Direktoratet for
medisinske produkter

Hva skjer med endringsforordning 1234/2008/EC?

Anne Kulseth Dahl – Seniorrådgiver Regulatorisk etter MT

►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

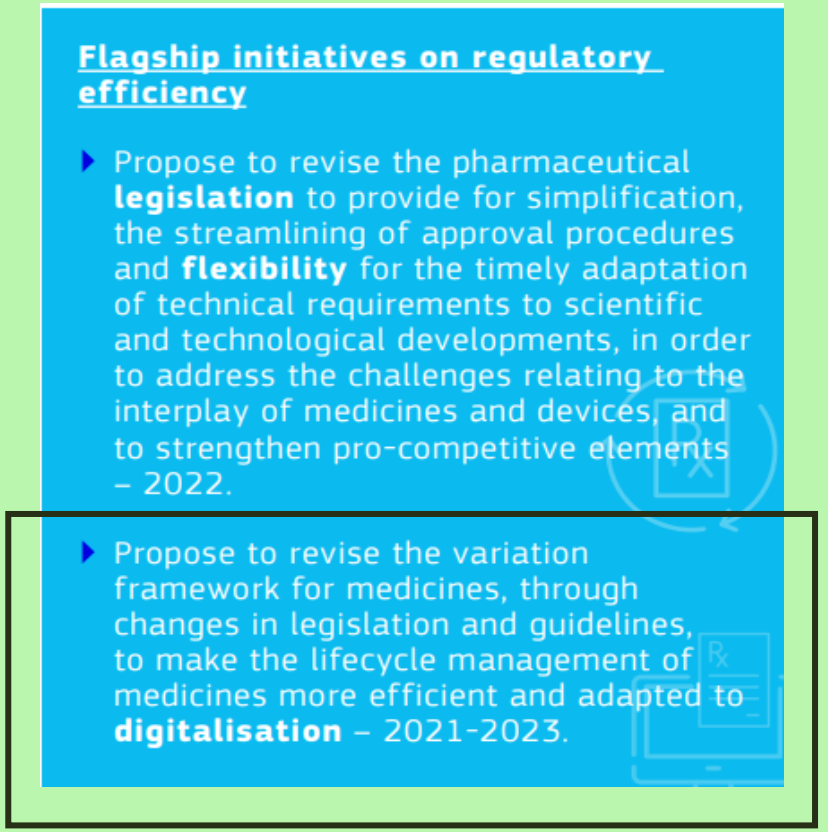
(Text with EEA relevance)

(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»



Ref. Ares(2023)5859980 - 29/08/2023

European Commission

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.

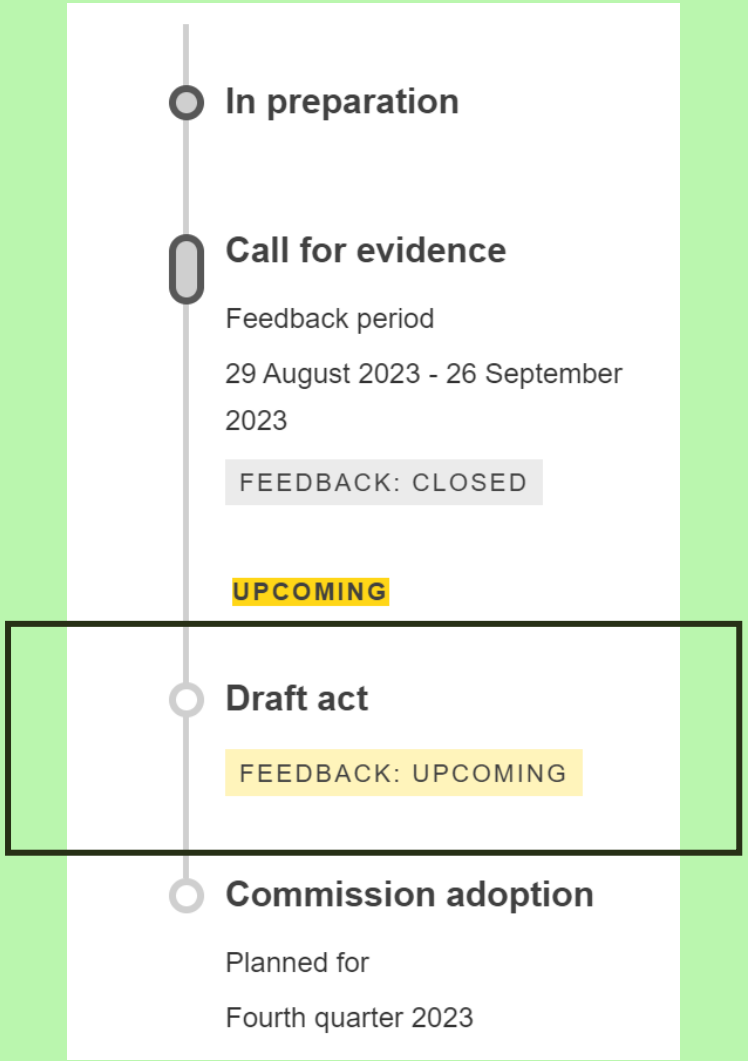
TITLE OF THE INITIATIVE	Pharmaceuticals – changes to marketing authorisations (Revision of the variation framework for medicines)
LEAD DG – RESPONSIBLE UNIT	DG SANTE D1
LIKELY TYPE OF INITIATIVE	Delegated Regulation
INDICATIVE TIMING	Q4-2023
ADDITIONAL INFORMATION	Medicinal products (europa.eu) A pharmaceutical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



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)