – Subsequent marketing authorisation for a component of the combination medicinal product – Assessment of the existence of a global marketing authorisation (official headnote)

Legislation: 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, OJ L 311, 28.11.2001, pp 67–128

Timeline:

9 August 1994	Federal Institute for Drugs and Medical Devices, Germany (BfArM), grants marketing authorisation for Fumaderm
28 February 2012	Biogen submits application marketing authorisation to European Medicines Agency (EMA) for Tecfidera
30 January 2014	Implementing Decision granting marketing authorisation under Regulation No 726/2004 for Tecfidera ("Implementing Decision") Recital 3 of Implementing Decision states that Tecfidera and Fumaderm do not belong to the same global marketing authorisation under Article 6(1) of Directive 2001/83
27 November 2017	Polpharma submits request to EMA for confirmation that it is eligible to submit an application for marketing authorisation for its generic version of Tecfidera
30 July 2018	EMA issues decision informing Polpharma that its application has been unsuccessful ("decision at issue") This decision refers back to Recital 3 of Implementing Decision
9 October 2018	Polpharma brings a claim before General Court asking for annulment of the decision at issue
5 May 2021	General Court issues judgment upholding Polpharma's plea and annuls the decision at issue whereby EMA rejected Polpharma's application

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I. Introduction

Regulatory approval for innovative medicinal products requires the applicant to submit extensive data from the pre-clinical tests and clinical trials that they conducted.[1] However, these requirements are waived off for generic products. Under Article 10(1) of EC Directive 2001/83 ("the Directive"), producers of generic pharmaceuticals have an exemption from providing the results of pre-clinical tests and clinical trials if they "can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised ... in a Member State or in the [European Union]".[2]

This is beneficial for generic producers as conducting fresh pre-clinical tests and clinical trials can be extremely expensive.[3] Facilitating the entry of generic products into the market results in increased competition in the market and ultimately is considered to lead to more affordable medicinal products for the public. On the other hand, it is also important to incentivise the entry of new and innovative medicinal products into the market by protecting the investments made by producers of innovative medicinal products and allowing them to profit from their investments.

The European legislative framework attempts to balance these interests by specifying a period of time during which generic producers are prevented from relying on the pre-clinical and clinical data of the reference medicinal product. Article 10(1) of the Directive provides for an "8 + 2" formulation[4] for protecting the regulatory data of the reference medicinal product, such that for a period of eight years from the authorisation of the reference medicinal product applicants of generic products cannot rely on that data when requesting market authorisation for their product. Furthermore, the generic version is also prohibited from being placed on the market for a period of ten years from the initial authorisation of the reference medicinal product.[5] This period has since come to be known as the "regulatory data protection period" (RDP).[6]

A related concept relevant for determining the RDP available to a particular medicinal product is that of the "same global marketing authorisation", enshrined in Article 6(1) of Directive 2001/83. The second subparagraph of Article 6(1) provides:

> When a medicinal product has been granted an initial marketing authorisation ... *any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions* shall also be granted an authorisation ... or be included in the initial marketing authorisation. *All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10(1).*[7]

[1] See 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 L 311, 28.11.2001, p 67 (Directive 2001/83), Art 8.3(i), Annex I.

[2] Directive 2001/83, Art 10(1).

[3] See, for example, E t' Hoen, "Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity" in CM Correa and RM Hilty (eds), *Access to Medicines and Vaccines* (Berlin, Springer 2022). Additionally, reference to pre-existing data from the original reference product also prevents unnecessary testing on human and animal subjects; see Directive 2001/83, Recital 10.

[4] See C Schoonderbeek and B Jong, "Regulatory exclusivities for medicinal products for human use in the EU" (2016) 5(1) Pharmaceutical Patent Analyst 5–8, 6.

[5] Directive 2001/83, Art 10(1).

