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Estonian State Agency of Medicines (Ravimiamet)
Attn. Mrs. Aet Viispert and Mrs. Heleni Mae
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Dear Madam,

Re: Sandoz / Raviamiamet (DMF)

1. We refer to the letter of Ravimiamet of 28 March 2024. In this letter, Ravimiamet has expressed its intention to declare invalid the marketing authorisations (hereafter "**MA**") for 120 mg and 240 mg generic dimethyl fumarate (hereafter "**DMF**") products, which, according to Sandoz' understanding, would lead to the revocation of the DCP MA already granted on 09 November 2022.

2. Ravimiamet holds on the one hand the believe that the Court of Justice of the EU (hereafter "**CJEU**") judgment of 16 March 2023 (C-438/21 P bis C-440/21 P) had as effect that the regulatory data protection (hereafter "**RDP**") rights of Tecfidera 'resurrected' and on the other hand that for reason that the applications for MAs were submitted on 20 July 2021 that it violated the alleged 'resurrected' RDP rights of Tecfidera.

3. Ravimiamet has given Sandoz until 26 April 2024 to reply to the letter of Ravimiamet.

4. Sandoz respectfully disagrees as the decision is founded on incorrect premises as will be explained in more detail below and would therefore request Ravimiamet to reconsider its position.

I. The judgment of 16 March 2023 did not 'resurrect the RDP rights of Tecfidera

5. On the basis of a proper reading of the General Court judgment of 5 May 2021 (T-611/18) and the CJEU judgment of 16 March 2023, it is clear that the latter did not and could not 'resurrect' the RDP rights of Tecfidera.

6. Indeed recital 72 of the General Court judgment of 5 May 2021 has stated that *"The finding of illegality made by the court **does not have erga omnes effect**, but entails the illegality of the individual contested decision, **whilst leaving the act of general application in the legal order** without affecting the legality of other acts which have been adopted pursuant thereto and which were not challenged within the period for appeal"*. If the General Court judgment of 5 May 2021 had no effect on the RDP rights of Tecfidera this also means that the CJEU judgment of 16 March 2023 could not 'resurrect' anything.

7. Ravimiamet should understand that it was on the basis of the latest scientific evidence, established in the ad hoc Committee for Medicinal Products for Human Use (hereafter "**CHMP**") opinion of 11 November 2021, that Tecfidera was not entitled to RDP rights. The scientific evidence on the basis of which Sandoz has filed its MA applications has not changed since then. The CJEU, who was tasked with examining the facts as they existed in 2018, did not take the latest scientific evidence into account.

8. Furthermore, the CJEU decided on the Commission Implementing Decision granting Biogen an MA for Tecfidera as issued in 2014 (hereafter, "**the 2014 Tecfidera MA**"). However, this 2014 Tecfidera MA was amended on 13 May 2022 (hereafter, "**the 2022 Tecfidera MA**") at the same time as the Commission granted the centralized DMF MAs. At that moment, the Tecfidera MA as granted in 2014 thus did no longer exist in that form. On the basis of not only the latest scientific evidence, established in the CHMP opinion of 11 November 2021, but also additional clinical and non-clinical data provided by Biogen, the Commission amended the 2014 Tecfidera MA to state that Tecfidera is not entitled to RDP rights and included the scientific conclusions as annex IV to the Commission Implementing Decision. It was only on 2 May 2023 that the Commission once again amended the Tecfidera MA by the Commission Implementing Decision granting an additional year of market protection (hereafter, the "**2023 Tecfidera MA**" or "**the +1 Decision**"). However, the CJEU considers the aforementioned decision "at first glance" in violation of Article 14(11) Regulation 726/2004 and the CJEU considers it to only enter into force on 3 February 2024, without effects before that date (*cf. infra*).

9. It was under these circumstances (i.e. at a time that there was no data exclusivity), that Sandoz had filed its decentralized applications for an MA with Germany as the Reference Member State (hereafter "**RMS**") and Estonia among others as Concerned Member State (hereafter "**CMS**").

10. On 28 September 2022, BfArM (Germany) as RMS published its Public Assessment Report relating to Sandoz its decentralized DMF MA and made a conscious choice to list Fumaderm as reference medicinal product:

> *"The reference medicinal product first approved in the EU is Fumaderm 120 mg gastro-resistant tablets (registered in Germany since 19 August 1994), which belongs to the same Global Marketing Authorisation (GMA) as Tecfidera 120 mg and 240 mg gastro-resistant hard capsules by Biogen Idec Ltd., which is the reference used for this application"* (p. 4 of the Public Assessment Report).

