Informationen zum Umgang mit elektronischen Produktinformationen

in einzelnen EEA-Ländern

Nachfolgend sind einige Informationen zusammengestellt, wie das Thema elektronische Packungsbeilage in unterschiedlichen Ländern des europäischen Wirtschaftsraums unter Berücksichtig der gemeinsamen Rechtsgrundlage der RL 2001/83/EG umgesetzt wird. Die Informationen sind frei zugänglich und öffentlich verfügbar. Soweit Informationen Websites entnommen wurden, sind die Links entsprechend beigefügt, um eine Überprüfung bzw. weitergehende Lektüre zu ermöglichen.

Die Informationen gliedern sich wie folgt:

1. Informationen zu den Regelungen in den Niederlanden bzw. zum dortigen Pilotprojekt
2. Informationen zu Dänemark, wo elektronische Patienteninformation bereits verfügbar sind.
3. Informationen zu Norwegen, wo elektronische Produktinformationen für Rx-Produkte zur Verfügung stehen.

Neben dem o.g. Pilotprojekt in den Niederlanden, welches behördlich unterstützt wird, wird auch das Projekt in Frankreich durch die nationale Zulassungsbehörde gesteuert. Weitere Details zu den derzeit laufenden bzw. durchgeführten Pilotprojeken im EWR sind in den jeweiligen Anlagen zu finden. Die Übersichten wurden freundlicherweise von der Rote Liste Service GmbH, welche auch am deutschen Pilotprojekt „diGItal“ beteiligt ist, zur Verfügung gestellt. Einige der Präsentationen wurden im Rahmen des letztjährigen ***ePI Summit 2023*** gezeigt.

Weitere Informationen zum Pilotprojekt „diGItal“, welches von den Herstellerverbänden BPI, ProGenerika, Pharma Deutschland und VfA in Deutschland gemeinschaftlich unterstützt wird, können gerne zur Verfügung gestellt werden.

Nach Verständnis von Pharma Deutschland gilt in allen EWR-Ländern, in denen Pilotprojekte durchgeführt werden, generell die Anforderung einer gedruckten Packungsbeilage in der Packung eines Arzneimittels. Ggf. sind Ausnahmen für Krankenhausprodukte unter bestimmten Bedingungen möglich (vgl. Regelungen, welche während der Corona-Pandemie galten).

Hintergrund der Regelung, einen Code auf der Packung zu erlauben, welcher zu weiteren Informationen über das Arzneimittel, einschließlich der Packungsbeilage, führt, ist Artikel 62 der RL 2001/83/EG. Weitere Informationen zu der auf Ebene der CMDh abgestimmten Vorgehensweise hierzu finden sich im beigefügten CMDh_position_paper_on_mobile_scanning_and other technologies (aufgerufen am 15.08.2024, als Anlage beigefügt).

1. Informationen zu den Regelungen in den Niederlanden

„A package leaflet is inserted in a medicinal product's packaging (Section 69, subsection 2 of the Medicines Act).“

„In exceptional cases, it is possible that the Dutch package leaflet is not delivered IN the package but WITH the package. Further information about this can be found in section 6.4 of this document. Reference is also made to the EMA website for further information and the procedure that must be followed for products that are accepted through the Centralised procedure.“

> „6.4 QR code
>
> It is permitted to include a QR code on the packaging and/or in the package leaflet. Annex 2 at the end of this document describes the conditions that must be met for the use of the QR code on the packaging and/or in the package leaflet for products that have been granted a national marketing authorisation. This policy also applies to parallel-imported medicinal products and for marketing authorisations authorised via replica marketing authorisation procedures. The same approach applies for techniques that have the same function as the QR code.“
>
> Annex II
>
> „(...) In order to draw patients' attention to the potential differences between the most recently approved product information and the printed package leaflet, the following sentences must be stated in the package leaflet:
> 'Detailed and up-to-date information for this medicinal product can be obtained by scanning the QR code with a QR reader, an application (app) for smartphone or tablet. The same upto-date information about the medicinal product is also available via the following URL: and on the website of the Medicines Evaluation Board. (www.geneesmiddeleninformatiebank.nl)'.
> These sentences must be included at the end of the package leaflet (as the last sentences).“
>
> (siehe Anlage: Policy document Package leaflet of pharmaceutical products, MEB 5, December 2021)

NL: Antrag auf Ausnahmegenehmigung:

Kamerbrief verzoek ontheffing voor onderzoek digitale productinformatie ziekenhuisgeneesmiddelen | Kamerstuk | Rijksoverheid.nl