[6] See C-629/15 P and C-630/15 *Novartis Europharm* v *Commission* [2017] EU:C:2017:498, paras 65, 69; C Koenig and L Ghazarian, "The Scope of Global Marketing Authorisations within the EU Legal Framework of Regulatory Data Protection for Reference Medicinal Products" (2013) 10(4) Zeitschrift für Stoffrecht 173–80.

[7] Directive 2001/83, Art 10(1), emphasis added.

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In other words, the notion of the "same global marketing authorisation" means that subsequent developments to a medicinal product ("any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions"), whether they are included within the same authorisation as the initial marketing authorisation or a different authorisation, shall be subject to the same RDP running since the initial marketing authorisation. Thus, the concept of the "same global marketing authorisation" in effect places certain limits on the period of regulatory data protection and prevents this period from being unduly prolonged by subsequent developments to the same medicinal product.[8]

This present case centres around this concept of the "same global marketing authorisation" and contributes to the jurisprudence on determining the applicability of this concept to different medicinal products. Uniquely, this was the first case in which the Court of Justice of the European Union (CJEU) had the opportunity to address whether a combination medicinal product containing two active substances and another medicinal product containing only one of the active substances as the earlier combination can both belong to the same global marketing authorisation.

The subsequent sections of this Case Note examine the background and facts of the case before turning to the CJEU's decision in the case, placing the latter in context against the previous relevant jurisprudence of the CJEU and looking at its implications.

II. Facts

In 1994, the German national regulator (Federal Institute for Drugs and Medical Devices, Germany; BfArM) granted Fumapharm AG two marketing authorisations for two different strengths of their medicinal product Fumaderm, used to treat psoriasis. The drug was approved as a fixed-dose combination containing two active substances: dimethyl fumarate (DMF) and various monoethyl fumarate (MEF) salts. In accordance with Article 10(1) of Directive 2001/83, Fumaderm enjoyed regulatory data protection for ten years, until 2004.

Eventually, another pharmaceutical company, Biogen Idec Ltd ("Biogen"), acquired the marketing authorisations for Fumaderm. Subsequently, Biogen applied to the European Medicines Agency (EMA) for marketing authorisation for Tecfidera, a mono-substance medicinal product containing only one active substance: DMF. In 2014, the EMA adopted an Implementing Decision granting marketing authorisation to Tecfidera under Regulation No 726/2004.[9] The Implementing Decision relied on an assessment by the Committee for Medicinal Products for Human Use (CHMP) that MEF and DMF are not the same active substance since they do not share the same therapeutic moiety, and thus the CHMP stated that Tecfidera (containing only DMF) and Fumaderm (fixed-dose combination of DMF and MEF) do not belong to the same global marketing authorisation under Article 6(1) of Directive 2001/83.

Subsequently, another pharmaceutical company, Polpharma, requested that the EMA confirm whether it was eligible to apply for a marketing authorisation for its generic version of Tecfidera. However, in 2018, the EMA issued a decision informing Polpharma that its request had been unsuccessful ("decision at issue"). In this decision, the EMA referenced the Implementing Decision of 30 January 2014 – in particular, its Recital 3, which stated that Tecfidera and Fumaderm did not belong to the same global marketing authorisation – and consequently Tecfidera benefitted from its own eight-year RDP

[8] Supra, note 6.

[9] Commission Implementing Decision of 30.1.2014 granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Tecfidera – Dimethyl fumarate", a medicinal product for human use [2014] C(2014)601.

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independent of Fumaderm. Since the RDP for Tecfidera had not yet expired, the EMA stated in its 2018 decision that, as per Article 10(1) of Directive 2001/83, any reference to clinical trial and pre-clinical test data as set out in the Tecfidera file could not be authorised for submitting an application for marketing authorisation. Accordingly, Polpharma did not receive confirmation to submit a marketing authorisation application for its generic version of Tecfidera.

