Direktoratet for
medisinske produkter

Endringsforordningen etter 01.01.2025

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Rådgiver, Enhet for Regulatorisk etter MT

Regulatorisk informasjonsmøte møte 08.05.2025

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COMMISSION DELEGATED REGULATION (EU) 2024/1701

of 11 March 2024

amending Regulation (EC) No 1234/2008 as regards the examination of variations to the terms of marketing authorisations for medicinal products for human use

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([1]), and in particular Article 23b(2a) thereof,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency ([2]), and in particular Article 16a(3) thereof,

Whereas:

(1) The Union legal framework regarding variations to the terms of marketing authorisations is laid down in Commission Regulation (EC) No 1234/2008 ([3]). In the light of practical experience in the application of that Regulation, it is appropriate to proceed to its review in order to establish a simpler, clearer and more flexible legal framework, while guaranteeing the same level of public health protection.

(2) The procedures laid down in Regulation (EC) No 1234/2008 should therefore be adjusted, without departing from the general principles on which those procedures are based.

(3) In order to achieve efficiency gains and to reduce the administrative burden for the pharmaceutical industry and to better use the

Flere veier til målet

1. Oppdatering i klassifiseringsguidelines
2. Annual updates
3. Supergrouping
4. Worksharing

1 - **Kommende** oppdatering av klassifiseringsguidelines

- Behov for å friske opp guidelines
  - Forenkling av eksisterende kategorier
  - Tillegg av nye kategorier (f.eks fra art.5 recommendations)
  - Kodesystemet endres

- Oppdatert guideline forventes mot slutten av Q2
  - Nåværende guideline gyldig i en overgangsperiode etter publisering frem mot en satt **cut-off** dato.
  - Vil gjenspeiles i eAF, bruk nyeste versjon.

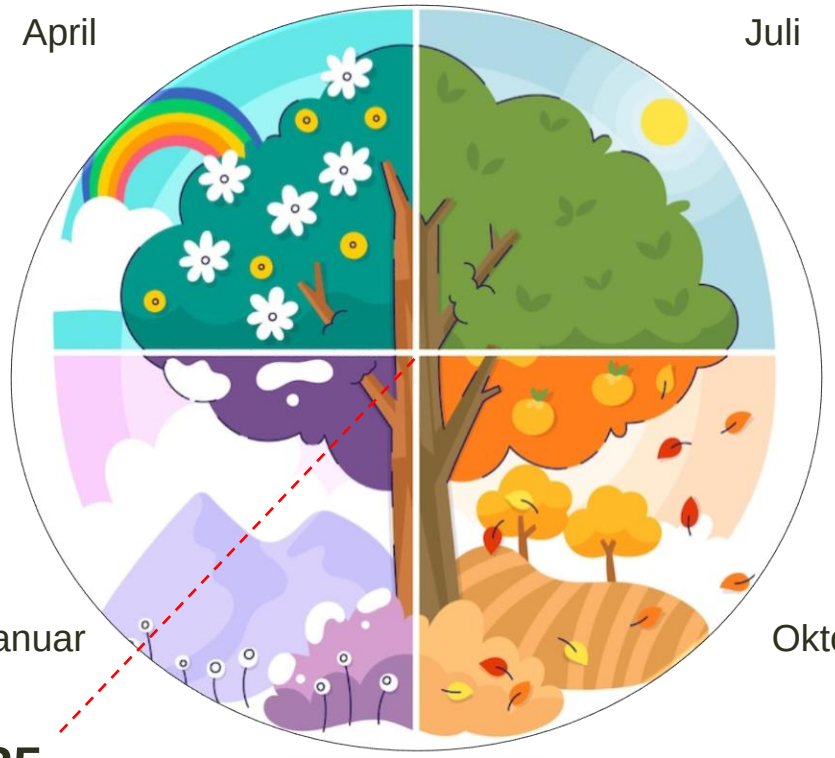
- Mer informasjon forventes på senere tidspunkt

B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product	Conditions to be fulfilled	Documentation to be supplied	Procedure type
a) Replacement or addition of a site where batch control/testing takes place	2, 3, 4, 5	1, 2, 5	IA
b) Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method			II
c) Replacement or addition of a manufacturer responsible for importation and/or batch release			
1. Not including batch control/testing	1, 2,5	1, 2, 3, 4, 5	IA_{IN}
2. Including batch control/testing	1, 2, 3, 4, 5	1, 2, 3, 4, 5	IA_{IN}