„Minister Dijkstra (Medizinische Versorgung) informiert die Abgeordnetenkammer über den Antrag an die Europäische Kommission auf eine Befreiung von der Verpflichtung, Arzneimittel mit einer Packungsbeilage aus Papier zu liefern. Mit dieser Ausnahmeregelung will der Minister eine Pilotstudie für zwei Jahre genehmigen, um digitale Produktinformationen für Krankenhausarzneimittel zu erforschen, die die Packungsbeilage aus Papier ersetzen.“

Siehe auch beigelegter Brief an die EU-Kommission; [Request for permission to start a pilot project of electronic package leaflet for medical products in hospitals | Brief | Rijksoverheid.nl]

2. **Informationen zu Dänemark:**

„**A package leaflet with information about the medicine comes with all medicine packs**. You can find **all the package leaflets placed in packs** of medicine that are sold in Denmark at **indlaegsseddel.dk**“

→ Find medicines (laegemiddelstyrelsen.dk)

Q & A about package leaflets and labelling (laegemiddelstyrelsen.dk):

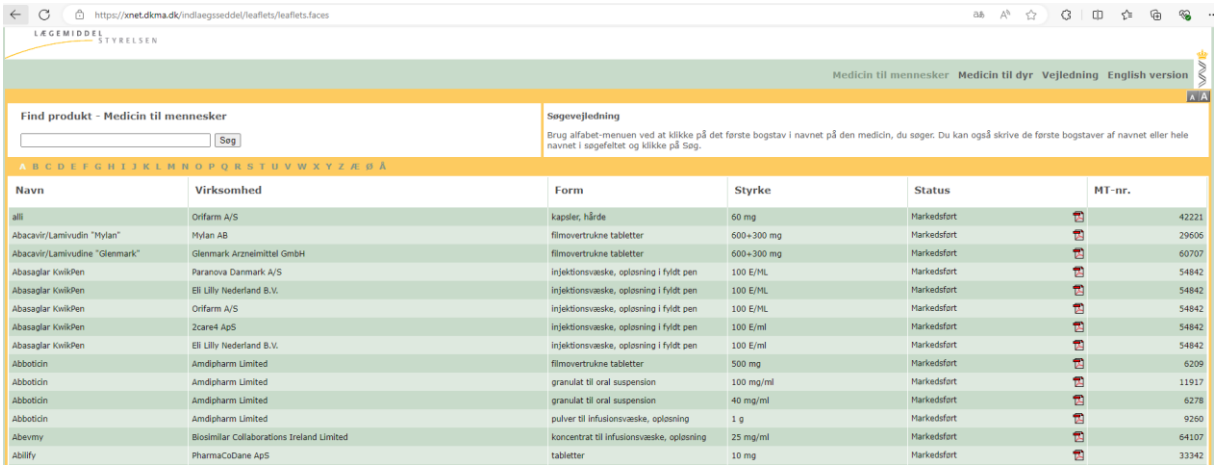
How fast should variations be implemented into the package leaflet?

Answer: Generally, the deadline for implementing variations into the package leaflet is one year ***if it appears from the current package leaflet that the most recent package leaflet is available at indlægsseddel.dk and the updated package leaflet is uploaded no later than 3 months after approval of the variation.***(...)

If these two conditions are not satisfied, changes to the package leaflet must be implemented within 6 months after approval of the variation.

In this context, implementation means the time when packages with the updated package leaflet are supplied to the wholesaler.

(Ref.: Guidelines no. 9846 of 6. juli 2020 on variations to marketing authorisations for medicinal products).



3. **Informationen zu Norwegen:**

Digital package leaflet - Norwegian Medical Products Agency (dmp.no) - aufgerufen am 15. August 2024

- **Digital package leaflet**

All medicines have a package leaflet with important information. ***The package leaflet is available inside the pack and as a digital version online at felleskatalogen.no. The digital version is always up-to-date which increases patient safety.***

The paper package leaflet available inside the pack has clear limitations. Among other things, it takes a long time to update them: printing, packing and distribution, for example.

- **Benefits of the digital package leaflet**

The main advantage of the digital package leaflet is that it's always up-to-date. The digital version makes it possible to add useful information for patients, such as video with instructions for proper use. It's easily accessible via mobile phone and computers, and scanning of the barcode printed on the pack takes you directly to the latest version of the package leaflet at felleskatalogen.no

- **How to find the digital package leaflet**

You can find the digital version by scanning the barcode on the medicine pack. Follow these steps:

  - Using your mobile phone, go to the website felleskatalogen.no
  - Tap the icon in the search bar that looks like a QR code, or tap the Finn pakningsvedlegg (Find package leaflet) menu option
  - A black screen with a red stripe is displayed
  - Give the website access to your camera
  - Scan the barcode with your camera
  - The package leaflet is displayed
  - Use of digital package leaflets may bring many benefits.

