EUROPEAN ASSOCIATION OF E-PHARMACIES

27 February 2026

European Commission
DG GROW Unit E.3
Avenue d'Auderghem 45
1040 Bruxelles
Email: grow-dir2015-1535-central@ec.europa.eu

RE: EU law concerns arising from TRIS Notification 2026/0010/DE regarding the Regulation amending the Regulations on the Operation of Pharmacies and other Regulations

1. On 13 January 2026, the German Federal Ministry for Economic Affairs and Energy (*Bundesministerium für Wirtschaft und Energie*, "**BMWE**") and the Federal Ministry of Health (*Bundesministerium für Gesundheit*, "**BMG**") notified the draft "Regulation amending the Regulations on the Operation of Pharmacies and other regulations" (*Verordnung zur Änderung der Apothekenbetriebsordnung und weiterer Verordnungen*, "**Draft Regulation**")[1] to the European Commission ("**Commission**") (TRIS Notification: 2026/0010/DE).[2]

2. The European Association of E-Pharmacies ("**EAEP**")[3] hereby respectfully requests that the Commission exercise its powers under Directive (EU) 2015/1535[4] by inviting Germany to delete, or at the very least substantially amend, the proposed new § 9a to be added in the Regulation on wholesale trade and the brokering of medicinal products (*Verordnung über den Großhandel und die Arzneimittelvermittlung*, "**AM-HandelsV**")[5] and the associated extension of scope in § 1 AM-HandelsV, and to strike the new proposed § 35b to be added in the Regulation on the operation of pharmacies (*Verordnung über den Betrieb von Apotheken*, "**ApBetrO**"), as well as the proposed

[1] The Draft Regulation in its version of 6 January 2026 and including the explanatory memorandum is attached as **Annex 1**.
[2] TRIS notification details of the Draft Regulation are available at https://technical-regulation-information-system.ec.europa.eu/en/notification/27611 (last accessed on 24 February 2026).
[3] The EAEP represents the interests of its members and safeguards the needs of their patients and customers. EAEP members are pioneers in providing digital solutions that continuously improve the quality, safety,F and efficiency of healthcare for Europeans. The EAEP's aim is to strengthen the European healthcare system by ensuring better access to health-related products and services across Europe. More information about the EAEP is available at https://www.eaep.com/en/ (last accessed on 24 February 2026).
[4] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, OJ L 241.
[5] Ordinance on the Trade in Medicinal Products of 10 November 1987 (Federal Law Gazette I p. 2370), as last amended by Article 2c of the Act of 18 November 2020 (Federal Law Gazette I p. 2397). The current version of the AM-HandelsV is available at https://www.gesetze-im-internet.de/amgrhdlbetrv/ (last accessed on 24 February 2026).

amendments to § 17(2a) ApBetrO.[6]

3. As explained below, the notified Draft Regulation would introduce, amongst others, detailed national rules and obligations applicable to third party logistics companies (*Logistikunternehmen*). Online pharmacies, especially those established in other EU Member States and selling medicinal products cross-border to consumers in Germany, rely on those logistics companies for the delivery of their products. They would therefore also be directly impacted by the proposed changes.

4. More specifically, the proposed measures risk (i) leading to unnecessary fragmentation and overregulation in a field already sufficiently regulated; and (ii) introducing unjustified and disproportionate restrictions on the free movement of goods (infringing Article 34 of the Treaty on the Functioning of the European Union, "**TFEU**") and the freedom to provide services (infringing Article 56 TFEU).

I. BACKGROUND AND CONTEXT

5. Under the current legal framework, pharmacies bear full legal responsibility for the delivery of the medicinal products they dispense, including where delivery is carried out by third-party logistics companies acting as intermediaries. § 17 ApBetrO, in its current version, already regulates the mail-order delivery of medicinal products. § 17(2a) sentence 1 no. 1 ApBetrO obliges the pharmacy manager to ensure that medicinal products are packaged, transported, and delivered in a manner that preserves their quality and efficacy, including compliance with applicable temperature requirements during transit. These obligations apply throughout the entire delivery process, from dispatch to handover to the end recipient, irrespective of whether transport is performed by the pharmacy itself or by commissioned logistics companies.

