



Direktoratet for
medisinske produkter

Hva skjer med endringsforordning 1234/2008/EC?

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► B

COMMISSION REGULATION (EC) No 1234/2008

of 24 November 2008

concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products

(Text with EEA relevance)

(OJ L 334, 12.12.2008, p. 7)

Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures

(2013/C 223/01)

Ny «Pharmaceutical Strategy for Europe»

Flagship initiatives on regulatory efficiency

- ▶ Propose to revise the pharmaceutical **legislation** to provide for simplification, the streamlining of approval procedures and **flexibility** for the timely adaptation of technical requirements to scientific and technological developments, in order to address the challenges relating to the interplay of medicines and devices, and to strengthen pro-competitive elements – 2022.
- ▶ Propose to revise the variation framework for medicines, through changes in legislation and guidelines, to make the lifecycle management of medicines more efficient and adapted to **digitalisation** – 2021-2023.

CALL FOR EVIDENCE FOR AN INITIATIVE (without an impact assessment)

This document aims to inform the public and stakeholders about the Commission's work, so they can provide feedback and participate effectively in consultation activities.

We ask these groups to provide views on the Commission's understanding of the problem and possible solutions, and to give us any relevant information they may have.

TITLE OF THE INITIATIVE	Pharmaceuticals – changes to marketing authorisations (Revision of the variation framework for medicines)
LEAD DG – RESPONSIBLE UNIT	DG SANTE D1
LIKELY TYPE OF INITIATIVE	Delegated Regulation
INDICATIVE TIMING	Q4-2023
ADDITIONAL INFORMATION	Medicinal products (europa.eu) A pharmaceutical strategy for Europe (europa.eu) Reform of the EU pharmaceutical legislation

Hovedmål

- Økt fleksibilitet
- Økt effektivitet
- Redusere administrasjon

Tiltak

- Reklassifisering av endringer
- Forenkle prosess for notifikasjoner og WS
- Risikobasert tilnærming for kategorisering av endringer for gitte biologiske legemidler

○ In preparation

● Call for evidence

Feedback period

29 August 2023 - 26 September
2023

FEEDBACK: CLOSED

UPCOMING

○ Draft act

FEEDBACK: UPCOMING

○ Commission adoption

Planned for

Fourth quarter 2023

08.08.2024: Draft act publisert på
kommisjonens nettside 07.02.24:
[Pharmaceuticals – changes to
marketing authorisations \(review of
EU rules\) \(europa.eu\)](#)

Kilder

- [Pharmaceuticals – changes to marketing authorisations \(review of EU rules\) \(europa.eu\)](#)
- [pharma-strategy_report_en_0.pdf \(europa.eu\)](#)