11. To come to that conclusion, BfArM relied on the latest scientific evidence, as established in the aforementoned CHMP opinions:

> *"In light of the scientific conclusions outlined in its Opinion of 11 November 2021, the CHMP is of the view that the totality of the available data cannot establish that MEF exerts a clinically relevant therapeutic contribution within Fumaderm. Those scientific conclusions and the Judgment of the General Court of 5 May 2021 in Case T-611/18 support the determination that Tecfidera does not benefit from an independent global marketing authorisation. This also entails that, following the General Court's reasoning, Tecfidera could not benefit, at the time of the submission of this generic application, from any data or marketing protection. This position is without prejudice to the outcome of the above referenced appellate proceedings"* (p. 5 of the Public Assessment Report).

12. It is thus an unchallengeable fact that at the time Sandoz filed its decentralized MA applications Tecfidera did not benefit from any data exclusivity and this has not and could not be changed by the CJEU judgment of 16 March 2023 as described above.

13. A CMS has no authority to now challenge this scientific finding made by the RMS, nor to take any action that would hinder the company in question from commercializing its products[1].

14. RAVIMIAMET, as CMS, already granted a decentralized MA to Sandoz on 09 November 2022. RAVIMIAMET considered that all conditions were met at the time. This was not challenged by Biogen, nor were any of the available legal remedies used. By operation of the law, the administrative act granting the decentralized MA to Sandoz has become final. This thus cannot be called into question anymore, especially not almost two years later.

15. In its judgment of 16 October 2008 the CJEU decided that a CMS can only withdraw a DCP if there is a "*possible serious risk to public health*", which is not present in this case (CJEU 16 October 2008, C-452/06, Synthon).

16. The CJEU in its judgment of 14 March 2018, expressly states that once the DCP MA proceedings have been completed, the holder of the MA for the reference product can no longer have the start of the data exclusivity period reviewed by a court in any Member State, but only in the Member State that decided on the approval - in this case, this is the RMS Germany and not CMS Estonia (CJEU 14 March 2018, Case C-557/16, Helm Astellas). Firstly, the CJEU rejected the national authorities' power to decide on the start date of the data exclusivity period on the grounds that the DCP MA procedure ends when the reference Member State has obtained the agreement of all Member States in which the application for an MA has been submitted. Once this agreement of all Member States has been established, the competent authorities of the Member States no longer have the possibility to question the outcome of this procedure when adopting their decision on the marketing of this medicinal product on their territory. That procedure includes an examination of the expiry of the data exclusivity period of the reference medicinal product, so that the competent authorities of those Member States cannot carry out such an examination again once that agreement has been established. Secondly, the CJEU stated that the holder of the MA for the reference product can assert its data exclusivity rights before a court, but only that of the Member State whose competent authority was the RMS. The holder of the MA for the reference product is not permitted to challenge this in other Member States.

17. This means that these questions are only subject to judicial review in Germany, the RMS of the DCP procedure. Here, the **RMS with a decision of 21 April 2023 has already clearly positioned itself**, with reference to relevant national supreme court rulings, to the effect that there has been no breach of the data exclusivity period and that the decentralized MAs were granted lawfully.

II. The date of application is not relevant for an alleged infringement of data exclusivity period of Tecfidera

18. Although the Sandoz decentralized MAs were applied for before 6 February 2022, all the relevant actions took place **after** the eight-year period, such as the 14 June 2022 Public Assessment Report from BfArM, the decision to grant the decentralized MA in Germany on 28 September 2022 and the decision to grant the decentralized MA in Estonia on 09 November 2022. Generic MAs are applied for on the basis of Article 10 of Directive 2001/83/EC which does not require the national authority to look only at the date of

[1] CJEU 16 October 2008, C-452/06, Synthon; CJEU 14 March 2018, Case C-557/16, Helm Astellas.

application. This article merely states "*the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community*". In other words, the actual use of Tecfidera's data occurred only after the data exclusivity period (to the extent that it existed at the relevant time) had expired.

19. Once the conditions are fulfilled, data exclusivity can no longer be re-examined. This was confirmed by the EMA in its reply to the question of the GCEU in case T-703/20: "(...) *the qualitative composition in terms of active substance of a medicinal product is fixed at the moment of its authorisation*" (§41). The Commission agrees that Directive 2001/83/EC or Regulation 726/2004 does not foresee the review of the conditions under which a MA was granted (other than health risks): "*Therefore, it would appear that the judicial review should be exercised to verify whether the Commission acted lawfully in adopting the Contested Decision on the basis that the MAH of Tecfidera had met the conditions for granting an additional year of marketing protection, as laid down in Article 14(11) of Regulation 726/2004. These conditions do not include the re-assessment of the GMA concept, given that an additional year of marketing protection is only granted to products that, like Tecfidera, already benefit from a period of regulatory data and marketing protection as a result of the assessment of the GMA concept carried out at the moment of the granting of a marketing authorisation.*" (Commission Defense in case T-256/23, § 63). It goes without saying that if for the reference medicinal MA there is only an assessment of the conditions of the MA possible at the time of granting, this is the same for generic MAs as it concerns the same 8 year period.