6. The obligations and requirements foreseen in the AM-HandelsV apply, according to the current § 1 AM-HandelsV, only to businesses and establishments engaged in the wholesale trade of medicinal products (i.e., pharmacy wholesalers)[7] and to brokers in medicinal products.[8] The notified Draft Regulation proposes to expand the scope of

[6] Pharmacy Act as promulgated on 15 October 1980 (Federal Law Gazette I p. 1993), as last amended by Article 3 of the Act of 22 December 2025 (Federal Law Gazette 2025 I No. 355). The current version of the ApBetrO is available at https://www.gesetze-im-internet.de/apobetro_1987/BJNR005470987.html (last accessed on 24 February 2026).

[7] According to § 4(22) of the Medicinal Products Act as amended by Article 2 of the Act of 23 October 2024 (Federal Law Gazette 2024 I no. 324) (*Gesetz über den Verkehr mit Arzneimitteln*, "**AMG**"), wholesale trade in medicinal products means any professional or commercial activity carried out for the purpose of trading which consists of the procurement, storage, supply or export of medicinal products, with the exception of the supply of medicinal products to consumers other than doctors, dentists, veterinarians or hospitals. The AMG is available at https://www.gesetze-im-internet.de/amg_1976/ (last accessed on 24 February 2026).

[8] According to § 4(22a) AMG, drug brokering means any professional or commercial activity carried out by persons who, without operating wholesale businesses, trade in medicinal products independently and on behalf of others, without obtaining actual control over the medicinal products.

the AM-HandelsV to include logistics companies commissioned by online pharmacies to deliver pharmacy-only medicinal products[9] to end consumers.

7. Further, the Draft Regulation proposes to introduce additional obligations that would apply to the dispatch and delivery of medicinal products to end consumers via mail-order, notably by proposing to introduce a new § 35b ApBetrO (*Versand von Arzneimitteln*) applicable to pharmacies, and a new § 9a AM-HandelsV applicable to logistic companies commissioned by online pharmacies (as explained at para. 6 above).

8. The explanatory memorandum of the Draft Regulation states that the new § 35b ApBetrO is meant to establish "detailed logistical requirements" for the dispatching by pharmacies of medicinal products and "concretise" the existing obligation in § 17(2a) sentence 1 no. 1 ApBetrO.[10]

9. Under the new proposed § 9a AM-HandelsV, a commissioned logistics provider must now also "ensure" that quality and efficacy are not impaired during storage and transport and must, amongst others, use suitable vehicles, comply with the pharmacy's temperature and other shipping conditions (including during transitional periods until successful delivery), record temperature conditions where active cooling is used, and prevent unauthorised access until handover to the recipient.

10. In addition, as a result of the newly proposed rules, logistics companies, typically acting as subcontractors of pharmacies, would become subject to direct supervision by the State (*Länder*) healthcare supervisory authorities. This follows from the explanatory memorandum, which, in the explanation in relation to the new proposed § 9a AM-HandelsV references § 64 AMG.[11] The current § 64(1) sentence 1 no. 1 AMG only covers businesses or facilities, in which medicinal products are manufactured, tested, stored, packaged, or that place medicinal products on the market, but it does not expressly mention transport activities. The German Federal Council (*Bundesrat*), in its recommendations of 15 January 2026 (BR-Drs. 770/1/25), proposed the introduction of a new § 64(1) sentence 1 no. 2a AMG, which would extend

[9] Pharmacy-only medicines may be supplied exclusively through a pharmacy and under the supervision of a pharmacist.
[10] *See* Annex 1, p. 32, no. 13. § 17(2a) sentence 1 no. 1 ApBetrO currently determines that medicinal products must be packaged, transported, and delivered in such a way as to maintain their quality and efficacy. In particular, the temperature requirements applicable to certain medicinal products must be observed during transport until delivery to the recipient. Compliance must be validly demonstrated, where necessary, by accompanying temperature control devices in the case of particularly temperature-sensitive medicinal products. Pursuant to § 17(2a) sentence 3 ApBetrO, this obligation equally applies to online pharmacies established in other EU Member States that deliver medicinal products to patients in Germany. The explanatory memorandum notes that these requirements are aligned with the EU Good Distribution Practice ("**GDP**") process standards; *see* Guidelines on GDP of medicinal products for human use of 5 November 2023, 2013/C 343/01 ("**GDP Guidelines**") (last accessed on 24 February 2026).
[11] *See* Annex 1, p. 36, no. 1.

supervision to businesses that are commissioned by pharmacies for the dispatch and delivery of pharmacy-only medicinal products.[12] As a result, if adopted, logistics companies transporting medicinal products would also be subject to supervision under § 64 AMG.[13] The competent *Länder* authorities would be responsible for supervising logistics companies in their respective territories.[14] Such supervision includes inspection powers, in particular with regard to the proper storage and quality-assured transport of medicinal products. Where deficiencies are identified, the authorities may order remedial measures (*see* § 69 AMG).