2 - Annual updates fra 01.01.2025

- Type IA endringer skal ikke lengre sendes inn enkeltvis
- Samtidig årlig innsendelse av type IA endringer
  - Tidligere vært frivillig, nå **obligatorisk** for endringer implementert etter 01.01.2025
  - Sendes inn tidligst 9 måneder og senest 12 måneder etter implementering av eldste endring
  - Unntak: Type IAin, grupperinger med type IB/II m.fl – Se CMDh Best Practice Guide Chapter 6
  - Letter den administrative byrden

Annual update syklus



Første implementerte endring

Sender første annual update Januar 2026

Andre annual update tidligst september 2026

Tidligste tidspunkt for innsending - November 2025

Endring som ikke rekker 1. annual update

3 - Supergrouping fra 01.01.2025

- Supergrouping – når samme IA/IAin-endringene gjelder **flere MT** i porteføljen
  - NYTT fra 01.01.2025 – Man kan inkludere preparater i nasjonal prosedyre.

- **Kun for administrative- og kvalitetsendringer dersom**
  - Miks av MT i MRP/DCP med ulik RMS og/eller
  - Miks av MT i nasjonal prosedyre fra flere land

- **Sikkerhetsendringer også mulig dersom**
  - Miks av MT med samme RMS

- Ikke obligatorisk, men oppfordret.

4 - Worksharing fra 01.01.2025

- Når de samme type IB/II-endringene gjelder flere MT

- **Obligatorisk fra 01.01** – for type IB/II endringer som gjelder for flere MT, tilhørende *samme* MT-innehaver
- **Frivillig** – for type IB/II endringer som gjelder for flere MT, tilhørende *ulike* MT-innehavere

- Introduksjon av 30-dagers tidtabell for type IB

Erfaringer med worksharing etter 01.01.25

Mye positivt!

- Økt antall innsendelser av WS
- Færre nasjonale søknader

Noen utfordringer..

- Mangelfulle begrunnelser for hvorfor worksharing ikke er aktuelt
- Misforståelser knyttet til «produktspesifikke vurderinger»
  - Produktene kan ha ulikt utgangspunkt, men harmonisert utfall

Fiktiv case:
Type IB C.I.z PRAC signal recommendation

Bruk av sjokolade (API) hos diabetespasienter:

4.4 Special warnings and precautions for use

Hyperglycemia in patients treated for diabetes

There have been reports of hyperglycaemia following initiation of *chocolate* in patients receiving medication for diabetes. Dose adjustments of anti-diabetic medication may be necessary in the event that hyperglycaemia occurs.

Sjok-faktor A/S har nasjonale MT i Norge og Sverige for legemiddel med sjokolade.

Den anbefalte teksten skal nå implementeres for begge produkter, men det må gjøres noen tilpasninger til opprinnelige nasjonale tekster.

Porteføljen er ikke harmonisert..

- Norsk MT «Kakao 50mg/ml pulver til mikstur»

  4.4 Advarsler og forsiktighetsregler

  Diabetes

  Hyperglykemi er rapportert hos pasienter med diabetes ved oppstart og kontinuerlig behandling med sjokolade. Dosen bør tilpasses individuelt.

- Svensk MT «Choklad 150g platta»

  4.4 Varningar och försiktighet

  Diabetes

  Chocklad kan höja blodsockervärdet, förvärra redan befintlig diabetes samt ökar risken för utveckling av diabetes hos patienter som står på långtidsbehandling med chocklad.

