

Preliminary Note

Objectives

Objective 1: Adapting the ÖAB to current circumstances

Content

The proposed legislation primarily comprises the following measure:

Measure 1: Entry into force of the ÖAB 2026, repeal of the ÖAB 2025

Significant impacts

There is no significant impact in the dimensions of impact outlined under Section 17(1) of the Federal Budget Act (BHG) 2013.

Financial impacts on the federal budget and other public budgets

The measure in question has no financial impact on the federal government, the provinces, the municipalities or social security institutions.

Relationship with European Union legislation

The proposed legislation serves to transpose an EU Directive

Special features of the legislative procedure

Completed information procedure in accordance with the Notification Act or the Directive implemented by this Act

Simplified outcome-oriented impact assessment

91st Supplement to the Pharmacopoeia

Submitting entity: Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection

Title of the project: Regulation of the Federal Minister for Labour, Social Affairs, Health, Care and Consumer Protection concerning the 91st Supplement to the Pharmacopoeia

Type of proposed legislation: Regulation

Entry into force / effective date: 2026

Year created: 2026

Last updated: 14 August 2026

Contribution to outcome objective or measure in the federal budget

Contribution to:

- Outcome objective: In the context of healthcare structure policy, to ensure the highest level of quality-assured, comprehensive, easily accessible and solidarity-financed integrated healthcare for the population, without discrimination based, for example, on education, status and gender. (Sub-section 24: Health – Federal Budget Estimate 2026)

Systems analysis

Definition of the problem

The Pharmacopoeia is a collection of recognised pharmaceutical rules governing the definition, manufacture, quality, composition, dosage, labelling, storage, dispensing and testing of medicinal products, as well as the characteristics of their containers and packaging. It comprises the European Pharmacopoeia and the Austrian Pharmacopoeia.

The primary purpose of the Austrian Pharmacopoeia is to address specific national requirements. The Federal Minister responsible for healthcare shall, by order, declare the provisions of the Austrian Pharmacopoeia that are not superseded by the European Pharmacopoeia to be binding as the 'Austrian Pharmacopoeia, Official Edition', considering the current state of scientific knowledge and Austria's specific requirements.

The Austrian Pharmacopoeia, Official Edition 2026, is therefore to be brought into force in accordance with Section 2 of the Pharmacopoeia Act 2012.

Interoperability assessment pursuant to Article 3(1) of the Interoperable Europe Act

It was not necessary to carry out an Interoperability assessment pursuant to Article 3(1) of the Interoperable Europe Act (IEA).

Explanatory notes:

The project does not involve any cross-border interactions.

Digi-Ready-Check

The Digi-Ready-Check was carried out. This is available as a separate document.

Explanatory notes:

The project has no implications in terms of information and communication technology.

Objectives

Objective 1: Adapting the ÖAB to current circumstances

Description of the objective:

On the basis of the recommendations of the Pharmacopoeia Commission, amendments are to be made to the Austrian Pharmacopoeia (ÖAB) that take account of specific national requirements.

Implemented by:

Measure 1: Entry into force of the ÖAB 2026, repeal of the ÖAB 2025

Measures Measure 1:

Entry into force of the ÖAB 2026, repeal of the ÖAB 2025

Description of the measure:

This Regulation comes into force to bring the 2026 edition of the Austrian Pharmacopoeia into effect and to repeal the 2025 edition.

Implementation of:

Objective 1: Adapting the ÖAB to current circumstances

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