11. In addition, if a logistics provider fails to "ensure" quality and efficacy as required by § 9a AM-HandelsV, it would commit an administrative offence and may be subject to fines.[15] The expanded supervisory regime would therefore risk significantly increasing compliance and operational costs for logistics companies, in particular due to the need to implement quality management systems, prepare for inspections, and potentially invest in upgraded transport and storage infrastructure.

12. Pharmacies themselves would be impacted by the new proposed rules because of the contractual architecture proposed in § 35b(4) ApBetrO: the pharmacy operator must contractually ensure that the commissioned logistics company complies not only with the required temperature conditions, but also with its duty to inform the pharmacy in case of an event that could negatively impact the quality and efficacy of the medicinal product being transported. In addition, pursuant to the proposed amended § 17(2a) sentence 1 no. 1 ApBetrO, the pharmacy itself must ensure compliance with the requirements foreseen in § 35b(1) - (3) ApBetrO, and must ensure that the commissioned logistics company performs its contractually agreed obligations under § 35b(4) ApBetrO.

[12] Bundesrat Committee Recommendation BR-Drs. 770/1/25 of 15 January 2026, available at https://www.bundesrat.de/SharedDocs/drucksachen/2025/0701-0800/770-1-25.pdf?__blob=publicationFile&v=1 (last accessed on 24 February 2025).
[13] In the absence of a specific allocation of responsibilities under § 77 AMG, enforcement of the AMG lies with the *Länder* pursuant to Article 83 of the Basic Law (*Grundgesetz*, "**GG**"). The Basic Law for the Federal Republic of Germany in the consolidated version published in the Federal Law Gazette Part III, Classification Number 100-1, as last amended by Article 1 of the Law of 22 March 2025 (Federal Law Gazette 2025 I No. 94) is available at https://www.gesetze-im-internet.de/gg/BJNR000010949.html (last accessed on 24 February 2026).
[14] For the avoidance of doubt, the *Länder* authorities are competent to supervise businesses, facilities, and persons that have their registered office or place of residence within their respective territory (*see* § 64 AMG).
[15] *See* proposed § 10 no. 4 AM-HandelsV: pursuant to the current § 10 AM-HandelsV in conjunction with §§ 97(2) no. 1 and 97(3) AMG, intentional or negligent infringements constitute an administrative offence punishable by a fine of up to EUR 25,000.

II. THE DRAFT REGULATION RISKS INFRINGING EU LAW

A. Restriction of the free movement of goods (Article 34 TFEU)

13. The proposed requirements, and in particular the proposed § 9a AM-HandelsV, risks restricting the free movement of goods and would thereby infringe Article 34 TFEU.

14. The proposed obligations primarily affect the logistics companies themselves, but also EU online pharmacies that rely on such logistics companies to deliver medicinal products to consumers in Germany. As noted above, online pharmacies established in other EU Member States have to rely on logistics companies to deliver medicinal products to patients in Germany. For those pharmacies, mail-order sales constitute their only means of accessing the German market and selling to consumers in Germany (*see* § 73(1) sentence 1 no. 1 AMG).[16] The Court of Justice of the European Union ("**CJEU**") has repeatedly confirmed that online pharmacies established in other EU Member States have to rely on distance selling to gain access to, in this case, the German market.[17] By contrast, pursuant to the current § 17(2) ApBetrO, community pharmacies can rely on their physical brick-and-mortar facilities to dispense medicinal products to patients and have the option of offering courier services (*Botendienste*). These services are performed by instruction-bound employees of the pharmacy and are even subsidised by the statutory health insurance system, granting a fee of EUR 2.50 for each prescription drug delivered.

15. The Draft Regulation risks establishing differing compliance and supervisory obligations for the transport of medicinal products depending on whether delivery is carried out via courier services operated by brick-and-mortar pharmacies or via distance selling by online pharmacies.[18] This would be unfortunate given that comparable safety interests exist in the case of delivery by courier services as well.

