Federal Institute for Drugs and Medical Devices

Notice
on the German Pharmacopoeia 2026[1]

of xx.yy. 2026

1. In accordance with § 55(2) and (6) of the Medicinal Products Act (AMG), the rules contained in the Pharmacopoeia are decided by the German Pharmacopoeia Commission, the European Pharmacopoeia Commission or the German Homoeopathic Pharmacopoeia Commission.

2. The texts and monographs of the German Pharmacopoeia adopted by the German Pharmacopoeia Commission on 8 October 2025 are hereby announced in accordance with § 55(7) AMG. In accordance with § 55(7)(2) AMG, the Notice is limited to the publication of the titles of the texts and monographs in the Annex. The German Pharmacopoeia in its current version is being amended as follows:

   a) The monographs referred to in Section A of the Annex shall be included in a revised version.
   b) The texts and monographs referred to in Section B of the Annex shall be deleted.

3. The Pharmacopoeia as amended and recast in accordance with this Notice shall be named ‘German Pharmacopoeia 2026 (DAB 2026)’. The German Pharmacopoeia 2026 shall enter into effect starting on x.xx.2026.

4. The German Pharmacopoeia 2026 can be obtained from Deutscher Apotheker Verlag.

[1] *‘Notified in accordance with 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, 17.9.2015, p. 1.)’*

5. For medicinal products that are on the market on x.xx. 2026 and that do not meet the requirements of the German Pharmacopoeia 2026 (DAB 2026) or have not been manufactured, tested, or labelled in accordance with its provisions, but comply with the provisions applicable on yy.yy. 2026, this Notice shall only enter into effect starting on z.zz. 2026.

6. All relevant provisions of the European Pharmacopoeia, the German Pharmacopoeia and the Homeopathic Pharmacopoeia, as well as any applicable, up-to-date and further-reaching provisions on the use of certain substances to avoid the risk of transmissible spongiform encephalopathies by medicinal products must be observed for source materials for the manufacture of medicinal products.

7. The Notice is issued in accordance with § 55(1) AMG, where applicable in conjunction with § 63 of the Veterinary Medicinal Products Act (TAMG), in agreement with the Federal Office of Consumer Protection and Food Safety and the Paul-Ehrlich-Institut.

Bonn, xx.xx.xxxx

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for Drugs and Medical Devices

Annex 1

Chapter A: Revised Monograph

Coumarin (Cumarinum)

Chapter B: Deleted Methods and Reagents

N 2.8.10 Water-soluble components in essential oils
N 2.8.11 Halogenated impurities in essential oils

Ephedrine hydrochloride RN
Potassium hydroxide solution, methanolic RN
Lanatoside RN
Scopoletin RN