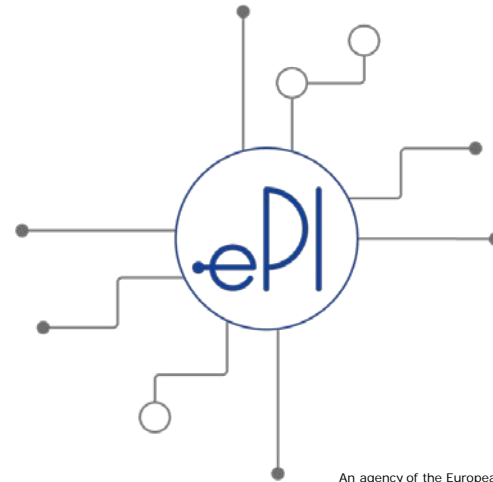


Collaboration with the Norwegian Pharmaceutical Compendium

Electronic structured data is key to successful dissemination of medicinal product information

Vibeke Åbyholm – Norwegian Medicines Agency



The Norwegian Pharmaceutical Compendium (Felleskatalogen)

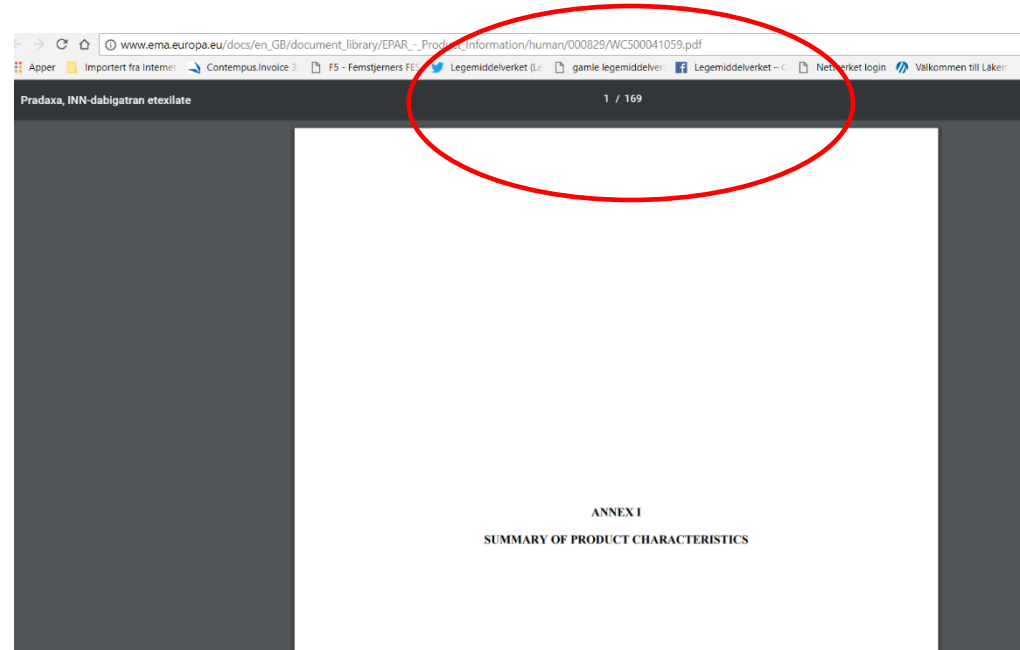
- The compendium is the most used source to information on medicinal products among HCPs and patients in Norway.
- Information about all medicinal products in Norway (including generics & medicinal products without MA used in compassionate use programs).
- The compendium refines the SmPC and presents it in a user-friendly structured format, allowing the information to “talk” to other electronic health systems. Free to use.
- It is the only source to PIL in Norway.

The Norwegian Pharmaceutical Product Compendium



A PDF can not compete with electronic structured data

- The Norwegian Medicines Agency has a «search for medicines» web-page – we link to EMA's website with pdfs of the SmPCs.
- We know that HCPs do not use this as a tool- it is too comprehensive – impossible to navigate a pdf.
- The ePI project enables the NCAs to offer information about medicinal products in a relevant format.