Fortsatt ikke til hinder for WS! ☺

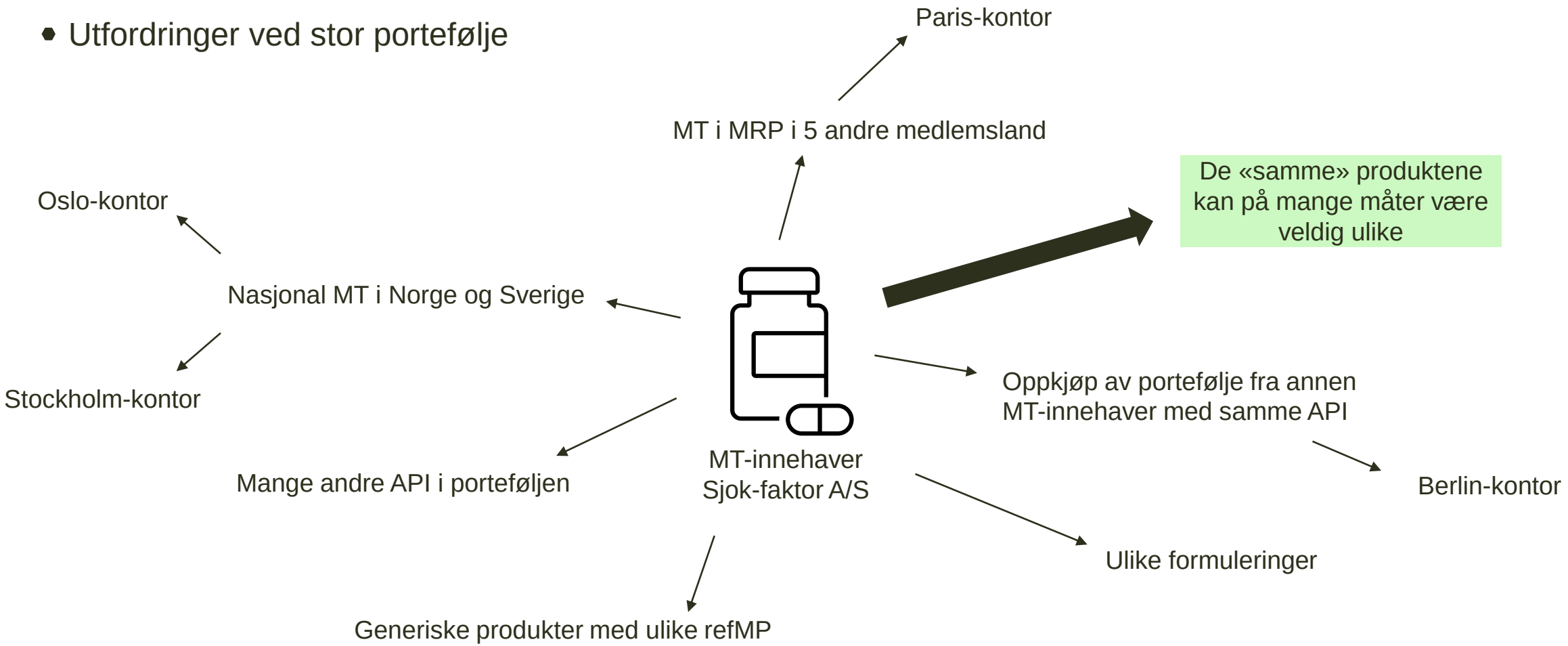
… men utfallet er likt!

- Ikke krav om «common» produktinformasjon, endringene fremstilles i present & proposed tabell

Present	Proposed	Comment Type IB C.I.z
4.4 Special warnings and precautions for use Diabetes There have been reports of hyperglycaemia following initiation and continuous treatment with chocolate in patients with diabetes. The dose should be adjusted according to individual response. Chocolate may increase blood sugar levels, aggravate existing diabetes and increase the risk of developing diabetes in patients receiving long-term treatment.	4.4 Special warnings and precautions for use Hyperglycemia in patients with~~D~~diabetes There have been reports of hyperglycaemia following initiation and continuous treatment with chocolate in patients with diabetes and in patients receiving medication for diabetes. ~~The dose should be adjusted according to individual response.~~ Dose adjustments of anti-diabetic medication may be necessary in the event that hyperglycaemia occurs. Chocolate may ~~increase blood sugar levels,~~ aggravate existing diabetes and increase the risk of developing diabetes in patients receiving long-term treatment.	Agreed wording adjusted to be aligned with wording already present in the NO and SE SmPC.

Worksharing til glede eller besvær?

- Utfordringer ved stor portefølje



Worksharing til **glede** eller besvær?

- Redusert arbeidsbyrde
  - Myndigheter fra andre land kan kommentere
- Man unngår sprikende utfall
  - Enklere vedlikehold av MT
- 1 WS kan erstatte 5-10-20-50 […] enkle søknader

Alt i alt en vinn-vinn situasjon

Pasienten i panna

- Ambisjonen bør være å harmonisere produktinformasjonen.
  - Sjeldent grunn til særbehandling av svenske og norske pasienter

- Ved særlig behov for ulik informasjon skal dette tydelig begrunnes og rettferdiggjøres.

Hva forventer vi av industrien?

- Aktivt samarbeid med team på tvers av land
- Vurder alltid mulighet for worksharing
- Worksharing er **ikke** valgfritt og skal benyttes der det er relevant

Declaration of the applicant about the submission(s) of the same variation (or group of variations) in other Member States / EMA.

☐ **The applicant confirms that the same variation (or group of variations) does not apply to any other marketing authorisation held by the same holder *(only applicable for Type IB and/or Type II***

Hva kan industrien forvente av oss?