It is this 2018 decision by the EMA rejecting Polpharma's request that is the decision at issue in the present case. Polpharma brought an action before the General Court requesting it to annul the decision at issue. The General Court allowed Biogen and the European Commission ("Commission") to intervene in support of the form of order sought by the EMA.

III. Proceedings before the General Court

Before the General Court, Polpharma claimed that the decision at issue, which refused to validate Polpharma's application for marketing authorisation for its generic version of Tecfidera, had its sole legal basis in the Implementing Decision. It then alleged that the Implementing Decision was unlawful insofar that it considered Tecfidera and Fumaderm to be different and not belonging to the same global marketing authorisation. Consequently, according to Polpharma, the decision at issue had no legal basis and therefore must be annulled.[10]

The General Court first ruled favourably on the admissibility of Polpharma's plea regarding the illegality of the Implementing Decision. It then turned to an analysis of the alleged unlawfulness of the same.[11] Next, the General Court held that the Implementing Decision was in fact unlawful insofar as Recital 3 thereof stated that Tecfidera was different from Fumaderm and was not covered by the same global marketing authorisation. Since the Commission did not take into consideration the role of MEF within Fumaderm, the General Court held that the Commission had not analysed all relevant data in arriving at its conclusion.[12] Thus, according to the General Court, the Implementing Decision was vitiated by a manifest error of assessment, and consequently the decision at issue – whose sole legal basis was the Implementing Decision – was unfounded. As a result, the General Court ruled that the decision at issue had to be annulled.

IV. Proceedings before the CJEU: alleged misinterpretation of "global marketing authorisation" under Article 6(1) of Directive 2001/83

The present case came before the CJEU as a result of three appeals brought by the European Commission (C–438/21 P), Biogen (C–439/21 P) and the EMA (C–440/21 P; collectively referred to as "the appellants" here) to set aside the judgment of the General Court. The three appeals were joined into a combined case, with Polpharma as the respondent.

The appellants brought forth an appeal on four similar grounds[13] – most notably, that the General Court misinterpreted the concept of "global marketing authorisation" and accordingly infringed the second subparagraph of Article 6(1) of Directive 2001/83. The CJEU began its analysis from this ground of appeal,[14] and it eventually found that there was

[10] See T-611/18 *Pharmaceutical Works Polpharma S.A. v European Medicines Agency* [2021] ECLI:EU:T:2021:241, paras 78, 150.

[11] ibid, paras 80–149.

[12] ibid, para 289.

[13] ibid, paras 48–53.

[14] Prior to this, the CJEU also briefly addressed a preliminary objection from Biogen that Polpharma's plea of illegality against the Implementing Decision was inadmissible. The CJEU rejected this appeal as ineffective and held that Polpharma's claim was indeed admissible.

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no need to go into the other grounds of appeal. Accordingly, this Case Note also focuses primarily on this ground of appeal.

As mentioned previously, this case primarily hinged on the concept of "global marketing authorisation" under the second subparagraph of Article 6(1) of Directive 2001/83 and the applicable test for determining the same.

1. Appellants' arguments

The appellants claimed that the General Court infringed the second subparagraph of Article 6(1) of Directive 2001/83 by misinterpreting the notion of "global marketing authorisation" provided therein. In particular, they argued that the General Court erred in law in holding that the EMA and the Commission – while examining whether Tecfidera and Fumaderm belong to the same global marketing authorisation – should have carried out a reassessment of the qualitative composition of Fumaderm to confirm whether both active substances – MEF and DFM – each have a therapeutic contribution within that fixed-dose combination.

2. Respondent's arguments

The respondent, Polpharma, disputed the submissions made by the appellants, claiming that MEF does not make a relevant therapeutic contribution in the MEF–DMF combination in Fumaderm. Accordingly, they argued that the fixed–dose MEF–DMF combination (Fumaderm) has the same active profile as the mono-substance DMF (Tecfidera). Thus, according to the respondent, the General Court applied the correct test – verifying whether MEF made a relevant and significant therapeutic contribution – in order to determine whether there is a difference between Fumaderm and Tecfidera for the purposes of global marketing authorisation and RDP.