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[16] By way of background, pursuant to the German *Fremdbesitzverbot*, pharmacies in Germany may only be owned and operated by licensed pharmacists, and ownership by non-pharmacists or corporate groups is prohibited. As a result, pharmacies established in other EU Member States are legally precluded from opening or operating brick-and-mortar pharmacies in Germany; *see* in particular § 7(1) and § 8 of the Pharmacy Act as promulgated on 15 October 1980 (Federal Law Gazette I p. 1993), as last amended by Article 3 of the Act of 22 December 2025 (Federal Law Gazette 2025 I No. 355 (*Gesetz über das Apothekenwesen*, "**ApoG**"). The ApoG is available at https://www.gesetze-im-internet.de/apog/BJNR006970960.html (last accessed on 24 February 2026).

[17] *See* e.g., opinion of Advocate General Szpunar of 18 December 2025, *Farmakeio YZ & Sia*, Case C-604/24, EU:C:2025:1007, para. 63; judgment of 19 October 2016, *Deutsche Parkinsonvereinigung*, Case C-148/15, EU:C:2016:776, para. 25; judgment of 11 December 2003, *DocMorris*, Case C-322/01, EU:C:2003:664, para. 74.

[18] The proposed amendments to § 17(2) AM-HandelsV confirm that brick-and-mortar pharmacies may deliver medicinal products to patients using their own couriers without requiring a separate authorisation. The Draft Regulation also does not, or at least not explicitly, impose on pharmacy managers using courier services delivery a detailed set of obligations comparable to those introduced in § 35b ApBetrO for the mail-order distribution of medicinal products.

16. In addition, the fact that the proposed obligation must be implemented throughout the supply chain and must be integrated in the contractual structure poses a significant operational and administrative burden on logistic companies and on online pharmacies relying on those logistics companies. While the Draft Regulation's stated aim is to safeguard quality and efficacy during transport, its mechanism is not limited to pharmacy-internal controls. Instead, it would compel pharmacies to secure contractually, and logistics companies to "ensure" directly, operational standards that go beyond the general standardised transport terms of EU-wide parcel networks.

17. § 9a AM-HandelsV in particular requires the logistics companies to ensure quality and efficacy through equipment- and process-specific obligations (e.g., adequate vehicles (*geeignete Fahrzeuge*) and compliance with shipping and storage temperature conditions through to delivery to the end recipient). This is not a mere information duty; but requires significant system changes for carriers and network operators.

18. Some providers have already raised concerns that compliance with the new requirements would be a significant additional burden and entail significant additional costs. The EAEP has received signals that the largest logistics companies on which its members typically rely to deliver medicinal products cross-border to German consumers may decide to completely discontinue the relevant delivery services should the Draft Regulation be adopted.[19] If logistics companies decide to opt out, this would materially restrict the ability of online pharmacies established in other EU Member States, and effectively make it impossible for them, to deliver medicinal products to patients in Germany. The Draft Regulation therefore risks creating a "comply or exit" dynamic for logistics companies, with potentially serious consequences for EU online pharmacies, the cross-border supply of medicinal products within the EU, as well as for the millions of customers the pharmacies serve.

19. If online pharmacies established in other EU Member States can no longer rely on those logistics companies, they will effectively be prevented from supplying medicinal products to German consumers. The Draft Regulation would thereby further exacerbate the disadvantage EU online pharmacies face compared to local pharmacies and their already subsidised courier services.

20. As a result, the proposed provisions risk restricting the free movement of goods and infringing Article 34 TFEU.

[19] *See* also *Handelsblatt* article of 29 January 2026: "*Online-Apotheken - Medikamentenversand wird wohl teurer*", where DHL, the largest logistics company in Germany, stressed in relation to the Draft Regulation that: "*Mail-order distribution of medicinal products, as an essential component of the population's basic medical care, must not be impaired. We advocate for a regulatory framework that also enables logistics companies operating in the mass market to continue transporting medicinal products as standard parcels, without transport conditions being unnecessarily complicated and shipping becoming more expensive*" (free translation from German), submitted as **Annex 2**.

