Norwegian Medical Products Agency

Pilot for felles Nordiske ENEN pakninger - en status

8.5.2025

Tatjana Aune
Merkingslaget, PI

- Nordiske ENEN pakninger – informasjon på DMPs side
- Hva er en felles Nordisk ENEN pakning
- Hensikten med Nordiske ENEN pakninger

- Krav ved søkand om ENEN Nordisk pakning
- Consolidated list of “hospital medicinal products”
- Preparatkriterier
- Søknadsprosessen for å oppnå en ENEN Nordisk pakning

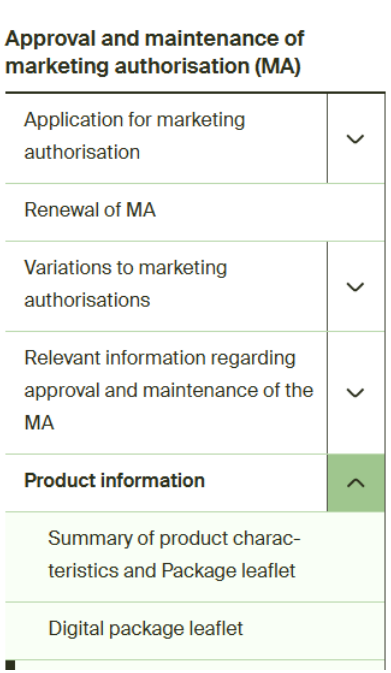
- De første to gokjente ENEN pakninger I Norden

- Hvordan jobber Norden med ENEN Nordiske pakninger
- Retningslinjer og veiledere for Nordiske ENEN pakninger

1. Nordiske flerspråklige pakninger

2. ENEN Nordiske pakninger – English-only Nordic packs

- 63(3) – unntak fra krav om nasjonalt språk på nordisk pakning



Packaging of medicinal products

Published: 21/10/2023 | Updated: 13/02/2025 See change log

Labeling includes both labeling text and mock-ups. All text on mock-ups must be in accordance with the approved labeling text.

National guideline on packaging

Nordic mock-up collaboration

Nordic multilingual packages

Nordic English-language packages

Kilde DMP:
https://www.dmp.no/en/approval-of-medicines/approval-and-follow-up-of-marketing-authorisation-ma/Product-information---templates-and-guidance/packaging#Nordisk-merkingssamarbeid-175759

Hva er en felles Nordisk ENEN pakning:

ytre og indre emballasje med kun engelsk spark på (mock-up)
\+ **pakningsvedlegg i pakningen med kun engelsk språk**
\+ **ePV tilgjendelig** i hvert Nordisk land – nasjonalt språk
\+ **Vnr.**
\- ~~Nasjonal BlueBox~~

= felles Nordisk ENEN pakning

Hensikt

Felles Nordisk tilnærming - tilgjengelighet

Legemidler der vi har sett at flerspråklige Nordiske pakninger ikke øker tilgjengeligheten

Bærekraft

Er ENEN pakninger
noe det Nordiske markedet
er klart for

Erfaringer

Samler erfaringer med ePV

Norwegian Medical Products Agency

English

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Common nordic packages for better availability

Published: 02/12/2024

Starting from the new year, a pilot project will introduce English-language common nordic packages. This aims to improve the availability by simplifying production and distribution.

he Nordic medicines agencies are collaborating on a project to increase the number of common Nordic packages. The project will test how English-language common Nordic packages will work across all Nordic countries: Denmark, Finland, Iceland, Norway, and Sweden.

The goal is to enhance supply security and availability to essential hospital products in all Nordic countries, ensuring that Nordic patients have access to more medicines.

Preventing Shortages

There has for a long time been a shortage of several essential medicines in the Nordic markets. Each Nordic country, being a relatively small market, is less attractive than larger markets. This issue often affects medicines used by small and specific patient groups that are rare but vital. Securing enough medicines becomes more challenging when separate packages in different languages are required.

Currently, there is a requirement for national languages on packages, and there is extensive use of common Nordic packages that includes various Nordic languages. The new pilot explores using only English for packages and the printed package leaflets for certain selected, particularly vulnerable medicinal products.