3. CJEU's findings

The CJEU noted that, as per the second subparagraph of Article 6(1), any authorisation granted to "any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extension ... shall be considered as belonging to the same global marketing authorisation".[15] The CJEU considered that, read in conjunction with Recital 9 of Directive 2001/83,[16] this subparagraph exhaustively defines the subsequent developments that could allow the corresponding future marketing authorisations to be considered to belong to the "same global marketing authorisation".[17] In stating so, the CJEU relied on its past judgment in *Novartis Europharm* v *Commission*.[18]

The CJEU noted that in light of the General Court's ruling and the appellants' submissions, it was necessary to examine whether a difference in the qualitative composition of a product in terms of the active substances present within it could constitute a subsequent development as understood in the second subparagraph of Article 6(1). There was no dispute amongst the parties that such a difference in terms of active substances does not constitute an additional strength, pharmaceutical form, administration route or presentation. The CJEU further noted that the terms "any variations and extension" in the second subparagraph of Article 6(1) refer to variations or extension to

[15] Directive 2001/83, Art 6(1)(a).

[16] Directive 2001/83, Recital 9.

[17] Joined Cases C-438/21 P to C-440/21 P, *European Commission and Others v Pharmaceutical Works Polpharma S.A.* [2023] ECLI:EU:C:2023:213, para 82.

[18] Supra, note 6, para 72.

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the terms of the initial marketing authorisation itself.[19] In this regard, it again relied on the previous judgment in *Novartis Europharm* v *Commission*,[20] as well as the opinion of the Advocate General.[21] The Advocate General in her opinion had stated that the terms "variation and extension" in the second subparagraph of Article 6(1) would not include a difference in the qualitative composition of a product as a result of replacement of an active substance by other substance(s) with a different therapeutic moiety.[22]

The CJEU then took note of the CHMP's assessment that Fumaderm, containing DMF and MEF as a fixed combination, differed from Tecfidera, containing only DMF as a mono-substance, since "DMF and MEF do not have the same therapeutic moiety and therefore do not correspond to the same active substance".[23] The CJEU held that this assessment by the CHMP was sufficient to determine that Fumaderm and Tecfidera do not belong to the "same global marketing authorisation" within the meaning of the second subparagraph of Article 6(1) of Directive 2001/83.

Furthermore, on the objectives of Article 6(1), the CJEU noted that the second subparagraph of Article 6(1) draws an explicit link between the "same global marketing authorisation" under that subparagraph and the determination of RDP as under Article 10(1).[24] In other words, the concept of global marketing authorisation becomes relevant for using the abridged procedure for the expiry of applicable RDP, and all products falling within the same global marketing authorisation will have the same RDP from the initial date of the global marketing authorisation.

According to the CJEU, the second subparagraph of Article 6(1) seeks to draw a balance between protecting the interests of innovative companies and other interests served by the placing of generic pharmaceutical products on the market. However, the CJEU clarified that these objectives can only justify a qualitative comparison to assess whether two different products belong to the same global marketing authorisation, and they do not in fact support a requirement to verify the therapeutic contribution of an active substance present in first product authorised.[25]

Thus, the CJEU concluded that the General Court had erred in holding that the Commission was required to verify whether MEF, as the active substance present in the first medicinal product authorised (Fumaderm) but not in the second (Tecfidera), had a relevant and significant therapeutic contribution.[26]

As a result of this error of law, the CJEU ordered that the judgment by the General Court be set aside. Pursuant to Article 61 of the Statute of the Court of Justice of the European Union,[27] the CJEU then proceeded to give the final judgment in the matter. It ruled on the substantive plea raised by Polpharma, reiterating its previous conclusion that the CHMP's/Commission's assessment was sufficient. Accordingly, the CJEU dismissed the plea raised by Polpharma.