- **Medicine distribution and multinational packs**

The requirement for a Norwegian package leaflet in all medicine packaging may be a barrier against implementing multinational packs. NOMA therefore works towards a transition to digital package leaflets in Norway and the Nordic region.

A larger market for the packs sold in Norway will reduce vulnerability to medicine shortages and will make it more cost-effective to market products in Norway as well. Most medicine shortages are being solved at present by allowing sales of packs from other countries than Norway. With increased use of multinational packs, the number of shortages will probably decrease because the "foreign pack" will be identical to those sold in Norway.

Many medicines that are particularly suitable for children are not distributed in Norway due to the small market, making it unprofitable. With multinational packs, the additional cost to access the Norwegian market will be significantly reduced.

A digital format provides more options for supplementary information, such as video, images and illustrations, which is updated quickly and is cost-effective.

- **Reuse across different channels**

In addition to the paper version in the pack, the European Medicines Agency (EMA) offers on its website the package leaflets in different EU languages as PDF documents. Pharmaceutical manufacturers and European pharmaceutical authorities have been pushing for these to be available in an open, structured data format, which enables access across different digital channels.

The national pharmaceutical product compendia in the Nordic region aim to make package leaflets available in all Nordic languages in a common European structured data format. In 2024, patients and healthcare professionals will be able to easily access package leaflets in all Nordic languages.

- **European cooperation**

In Europe, work has been underway for a long time on an agreement for the development, availability, and use of electronic product information, also called ePI. This work is under the direction of the EMA. Full adoption of digital product information relies on changes in the law and the regulatory environment. Thus far, the EMA has prepared key principles on how this is to happen in Europe. See the key principles on the EMA website(External link).

The adoption of the ePI is difficult because different European countries have different needs and different levels of digital maturity. European patient and healthcare personnel organisations have been critical of promoting digital versions, as many believe it will discriminate against the elderly population, who use medicines the most.

- **Regulatory changes**

The European Commission is now working on extensive changes to EU pharmaceutical legislation(External link). NOMA wants each member state to be able to decide whether and when it wants to use the digital package leaflet as a replacement for the paper version. If the EU's new pharmaceutical legislation gives this opportunity, Norway will take the lead in introducing digital package leaflets.

- **Norway and the Nordic countries – digital literacy**

In Norway and the Nordic countries, digital literacy is higher, and the infrastructure is better than in many other European countries. Almost everyone has access to the internet on their smartphones and/or computers. Digital information on medicine from Felleskatalogen is well known and is often used by Norwegian healthcare professionals and many patients. User surveys show that Felleskatalogen is the most widely used source of information on medicines in Norway. As of 22 January 2024, Felleskatalogen had 6,25 million site visits package leaflets in the last twelve months, corresponding to about 17 000 views per day.

Digital package leaflets are therefore ready to replace printed package leaflets in Norway and the Nordic countries.

On this basis, NOMA wants patients and healthcare professionals to use digital package leaflets as their first choice.

Regelungen zur Umsetzung von Textänderungen in Norwegen

"All QP released batches for a medicinal product shall have updated package leaflet implemented at least 6 months after the date of approval. ***Nevertheless, the Norwegian Medicines Agency may accept a 12 months implementation deadline from the approval***

date, if the conditions below are fulfilled. Delayed implementations in the package leaflet, later than 6 months, which do not fulfil the conditions below, shall be applied for as batch-specific variations