- Rask tilbakemelding på om DMP kan ta på seg RMS-rolle.
- Streng, men samarbeidsvillig tilnærming
- Forvent at vi ber om redegjørelse for om WS er vurdert
- Mangelfull eAF i retur

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Oppdaterte veiledningsdokumenter

CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

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- CMDh
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    - General Info
    - Application for MA
    - eSubmissions
    - Generics
    - Applicant´s Responses
    - Renewal
    - Consultation with

VARIATION PROCEDURE

- **Guidance on the Application of the Amended Variations Regulation from 1 January 2025**

In order to view some of the documents on this website you need **Acrobat Reader** (click here to download)

- **Best Practice Guides (BPGs) for the Submission and Processing of Variations in the Mutual Recognition Procedure**
  - **Chapter 1: CMDh BPG for the Allocation of the Mutual Recognition Variation Number for Type I Notifications, Type II Variations, Grouping and Worksharing** (October 2024) [*Track version*]
  - **Chapter 2: Procedure for Automatic Validation of Mutual Recognition Procedures for Variations** (October 2024) [*Track version*]
  - **Chapter 3: CMDh BPG for the Processing of Type IA Minor Variations (Notifications) in the Mutual Recognition Procedure** (January 2025) [*Track version*]
  - **Chapter 4: CMDh BPG for the Processing of Type IB Minor Variations (Notifications) in the Mutual Recognition Procedure** (October 2024) [*Track version*]

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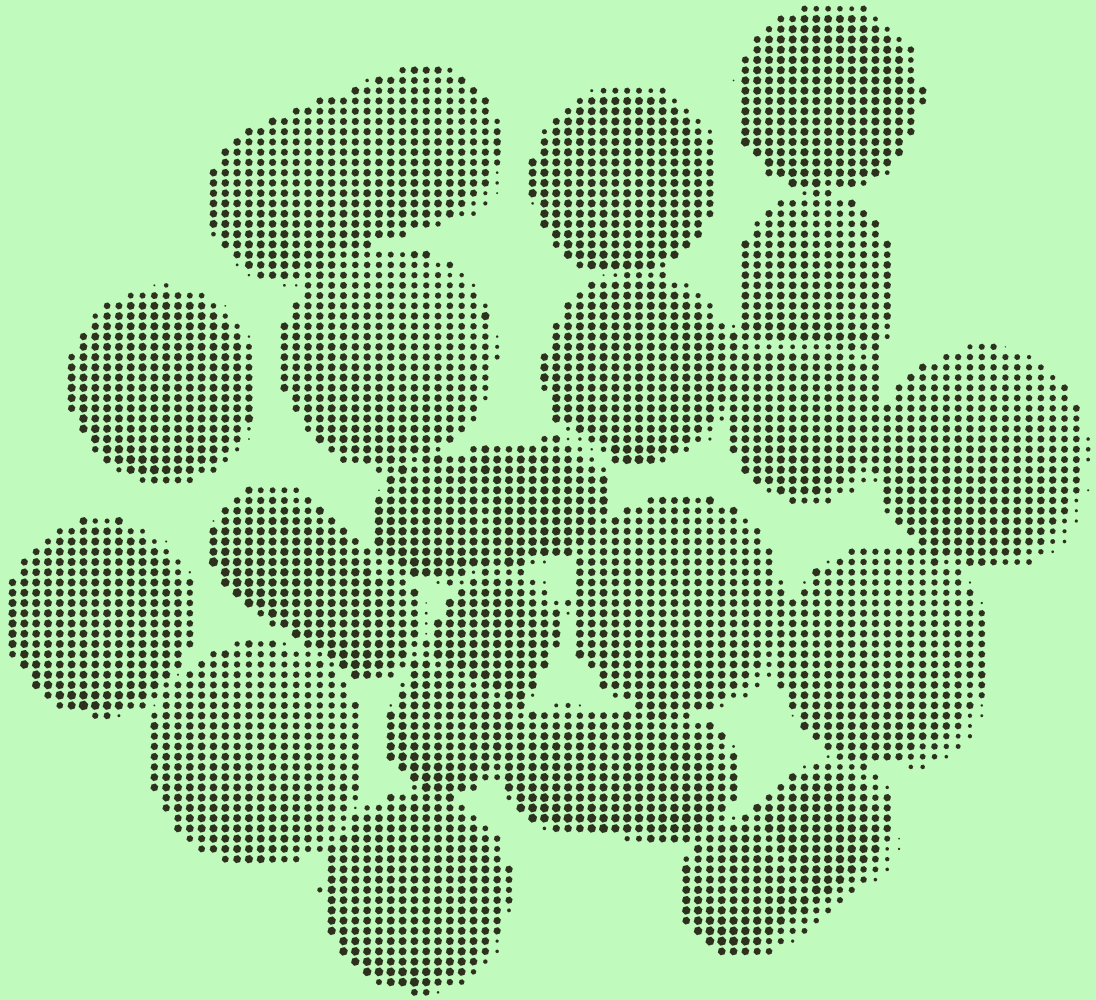
Spørsmål?

Ta gjerne kontakt med oss på **mt@dmp.no**



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