The intention is not for healthcare personnel and patients to have to read the English package leaflet. Package leaflets in all the Nordic languages will be digitally available.

Improved Access

"We hope this project will contribute to better access to essential medicines. Reducing the use of Nordic languages on certain packages is feasible as we have digital package leaflets available. These are always up-to-date and accessible to both patients and healthcare personnel," says Dag Jordbru, Strategic director, Regulatory affairs and better use of medicine at NOMA.

This pilot allows medicines produced in low volumes and listed on a shared list to be exempt from Nordic language requirements. This applies to certain hospital medicines, administered by healthcare personnel.

Application process for companies

The pilot allows marketing authorisation holders to apply for their products to be included in the pilot.

"We encourage relevant pharmaceutical companies to apply for participation in the pilot to strengthen supply security for these medicinal products throughout the Nordics. This can simplify production and distribution, and also help ensure that patients gain better access to essential medicines," says Jordbru.

The pilot will last for five years.

More information on which medicinal products are eligible for the pilot and guidance on applying for English-language common Nordic packages.

More information on packaging and nordic mock-up-collaboration.

Kilde DMP:
https://www.dmp.no/en/news/common-nordic-packages-for-better-availability

https://www.dmp.no/en

Krav ved søkand om ENEN Nordisk pakning?

1. Virkestoffet i Nordiske virkestoff listen for legemidler til sykehus bruk
2. Administreres av helsepersonell
3. < 5000 pakninger forventet solgt i Norden/år
4. Nasjonal ePV og eSmPC i hvert Nordisk land
5. Produktinformasjonen harmonisert i Norden

Kilde MPA Sverige:
https://www.lakemedelsverket.se/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/guideline-on-common-nordic-en-en-only-packages-1.pdf

Consolidated list of “hospital medicinal products”

ATC level 5	ATC description The Anatomical Therapeutic Chemical code: a unique code assigned to a medicine according to the organ or system it works on and how it works. The classification system is maintained by the World Health Organization (WHO).	Administration form is for some substances limited
B - Blood and blood forming organs		
	B01A - Antithrombotic agents	
B01AC16	EPTIFIBATIDE	
B01AD11	TENECTEPLASE	
J - Antiinfectives for systemic use		
	J01A - Tetracyclines	
J01AA02	DOXYCYCLINE	injection
	J01C - Beta-lactam antibacterials, penicillins	
J01CA04	AMOXICILLIN	injection
J01CR02	AMOXICILLIN, CLAVULANIC ACID	injection
	J01D - Other beta-lactam antibacterials	
J01DD02	CEFTAZIDIME	
J01DF01	AZTREONAM	
J01DI54	TAZOBACTAM, CEFTOLOZANE	
	J01G - Aminoglycoside antibacterials	
J01GB01	TOBRAMYCIN	injection
J01GB03	GENTAMICIN	Implant
	J02A - Antimycotics for systemic use	
J02AA01	AMPHOTERICIN B	
	J05A - Direct acting antivirals	
J05AB06	GANCICLOVIR	injection
L - Antineoplastic and immunomodulating agents		
	L01A - Antineoplastic agents	
L01AB01	BUSULFAN	
	L01B - Antimetabolites	
L01BB05	FLUDARABINE	
	L01C - Plant alkaloids and other natural products	

ATC level 5	ATC description The Anatomical Therapeutic Chemical code: a unique code assigned to a medicine according to the organ or system it works on and how it works. The classification system is maintained by the World Health Organization (WHO).	Administration form is for some substances limited
L01CA01	VINBLASTINE	
	L03A - Immunostimulants	
L03AX16	PLERIXAFOR	
	L04A - Immunosuppressants	
L04AC02	BASILIXIMAB	
N - Nervous system		
	N03A - Antiepileptics	
N03AE01	CLONAZEPAM	injection
S - Sensory organs		
	S01L - Ocular vascular disorder agents	
S01LA01	VERTEPORFIN	
V - Various		
	V03A - All other therapeutic products	
V03AF02	DEXRAZOXANE	