20. This principle is also confirmed in case law. The German Federal Administrative Court has confirmed in a judgment of 10 December 2015 that beyond the data exclusivity expiry date the MA holder does not have legal standing any more to claim an infringement of the data exclusivity period, even if a potentially infringing MA application was submitted prior to that date. According to the court, a premature MA application is without sanction under German and Community law. The Federal Administrative Court explicitly stated that *"accordingly, in the 8+2+1 successor regulation, the Community legislator again refrained from attaching a sanction to the premature processing of applications or granting of permits or from extending the protection period beyond ten or eleven years, respectively".*

III. National authorities cannot enforce Biogen's RDP rights

21. Even considering that Biogen's RDP rights would have resurrected with the CJEU judgment of 16 March 2023 (*quod non*), national authorities cannot enforce RDP rights, which is only for Biogen to do.

22. RDP rights, which are split up in 8 years data exclusivity rights and 2 years market protection rights, are private law rights granted to an original manufacturer as a reward for the original manufacturer's first commercialisation of a new medicine (based on Article 39(3) of the TRIPS Agreement). This is not intended to serve the public interest. RDP rights only regulate the relationship between commercial competitors in the pharmaceutical market – RDP right holders are in practice obliged to enforce RDP rights under civil law through the courts.

23. This is exactly what Biogen has started to do. After an extended period of silence towards the generic companies and of influencing of national authorities/tender authorities/customers and an attempt to solely rely on actions by the Commission and national health authorities, Biogen has commenced in September 2023 an EU wide litigation wave to enforce its market protection (and not its data exclusivity). The countries and generic companies implicated so far are:

- France: Mylan, Neuraxpharm, Polpharma and Sandoz;
- Belgium: Mylan;
- Austria: Neuraxpharm and Stada;
- Germany: Glenmark, Zentiva, Mylan, Neuraxpharm and Sandoz;
- Spain: Mylan, Neuraxpharm and Sandoz;
- The Netherlands: Glenmark, Mylan, Sandoz, Polpharma and Neuraxpharm;
- Denmark: Sandoz;
- Norway: Neuraxpharm;
- Portugal: Neuraxpharm Mylan;
- Italy: Mylan;
- Finland: Sandoz
- Hungary: Sandoz;
- Sweden: Glenmark; and
- Estonia: Mylan.

24. In these matters, Biogen is requesting hundreds of millions of euros in damages from the generic companies altogether. It is worth noting that the several courts have already accepted Biogen's request for preliminary injunction (e.g. in Germany and the Netherlands) and others rejected it (e.g. in Austria, Spain and Hungary). The courts that granted the preliminary injunction did not examine the validity of the +1 Decision, but merely relied on a presumption of validity. What matters more are the courts and authorities that did look at the validity and those have been unanimous going from the highest EU court (CJEU judgent of 2 February 2024) stating that at first glance the +1 decision should be annulled, to the Fimea (decision of 19 March 2024) stating that it's blatantly unlawful and cannot be a basis for regulatory action, to the UK authorities who have confirmed that the cut-off date of 2 February 2022 to have obtained the additional indication is essential to receive an additional year of market protection.

25. Furthermore, there are also courts like the Spanish court (and the Austrian court of first instance) that recognized the existence of conflicting rights, namely the generic's MA that was unconditionally granted and Biogen's alleged 'resurrected' market protection under the +1 Decision granting a year of market protection to Biogen. However, the court concluded that there are no factors that undermine the validity of the generic's MA or their ability to market generic DMF products under that MA. Therefore, the court decided that the generic in question cannot be prohibited from engaging in activities that it is legally permitted to do.

26. Several authorities, including the Commission, have already clearly expressed that it is not within their competences to enforce Biogen's (alleged 'resurrected') RDP rights on Tecfidera:

> *"131. (...) if the Applicant considers it appropriate to place its generic medicinal product on the market despite the ongoing marketing protection period,* ***it is not within the remit of the Commission to enforce the regulatory data protection.****"* (Commission's observations on the interim measures in Case T-256/23 R, T-257/23 R, T-258/23 R, T-278/23 R, para. 131)

