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Bundesverband Deutscher Versandapotheken

European Commission
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EU legal concerns arising from TRIS notification 2026/0010/DE regarding the regulation amending the Pharmacy Operating Regulations and other regulations, based on the Pharmacy Supply Development Act in Germany.

On January 13, 2026, the Federal Ministry for Economic Affairs and Energy (BMWE) and the Federal Ministry of Health (BMG) notified the European Commission of the draft "Regulation Amending the Pharmacy Operating Regulations and Other Regulations" (TRIS notification: 2026/0010/DE).

This concerns the Pharmacy Supply Development Act (ApoVWG) and, at its core, new obligations for mail-order pharmacies. Under a new Section 35b of the Pharmacy Operating Regulations (ApBetrO), German mail-order pharmacies would be required to:

- comply with detailed logistical requirements for shipping,
- structure contracts with logistics companies in such a way that they meet these requirements, and
- immediately report any potential transport issues.

These are our arguments against this proposal:

1) From the BVDVA's perspective, the violation contravenes EU internal market rules because it amounts to a restriction on the free movement of goods (Art. 34 TFEU).
    a. Furthermore, we believe that the freedom to provide services under Art. 56 is being impaired.
2) In effect, this regulation would spell the end for German mail-order pharmacies. These are pharmacies under German law that hold a mail-order license.
3) We also see an infringement on the freedom of occupation under Article 12 of the Basic Law.
4) There is unequal treatment of the supply channels: mail-order and brick-and-mortar pharmacies.
5) Indirectly, wholesale requirements (GDP/B2B) are being imposed on pharmacies (B2C) without them being formal wholesalers.
    a. This constitutes a circumvention of the pharmaceutical regulations in the Pharmacy Act and the Pharmacy Operating Regulations, as the requirements are based on the Pharmaceutical Trade Ordinance (AM-HandelsV).
6) Finally, there is no evidence to support the argument that the current regulations pose an increased safety risk.

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Specifically regarding 1) Implications under European law

The European Court of Justice has already ruled on multiple occasions that national regulations must not impose disproportionate restrictions on the mail-order sale of medicines. Well-known examples include the

- DocMorris ruling from 2003 or
- the Deutsche Parkinson Vereinigung ruling from 2016

Cross-border trade would be severely affected, particularly in regions near the border. If Germany now establishes transport requirements that apply only to the shipment of medicines, this will hinder market access for European companies that are not permitted to operate pharmacies in Germany due to the prohibition on third-party ownership. This would thus impede the free movement of goods in Europe. Furthermore, we see this as a restriction on the freedom to provide services under Article 56 of the Treaty on the Functioning of the European Union (TFEU).

Re 2)

There are currently no logistics partners capable of delivering the required volume in compliance with GDP standards at reasonable costs. As a result, mail-order pharmacies would no longer be able to fulfill their mandate to ensure comprehensive pharmaceutical care. They would thus be economically at risk (jobs, economic strength), and patients would have to accept disadvantages in care and/or extremely rising costs.

This circumstance inevitably leads to points 3–5:

3) Restriction on freedom of occupation: The rule effectively requires mail-order pharmacies to

- certify logistics companies
- implement GDP-like processes
- monitor and document shipments.

This would incur significant costs, entail bureaucratic organizational and documentation requirements, and pose substantial liability risks.

According to the case law of the Federal Constitutional Court, however, such interventions must be appropriate, necessary, and proportionate. In our view, they are not.

4) Unequal treatment of supply channels – brick-and-mortar and online

Brick-and-mortar pharmacies are permitted to:

- Dispense medications without temperature-controlled transport, including delivery services
- Patients transport the medications themselves.

Mail-order pharmacies (German brick-and-mortar pharmacies with a mail-order license), on the other hand, must:

- Monitor specific transport conditions
- Comply with documentation requirements and
- Qualify carriers.

Why do stricter requirements apply to the shipping of medicines than to the transport of medicines by patients (purchases at brick-and-mortar pharmacies)? From the BVDVA's perspective, this unequal treatment is not objectively justified.

5) The requirements are based on the Pharmaceutical Trade Regulation (AM-HandelsV).

- However, mail-order pharmacies are not wholesalers, and
- freight forwarders/logistics companies are not pharmaceutical companies or distributors

This creates a systematic regulatory inconsistency: The legislature imposes GDP obligations without the corresponding legal framework (Responsible Person, wholesale license, etc.). This results in major contradictions in the regulatory system for us.

Re 6) There are no known safety issues.

Mail-order pharmacies serve many millions of customers each year. They have been doing so for over 22 years, since the introduction of mail-order sales of pharmaceuticals in Germany for pharmacy-only and prescription-only medicines. There are no known cases where patient welfare or patient safety has been compromised. Medicines reach consumers securely packaged and, where necessary, passively cooled. However, medicines requiring a cold chain are transported separately, securely, and with proper documentation.

We ask the European Commission to review these arguments and are available to answer any questions regarding the situation of German mail-order pharmacies.

Signed

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