B. Restriction of the freedom to provide services (Article 56 TFEU)

21. The services provided by online pharmacies, including the online selling of medicinal products, and the transportation services provided by logistics companies are both economic activities that qualify as 'services' under Article 56 TFEU.[20]

22. The Draft Regulation restricts those services in two ways: (i) by creating burdensome Germany-specific obligations for logistics companies; and (ii) by restricting the ability of EU online pharmacies to procure cross-border transport services on standard terms. As noted above, if logistics companies decide to stop providing delivery services to online pharmacies, the latter would effectively be prevented from selling medicinal products cross-border to German consumers.

23. First, the proposed measures directly impact the ability of logistics companies to provide their cross-border delivery services. As noted above, the proposed measures create a significant compliance burden for companies who do not ordinarily operate as regulated pharmaceutical market participants. Crucially, as explained at para. 18, it cannot be excluded that the major logistics companies will decide to discontinue the delivery services they provide to online pharmacies, as complying with the new requirements would not be economically and operationally sustainable. As noted above, in addition to the new requirements, logistics companies would also be subject to *Länder* supervision and exposed to potentially significant fines if they fail to "ensure" the quality and efficacy of medicinal products.

24. Second, if online pharmacies established in other EU Member States can no longer rely on those logistics companies to deliver medicinal products, they will not be able to sell to German consumers. In practice, therefore, the Draft Regulation operates as a *de facto* barrier to the cross-border provision of online pharmacy services (*see* above paras. 19 and 22). In addition, as noted above, online pharmacies would themselves be subject to additional requirements and would have to ensure compliance by logistics companies.

25. While the Draft Regulation asserts that there is "*no discrimination based on nationality or residence*" and that the proposed measures are proportionate under Article 56 TFEU, this would in practice not be the case.[21] A measure can infringe Article 56 TFEU where it makes the cross-border provision of services less attractive or more difficult than the purely domestic provision of those services, particularly where national operational and contracting models are effectively imposed as a

[20] *See* e.g., judgment of 19 June 2025, *Commission v Poland*, Case C-200/24, EU:C:2025:459, para. 100 et. seq.; opinion of Advocate General Saugmandsgaard ØE of 27 February 2020, *A v B*, Case C-649/18, EU:C:2020:134, para. 60.
[21] *See* Annex 1, p. 17, no. IV (free translation from German).

condition for access.[22] This would likely be the case here if the proposed measures were adopted.

26. Moreover, as noted above, the Draft Regulation treats commissioned logistics companies in a manner akin to pharmacy wholesalers by requiring them to "ensure" quality and efficacy of medicinal products, yet carriers typically lack (and should not be expected to have) the expertise to do so. At EU level, responsibility to ensure correct transport conditions and ensure the maintenance of temperature conditions is allocated to qualified actors (mainly pharmacies and pharmacy wholesalers).[23]

III. LACK OF ADEQUATE JUSTIFICATION AND DISPROPORTIONALITY

27. Restrictions on the free movement of goods under Article 34 TFEU or services under 56 TFEU may be justified on public health grounds pursuant to Article 36 TFEU and Articles 52(1) and 62 TFEU respectively if certain conditions are fulfilled. In particular, such measures must be suitable, necessary, and proportionate to protect public health.

28. According to settled case law of the CJEU, Member States must support such restricting measures with concrete evidence, such as statistical data or other objective means, demonstrating that the measures are genuinely necessary and appropriate to achieve the stated public health objective.[24] Those same principles apply in case of a restriction on the freedom to provide services.

29. Germany has not provided any evidence that the proposed additional obligations foreseen in the Draft Regulation would be necessary to safeguard public health. No concrete incidents, systemic failures, or enforcement gaps under the existing regulatory framework and current logistics arrangements have been identified that would justify the introduction of new obligations or measures. EU-based online-pharmacies deliver close to 80 million medicinal products to more than 26 million patients in Germany per year[25] without any known or documented cases in which the effectiveness of a drug was impaired by transport conditions or even endangered patients.