> *"116, The Commission has no power to enforce the (private) marketing protection rights of reference medicinal product producers. As explained in paragraph 101, contrary to data protection rights which can be enforced by relevant competent authorities in the framework of the assessment of generic marketing authorisation applications in accordance with rules established by Directive 2001/83/EC and Regulation (EC) 726/2004,* ***only MAHs can enforce their marketing protection rights****. In the present case, only Biogen has the power to defend and take action against infringements of its rights, where appropriate, in the Member States concerned, in accordance with the rules and procedures laid down in national law."* (Commission's Statement of Defence in Case T-256/23, T-257/23, T-258/23, T-278/23, para. 116)

> *"172 (...) if the Applicant considers it appropriate to place its generic medicinal product on the market despite the ongoing marketing protection period,* ***it is not within the remit of the Commission to enforce the regulatory data or marketing protection.****"* (Commission's observations on interim measures in Case C-604/23 P(R)-R, Case C-607/23 P(R)-R, Case C-608/23 P(R)-R, Case C-609/23 P(R)-R, para. 172)

> "*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*" (Decision from Fimea of 19 March 2024, reference FIMEA/2023/001913, Biogen / Fimea, page 7, own emphasis).

> "***Nor does the commission see any authority in EU law*** *for the defendant* [Nederlandse Zorgautoriteit] ***to take enforcement action****. For example, Article 14 of the Regulation contains rules regarding (the validity of) marketing authorizations granted through the centralized procedure. However, no authority for the member state to take enforcement action in a situation such as the one at issue here can be inferred from this. The claimant's* [Biogen] *reference to a ruling by a German court does not shed any other light on the matter. Contrary to the claimant's view, this ruling and the public-law nature of market protection referred to have meaning only in relation to generic marketing authorizations granted in German domestic proceedings. In addition, the reference in the ruling to marketing authorizations granted by the EC through the central procedure refers only to the execution of an authorization granted after the expiration of eight years from the authorization of the reference drug. This says nothing about a power to proceed with enforcement in a situation such as the one at issue here*" (Decision from the Minister of Health, Welfare and Sports of 20 December 2023 after

obtaining an opinion from an advisory body, reference DWJZ-2023000993, Biogen / Nederlandse Zorgautoriteit, page 6, own emphasis)

IV. Conclusion

27. We hope Sandoz has been able to sufficiently inform Ravimiamet of Sandoz its specific situation and the reasons why Ravimiamet should reconsider its position.

28. As a closing statement, Sandoz would like to draw the attention of Ravimiamet to the fact that it has filed an application for annulment against the Commission Implementing Decision granting an additional year of market protection for Tecfidera because of the blatant and serious violation of Article 14(11) Regulation 726/2004 (Case T-299/23). Multiple other generic companies have also filed an annulment action together with a request for interim measures (Cases T-256/23, T-257/23, T-258/23, T-278/23)[2]. The CJEU has, earlier this month in a judgment of 2 February 2024, stated in the interim measures actions that the violation of Article 14(11) Regulation 726/2004 at "first glance" warrants an annulment of the Commission Implementing Decision (CJEU 2 February 2024, Case C-604/23 P(R), para. 60). However, as the CJEU considers that the aforementioned decision only enters into force on 3 February 2024 and has no effects before that date, the CJEU considered the interim measures actions premature.

29. More recently, Fimea has now also issued an official decision stating that the +1 Decision is manifestly unlawful: "*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*" (Decision from Fimea of 19 March 2024, reference FIMEA/2023/001913, Biogen / Fimea, page 8, own emphasis)

30. If the General Court annuls the Commission Implementing Decision granting an additional year of market protection for Tecfidera in any of the pending annulment actions, and Sandoz its DCP MA application is concurrently revoked in Estonia, there will be a period where no generic version of Tecfidera will be available on the market in Estonia, despite the absence of any market protection for Tecfidera. This situation could lead to a significant gap in the availability of this essential medicine, impacting patient access to treatment and increasing healthcare costs.

31. Sandoz submits that if Ravimiamet would reconsider its position and not withdraw the MAs, that it would wait until the European Courts provided more legal clarity in this unprecedented situation. Sandoz will thus not come on the market in Estonia under the concerned MAs with generic DMF products before this has happened and will otherwise wait until 2 February 2025, namely the end of the contested market protection period provided by the Commission Implementing Decision of 2 May 2023. Any new MA application can in any event unconditionally be granted as any other MA as these applications are filed after expiry of the data exclusivity period.

* * *

[2] There are more cases in which only an annulment action was filed (T-299/23, T-309/23, T-351/23 and T-393/23).

This letter is sent with the reservation of all rights and without any prejudicial acknowledgement.

Yours sincerely,

Gregor Pečnik
Procurator

Ksenija Butenko Černe
Member of the Board of Management

Annex: **1** (Decision of Fimea of 19 March 2024)

SANDOZ

Sandoz
Pharmaceuticals d.d. 1

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