Bundesinstitut
für Arzneimittel
und Medizinprodukte

FAQ for the „PharmNet.Bund portal for reporting active pharmaceutical ingredient manufacturers“

1. What ist the German Act to Combat and Improve the Supply of Medicines (Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz, ALBVVG)?

The Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz (ALBVVG) is a law that defines measures to combat supply shortages of medicinal products and to improve the supply of medicinal products.

2. What are the new reporting obligations under the ALBVVG?

When the ALBVVG came into force, new reporting obligations were introduced, including the obligation to report the active ingredient manufacturers of medicinal products that actually use certain criteria.

3. Which medicinal products are subject to the reporting obligation?

- Medicinal products that are subject to regular data transmission in accordance with Section 52b sub-section 3f AMG
- Medicinal products that are queried by hearings of the higher federal authorities in accordance with Section 52b sub-section 3e AMG
- Medicinal products that are eligible for an EU lot in health insurance discount contract tenders. Currently, this includes off-patent antibiotics in accordance with Section 130a sub-section. 8a and 8b SGB V
- other active substances, provided that a classification is published by the Federal Ministry of Health (Bundesministerium für Gesundheit, BMG) in the Federal Gazette

4. To whom can the health insurance funds send applications in accordance with Section 130a sub-section 8a SGB V?

Applications can be sent to the following e-mail address:

LE-Rabattvertraege@bfarm.de

5. For Section 52 sub-section 3f AMG: Which batches must be reported?

All newly released batches must be reported. Previously released batches should not be recorded retroactively.

6. What is to be stated under batch size?

The batch size refers to the number of packs of the released batch in relation to the respective reported pharmaceutical central number (PZN). The calculation is not based on the unit ZE (counting unit; e.g. tablet), but on the packaging unit.

7. Where can I find the portal for reporting active pharmaceutical ingredient manufacturers?

The PharmNet.Bund portal for reporting active pharmaceutical ingredient manufacturers can be accessed via the following link:

https://www.pharmnet-bund.de/dynamic/de/unternehmen/wirkstoffhersteller/index.html

8. What requirements must be met to use the portal?

A valid RuBen account and an assignment of the PharmNet.Bund application by the company's main user are required to use the portal. Furthermore, the terms of use and information on data protection must be accepted once.

9. What is meant by the "batch release date" in the notification form for active substance manufacturers?

The term "batch release date" refers to the date when a qualified person (QP) releases a batch of medicines.

10. Can I correct errors in the reported data on active pharmaceutical ingredient manufacturers in the PharmNet.Bund portal?

When reporting active pharmaceutical ingredient manufacturers in the PharmNet.Bund portal, you can correct certain fields, while others cannot be corrected.

a. Correctable fields:
   All fields below the ENR (processing number, "Einreichungsnummer") and the batch number can be corrected.
b. Non-correctable fields:
   - The ENR and the batch number serve as base values for the determined data and therefore cannot be corrected.
   - If there are errors when entering the ENR or batch number, you must make a separate message and add an additional identifier to the existing record to indicate that this record is invalid.

We recommend reporting any error messages or need for correction in the PharmNet.Bund portal.