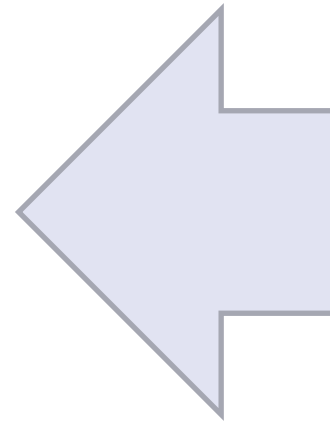
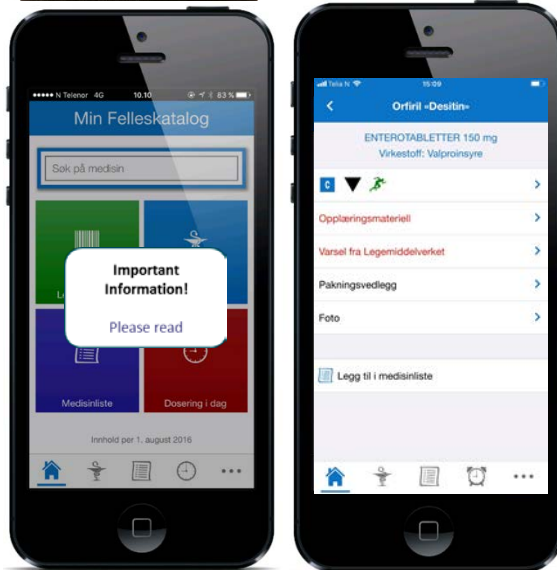
While waiting for the ePI..

- NOMA collaborates with the compendium - added value for both.
- NOMAs information is easily integrated into the compendium which structures the SmPCs & PILs into xml-format, making it easy for the user to get an overview of the content.
- NOMA makes sure that the information accurately presents the most important content of the SmPCs.
- The compendium uses standardised vocabularies.
- Supports accessibility formats (videos, graphics, audible formats).

The screenshot displays the 'Felleskatalogen' website interface. At the top, there is a search bar and navigation options like 'Legemidler til mennesker' and 'Legemidler til dyr'. The main content area shows the product 'Isotretinoin Orifarm' by Orifarm Generics. Key information includes:

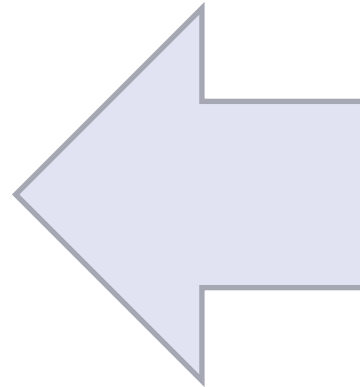
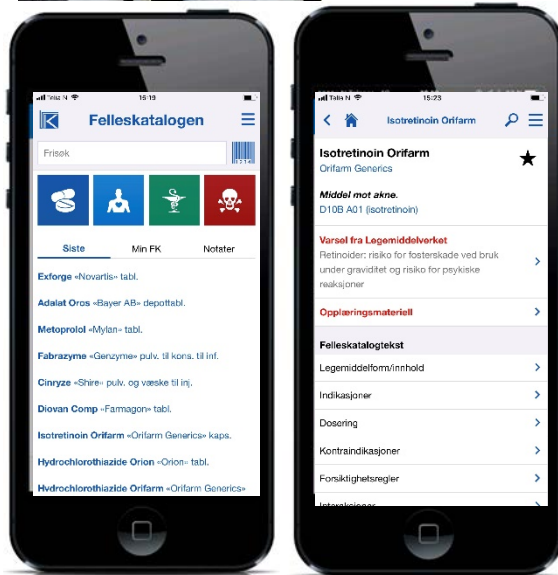
- Middel mot akne.** (Medicine for acne)
- ATC-nr.: D10B A01**
- Varsel fra Legemiddelverket:** Retinoider: risiko for fosterskade ved bruk under graviditet og risiko for psykiske reaksjoner.
- Oppføringsmaterieill:** RMP-materieill i samarbeid med Legemiddelverket - Les mer om RMP-materieill (risikominimeringstiltak) hos Legemiddelverket
- Brosjyre helsepersonell:** Isotretinoin Orifarm sjekkliste, farmasøyt Isotretinoin Orifarm sjekkliste, lege
- Brosjyre pasient:** Isotretinoin Orifarm påminnelseskort, pasient
- Indikasjoner:** Alvorlige former for akne (f.eks. nodular akne eller acne conglobata eller akne med risiko for permanent arrdannelse) som er resistent mot adekvat standardbehandling med systemiske antibiotika og lokal behandling.
- Dosering:** Skal bare forskrives av eller under overvåkning av lege med erfaring i bruk av

Patients



- Search for medicines
- Barcode reading
- Personalized medicines list
- My daily dose
- Package leaflets imported from EMA & NOMA
- Photos of tablets/capsules
- Instruction videos (patient content RMP)
- Real time alerts from NOMA on important safety issues, shortage situations etc.

Health Care Professionals



- Prescription texts (mainly based on the approved summaries of product characteristics (SmPCs))
- **Risk Management Plans (RMP) from NOMA**
- **Real time alerts from NOMA on important safety issues, shortage situations etc.**
- **Drug interactions from NOMA's database**

Any questions?

Further information

pcwpsecretariat@ema.europa.eu

See websites for contact details

European Medicines Agency www.ema.europa.eu

Heads of Medicines Agencies www.hma.eu

European Commission www.ec.europa.eu

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