30. The requirements in the notified Draft Regulation are moreover disproportionate. Restrictive measures must be suitable to achieve a legitimate objective, necessary in that no less restrictive alternative is available, and balanced so that the benefits of the

[22] Judgment of 19 May 2009, *Apothekerkammer des Saarlandes*, Case C-171/07, EU:C:2009:316, para. 23.
[23] *See* GDP Guidelines, chapters 2.4 and 9.
[24] Judgment of 19 October 2016, *Deutsche Parkinson Vereinigung*, Case C-148/15, EU:C:2016:776, paras. 35, 36, and 42.
[25] *See Versorgungsmonitor Deutscher Online Apotheken* available at www.versorgungsmonitor.de (last accessed 24 February 2026). By way of background, the *Versorgungsmonitor* is based on an exclusive database from DatamedIQ and contains transaction data for both non-prescription and prescription products.

measure outweigh the disadvantages or burdens imposed. Such measures must not go beyond what is appropriate and necessary to attain the intended aim, ensuring that individual rights are not unduly restricted in relation to the public interest pursued.[26]

31. Today, online pharmacies established in other EU Member States successfully secure compliance with § 17 ApBetrO through a balanced set of passive temperature controls, primarily based on validated passive controls (e.g., coolpacks and temperature loggers on a risk-based approach) as assessed by their respected pharmaceutical quality experts. Where necessary, in particular for cold-chain products, online pharmacies also make use of active temperature control solutions and specialised carriers. Additional requirements such as adapted vehicles or continuous temperature control applicable to all logistics companies go far beyond what is necessary to ensure a safe delivery of medicinal products to German patients.

32. Although Germany refers to an alignment with EU GDP Guidelines, the Draft Regulation goes beyond a mere concretisation of existing pharmacy obligations and extends requirements to logistics companies that are neither pharmacy wholesalers, nor regulated as such under EU law. Through the combined effect of § 35b ApBetrO and § 9a AM-HandelsV, logistics companies are required to "ensure" compliance with pharmacy-specific transport obligations and are thereby exposed to Germany-specific supervision and sanctions.

33. These obligations would be excessively burdensome and costly for logistics companies to implement, and as explained above, risk obliging the main logistics companies used by online pharmacies to discontinue the relevant delivery services altogether. The proposed requirements also disproportionately affect online pharmacies, especially those established in other EU Member States that rely on those logistics companies to deliver medicinal products, and could effectively result in them no longer being able to sell their medicinal products to German consumers.

34. In addition, less restrictive measures are available, such as reinforcing documentation, voluntary auditability and quality-system controls at pharmacy level in line with the current § 17(2a) ApBetrO.

[26] Judgment of 10 July 2025, *INTERZERO*, Case C-254/23, EU:C:2025:569, paras. 99 and 109; judgment of 19 October 2016, *Deutsche Parkinson Vereinigung*, Case C-148/15, EU:C:2016:776, para. 36 and case law cited.

IV. CONCLUSION AND REQUEST

35. For the above reasons, the EAEP submits that the notified Draft Regulation, especially the expansion of AM-HandelsV to logistics companies and the proposed introduction of § 9a AM-HandelsV, creates serious EU law concerns under Articles 34 and 56 TFEU and is not adequately justified or proportionate to protect public health.

36. Following notification of the Draft Regulation, the EAEP communicated its concerns to the BMG.[27] At the time of this submission, no modifications addressing these concerns appear to have been introduced.

37. The EAEP therefore respectfully requests that the Commission, in the context of the TRIS procedure under Directive (EU) 2015/1535, invites Germany to:

    a. Delete the proposed changes to the scope clause in § 1 AM-HandelsV insofar as it brings commissioned logistics companies within the AM-HandelsV, and more specifically, delete § 9a AM-HandelsV;

    b. Delete § 35b ApBetrO to avoid imposing market-closing contractual structures and to ensure that compliance responsibility remains appropriately allocated to the pharmacy as the regulated healthcare actor.

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We thank the Commission for its attention to this matter and remain at the Commission's disposal to answer any questions or provide further information and clarifications.

Yours sincerely,

Walter Hess Olaf Heinrich

[27] [redacted].

EUROPEAN ASSOCIATION OF E-PHARMACIES

List of Annexes

Annex	Description	First and last page number in the annexes	Page and paragraph number in the letter
Annex 1	Regulation amending the Regulations on the Operation of Pharmacies and other regulations of 13 January 2026 (TRIS 2026/0010/DE)	1-38	p. 1, para. 1
Annex 2	Handelsblatt article of 29 January 2026: "*Online-Apotheken - Medikamentenversand wird wohl teurer*"	39-41	p. 6, para. 18
Annex 3	[redacted]	[redacted]	[redacted]