V. Comment

This case arose from the EMA's finding in the decision at issue that the RDP for Tecfidera had not yet expired since Tecfidera did not belong to the same global marketing

[19] ibid, para 85.
[20] ibid, para 66.
[21] Supra, note 17, Opinion of AG Medina.
[22] ibid, paras 55–56.
[23] ibid, para 88.
[24] ibid, para 91.
[25] ibid, para 93.
[26] ibid, para 94.
[27] Consolidated version of the Treaty on the Functioning of the European Union, Protocol No. 3 of the Statute of the Court of Justice of The European Union [2016] OJ C 202, 7.6.2016, pp 210–29, Art 61.

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authorisation as Fumaderm and hence had its separate RDP starting from 2014. Given the explicit link between RDP and the concept of "same global marketing authorisation" (as codified in the second subparagraph of Article 6(1) of Directive 2001/83), the CJEU's judgment focused predominantly on interpreting the concept of "same global marketing authorisation". In particular, it looked at whether a marketing authorisation granted to a component (DMF) of a fixed-dose combination (DMF–MEF) could be considered as belonging to the same global marketing authorisation as the combination.

This judgment by the CJEU is notable for explicitly clarifying the applicable test for determining whether the medicinal products at issue belong to the "same global marketing authorisation". The CJEU overturned the decision of the General Court, instead holding that an assessment by the CHMP comparing the qualitative composition of the medicinal products in terms of their active substances was indeed sufficient to determine that the medicinal products do not belong to the same global marketing authorisation. The CHMP's assessment was based primarily on the fact that MEF and DMF were both active, and, since they did not have the same therapeutic moiety, they did not correspond to the same active substance. The simple fact that Fumaderm and Tecfidera differed in their qualitative compositions was thus sufficient to conclude that they did not belong to the same global marketing authorisation.[28]

Thus, the CJEU in its decision took a comparatively more restrictive approach to defining the terms of "same global marketing authorisation" as compared to the more extensive approach favoured by the General Court. This restrictive approach meant that medicinal products not falling within the scope of the subsequent developments exhaustively enumerated in the second subparagraph of Article 6(1) of the Directive would not belong to the same global marketing authorisation and thus would benefit from separate RDPs. This benefits the producers of innovative medicinal products by allowing for a longer RDP for their medicinal products – as long as these medicinal products have different active substances, thereby making their therapeutic compositions different from each other. The CJEU's judgment thus protects the interests of innovative producers against generic producers in this instance.

1. Previous jurisprudence

This decision is consistent with previous jurisprudence of the CJEU, where it ruled on similar issues. Two previous decisions are relevant here. First, in *Novartis Europharm* v *Commission*,[29] the CJEU previously had the opportunity to elaborate on the concept of "global marketing authorisation" under Article 6(1). In that case, the CJEU noted that all subsequent developments to a medicinal product would belong to the same global marketing authorisation, regardless of whether these subsequent developments were the subject of a new marketing authorisation or only a variation of the initial marketing authorisation.[30] It further noted that the phrase "any variations and extensions" in Article 6(1) refers to variations or extensions to the terms of the marketing authorisation.[31] Both of these findings were quoted with approval by the CJEU in the present case.

In that case, the new medicinal product contained the same active substance as the initial product but also contained new therapeutic conditions. The CJEU held that this constituted an additional strength and variation to the original medicinal product and

[28] Allen & Overy, "Court of Justice finally settles Tecfidera regulatory data exclusivity dispute" (*JDSUPRA*, 20 April 2023) <https://www.jdsupra.com/legalnews/court-of-justice-finally-settles-7125242/> (last accessed 26 May 2023).

[29] Supra, note 6.

[30] ibid, para 72.

[31] ibid, para 66.

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should therefore be considered to belong to the same global marketing authorisation. It is interesting to note that in that case that Advocate General Bobek's opinion had noted that the active substance is the most crucial part of a medicinal product, and that products with different active substances could hardly be considered as still belonging to the same global marketing authorisation.[32] However, the CJEU in that case did not expressly refer to this point in the Advocate General's opinion.