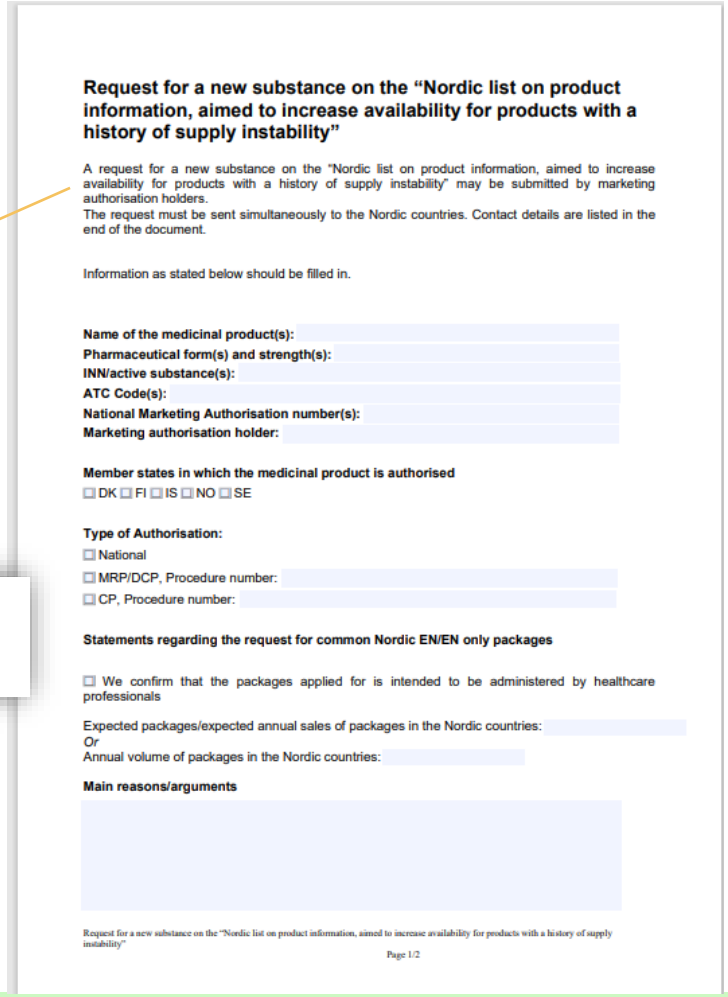
NB: Basert på kritisk legemiddelliste og legemidler med kjent tilgjengelighets utfordringer i de Nordiske landene.

Consolidated list of “hospital medicinal products”

Søknadsskjema for nytt virkestoff i Nordiske listen:

Request for a new substance on the “Nordic list on product information, aimed to increase availability for products with a history of supply instability”

A request for a new substance on the “Nordic list on product information, aimed to increase availability for products with a history of supply instability” may be submitted by marketing authorisation holders.



Request for a new substance on the “Nordic list on product information, aimed to increase availability for products with a history of supply instability”

A request for a new substance on the "Nordic list on product information, aimed to increase availability for products with a history of supply instability" may be submitted by marketing authorisation holders.
The request must be sent simultaneously to the Nordic countries. Contact details are listed in the end of the document.

Information as stated below should be filled in.

Name of the medicinal product(s):
Pharmaceutical form(s) and strength(s):
INN/active substance(s):
ATC Code(s):
National Marketing Authorisation number(s):
Marketing authorisation holder:

Member states in which the medicinal product is authorised
☐ DK ☐ FI ☐ IS ☐ NO ☐ SE

Type of Authorisation:
☐ National
☐ MRP/DCP, Procedure number:
☐ CP, Procedure number:

Statements regarding the request for common Nordic EN/EN only packages

☐ We confirm that the packages applied for is intended to be administered by healthcare professionals

Expected packages/expected annual sales of packages in the Nordic countries:
Or
Annual volume of packages in the Nordic countries:

Main reasons/arguments

Request for a new substance on the "Nordic list on product information, aimed to increase availability for products with a history of supply instability"

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Preparatkriterier:

CAPs og NAPs
Viktig at det foreligger harmonisert grunnlag!

Samme kriterier som for flerspråklige Nordiske pakninger:

- samme navn, styrke, legemiddelform
- identiske SmPC, pakningsvedlegg og merking (produktinformasjon)
- eksisterende MTer
- nye MTer

Søknadsprosessen for å oppnå en ENEN Nordisk pakning?