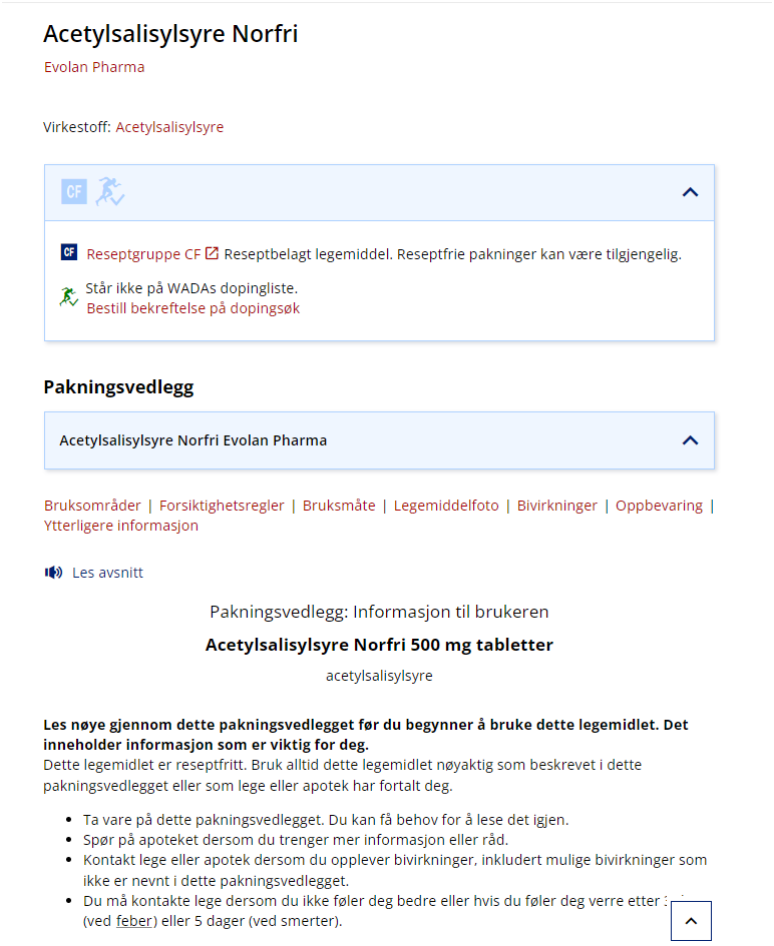
Conditions for 12-month implementation deadline

1. *Section 6 (last paragraph) in the package leaflet for human medicinal products shall contain a reference to Felleskatalogen.no . See «Q&A» below for further information.*
2. *The last approved Package Leaflet shall be available on Felleskatalogen.no web site within 3 months from the approval date.*

NoMA may determine a shorter implementation deadline of the updates in the package leaflet. If the updates include any safety issues for the medicinal product, NoMA may demand immediate implementation with the first produced batch or consequent withdrawal.“

Quelle: Implementation date and batch-specific variations - Norwegian Medical Products Agency (dmp.no) -aufgerufen am 15. August 2024

Felleskatalogen enthält aufbereitete Informationen für medizinische Fachkreise aber auch die Texte der Gebrauchsinformationen für Rx-Arzneimittel (Beispiel zufällig gewählt)**:**



Acetylsalisylsyre Norfri

Evolan Pharma

Virkestoff: Acetylsalisylsyre

CF

Reseptgruppe CF Reseptbelagt legemiddel. Reseptfrie pakninger kan være tilgjengelig.

Står ikke på WADAs dopingliste.
Bestill bekreftelse på dopingsøk

Pakningsvedlegg

Acetylsalisylsyre Norfri Evolan Pharma

Bruksområder | Forsiktighetsregler | Bruksmåte | Legemiddelfoto | Bivirkninger | Oppbevaring | Ytterligere informasjon

Les avsnitt

Pakningsvedlegg: Informasjon til brukeren

Acetylsalisylsyre Norfri 500 mg tabletter

acetylsalisylsyre

Les nøye gjennom dette pakningsvedlegget før du begynner å bruke dette legemidlet. Det inneholder informasjon som er viktig for deg.
Dette legemidlet er reseptfritt. Bruk alltid dette legemidlet nøyaktig som beskrevet i dette pakningsvedlegget eller som lege eller apotek har fortalt deg.

- Ta vare på dette pakningsvedlegget. Du kan få behov for å lese det igjen.
- Spør på apoteket dersom du trenger mer informasjon eller råd.
- Kontakt lege eller apotek dersom du opplever bivirkninger, inkludert mulige bivirkninger som ikke er nevnt i dette pakningsvedlegget.
- Du må kontakte lege dersom du ikke føler deg bedre eller hvis du føler deg verre etter : (ved feber) eller 5 dager (ved smerter).

Information to the Pharmaceutical companies
The Norwegian Pharmaceutical Product Compendium (Felleskatalogen AS) is a private company owned by the Association of Pharmaceutical Industry in Norway (LMI). The company was established in 1958.

The mission of Felleskatalogen is to provide healthcare personnel with structured, updated and easily available information about pharmaceutical products on the Norwegian market. Felleskatalogen is the “number one” information source for all groups of healthcare personnel in Norway[1]. We believe that knowledge about pharmaceutical products is critical for safe prescription and use of medicines.[1]Based on user surveillance 2016, The Norwegian Medicines Agency.

For information about our information elements, information platforms, cooperators and practical information, see brochure human and brochure veterinary.

FK SHARE
We use FK SHARE to share Felleskatalog texts, educational materials and instruction movies with the companies.

Information to the Pharmaceutical companies - Felleskatalogen (besucht am 15.08.2ß24)

Pharma Deutschland, 20240816/Pi