In the present case, the General Court referred both to the Advocate General's opinion in the *Novartis Europharm* case as well as the final judgment of the CJEU there, and it stated that the factual circumstances in the two cases were different.[33] In any case, the General Court's judgment in the present case was premised on a contrary presumption: that products with different active substances could still be considered to be part of the same global marketing authorisation (albeit since, according to the General Court, scientific evidence showed that MEF did not in fact play a role in Fumaderm). The CJEU's judgment in the present case overturned the General Court's reasoning and instead followed the same reasoning as the *Novartis Europharm* case and Advocate General Bobek's opinion there. Thus, a difference in the qualitative composition of medicinal products, in terms of their active substances, would indeed lead to a different global marketing authorisation.

Second, the CJEU also noted with approval its previous decision in *SmithKline Beecham*,[34] where it emphasised the significance of the therapeutic moiety in determining whether the medicinal products at issue were "essentially similar" as described under Article 4.8(a)(iii) of Directive 65/65. In that case, the CJEU held that in the context of abridged procedures for obtaining market authorisation, where a medicinal product is combined with a different salt but contains the same therapeutic moiety as the reference medicinal product, it should be considered "essentially similar" and be allowed to benefit from the abridged procedure for marketing authorisation.[35] The CJEU's emphasis on the therapeutic moiety in the present case in holding that Fumaderm and Tecfidera were not covered by the same global marketing authorisation because MEF and DMF were different in terms of their therapeutic moiety is consistent with the former decision.

2. *Implications*

In setting aside the General Court's judgment on grounds of an error in law, the CJEU restored the original decision at issue whereby the EMA rejected Polpharma's application for confirmation that it could apply for marketing authorisation of its generic version of Tecfidera. As a result, it is now confirmed that Tecfidera benefits from its own RDP (starting in 2014), and generic versions of the same cannot be placed on the market until at least 2024.

As the CJEU highlighted, a period of regulatory data protection allows pharmaceutical companies to recuperate their investments and reap profits from the development of innovative medicines. It is therefore a major incentive for pharmaceutical companies to invest in the development of innovative medicinal products, and this is considered an important tool to facilitate the supply of new medicinal products into the market.[36] In this regard, the CJEU noted that Article 6(1) of Directive 2001/83 is designed to strike a balance between incentivising innovation of new medicinal products and facilitating the entry of

[32] ibid, Opinion of AG Bobek, paras 43, 45.

[33] Supra, note 10, para 292.

[34] C-74/03, *SmithKline Beecham* [2005] EU:C:2005:39.

[35] ibid, para 44.

[36] See G Gobechia, "Does an Initially Authorised Combination Medicinal Product and a Later Authorised Single Component of That Combination Belong to the Same Global Marketing Authorization? – The Tecfidera Judgment of the General Court in Case T-611/18" (2021) 5 European Pharmaceutical Law Review 102, 105.

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generic medicinal products into the market by removing a disproportionate prolongation of RDP.

On a related note, Biogen had previously sought a one-year extension (until 2025) of the marketing protection for Tecfidera by proposing a new therapeutic indication that brought significant clinical benefit as compared to existing therapies. The EMA, via a 2022 Implementing Decision,[37] while agreeing that this new therapeutic indication did indeed bring significant clinical benefit compared to the existing therapies, decided that in light of the General Court's decision, it could not grant Biogen's request.[38] It remains to be seen whether Biogen will submit a fresh request for a one-year extension of marketing protection from 2024 to 2025.

Competing interests. The author declares none.

[37] Commission Implementing Decision of 13.5.2022 amending the marketing authorisation granted by Decision C(2014)601(final) for "Tecfidera-- Dimethyl fumarate", a medicinal product for human use [2022] C(2022) 3251.
[38] ibid, Recital 4.

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