- søker om ENEN Nordisk pakning søker du samtdig om unntak fra kravet om nasjonalt språk på pakningen og i pakningsvedlegget jamfør Art 63(3) Dir. 2001/83 EC
- bruker søkandsskjema for ENEN Nordisk pakning
- får svar fra et av de Nordiske myndighetene med et felles Nordisk vedtak
- får nasjonalt vedtak fra hvert Nordisk land

Dokumentasjonskrav:

- Utfyllende informasjon i veiledningen for ENEN Nordiske pakninger for CAPs og NAPs

https://www.lakemedelsverket.se/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/guideline-on-common-nordic-en-en-only-packages-1.pdf

De første godkjente ENEN pakninger I Norden

- sårbare for mangel
- lave salgsvolum I Norden
- sikker informasjon med EN på paknigen
  + HP bruker ePV som er fortløpende oppdatert

- **Iqtopam** (clonazepam), i.v.
  - DCP
  - antiepileptikum
  - Ikke på NO markedet ved godkjenningstidspunkt

4.1 Therapeutic indications

Treatment of epilepsy, generalized seizures (absences, myoclonic seizures, tonic clonic seizures), partial seizures and status epilepticus in adults and adolescents from 12 years of age.

- **Mozobil** (plerixafor), s.c.
  - DK/NO og SE/FI/IS pakninger på markedet
  - Immunmodulerende
  - Veldig lav salgsvolum per år
  - ENEN Nordisk pakning blir lansert på det Nordiske markedet

    august/September 2025

4.1 Therapeutic indications

Adult patients
Mozobil is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in adult patients with lymphoma or multiple myeloma whose cells mobilise poorly (see section 4.2).

Paediatric patients (1 to less than 18 years)
Mozobil is indicated in combination with G-CSF to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in children with lymphoma or solid malignant tumours, either:

- pre-emptively, when circulating stem cell count on the predicted day of collection after adequate mobilization with G-CSF (with or without chemotherapy) is expected to be insufficient with regards to desired hematopoietic stem cells yield, or
- who previously failed to collect sufficient haematopoietic stem cells (see section 4.2).

Metalyse	**p**lasminogenaktivator
Pharmaceutical form(s) and strength(s):	**10 000 units (50 mg) powder and solvent for solution for injection**
INN/active substance(s):	**tenecteplase**
ATC Code(s):	**B01AD11**
National Marketing Authorisation number (s):	**EU/1/00/169/006**

Hvordan jobber Norden med ENEN Nordiske pakninger?

NPG – Nordisk merkingsgruppe (DKMA + FIMEA + IMA + NOMA + MPA)

- Felles SOP for Nordisk prosedural samarbeid
- Guideline for ENEN Nordiske pakninger
- Mottak av søknader og behandling
- Nordisk vedtak
- Alle Nordiske myndigheter utstedere nasjonalt vedtak

- Rullerende RMS/CMS roller i Norden

Retningslinjer og veiledere for Nordiske ENEN pakninger:

Samleside MPA Sverige – felles Nordisk side:

How to prepare package labelling | Swedish Medical Products Agency | Läkemedelsverket

GUIDELINE ON COMMON NORDIC EN/EN ONLY

GUIDELINE ON COMMON NORDIC EN/EN ONLY PACKAGES

Request for exemption to allow common Nordic EN/EN only packages for human medicinal product(s

https://www.lakemedelsverket.se/en/forms/request-for-nordic-cooperation

Nordic list on product information, aimed to increase availability for products with a history of supply instability

https://www.lakemedelsverket.se/globalassets/dokument/tillstand-godkannande-och-kontroll/forsaljningstillstand/produktinformation/nordic-pi-list-to-increase-availability.pdf

Request for a new substance on the “List of substances included in the pilot”

https://www.lakemedelsverket.se/en/forms/request-for-a-new-substance-on-the-list-of-substances-included-in-the-pilot

Kontakt:
PI@noma.no

Emnefelt:
ENEN Nordiske pakninger

Takk

dmp.no

helsenorge.no

Direktoratet for medisinske produkter

Norwegian Medical Products Agency