Transition from paper PIL to electronic PIL in the packaging

Sustainable use of the Patient Information Leaflet

Vereniging
Innovatieve
Geneesmiddelen

Content

1. Description of the pilot project for the Netherlands

1.1 Concept of the pilot

The pilot project proposes a transition from paper patient information leaflet (PIL) in packaging to electronic PIL (e-PIL):

- For selected registered medicinal products available on the Dutch market but limited to medicinal products restricted to hospital use and in line with the SmPC (Summary of Product Characteristics).
- Using the MEB-CBG website www.geneesmiddeleninformatiebank.nl as the unique trusted reference source. Piloting during a pre-defined period with granted approval until 31-12-2026 by the European Commission or the National Competent Authorities.
- Exemption from Art 58 Dir2001/83 is granted.
- As cosigner of the Green Deal Sustainable Care 3.0, the VIG and its members have committed themselves to pillar 3, reducing the use of resources. With this pilot, the MAHs contribute to sustainability by reducing CO2 footprint and paper waste in packaging used in hospitals. Sustainability can be measured by the elimination of the paper leaflet in volumes. e.g., consumption of water, electricity, paper, and CO2 output.

1.2 Objective of the pilot

This pilot aims the following:

- To demonstrate the equivalence of e-PIL compared to paper PIL in terms of dissemination of information and effective use of medicines in the hospital setting.
- To demonstrate that HCPs feel just as comfortable using digital product information as they do using conventional paper leaflets.
- To measure if outcomes of the Dutch pilot are comparable with outcomes from other pilots (e.g., in Belgium & Luxembourg, Spain, Baltic States etc.). The outcomes are expected to be equivalent.
- To reduce paper use in medicinal packaging without compromising patient safety information.

1.3 Motivation of the pilot

The incentive to this pilot comes from a joint effort to reduce the use of paper in medicinal products and increase sustainability in our products:

- To meet a public desire of paper waste reduction
- To investigate possibilities in the light of the new Pharmaceutical Legislation at a national level
- To improve efficiency in packaging supply chain and hospitals and have the opportunity for a flexible approach.

1.4 Project members

The project group consists of the National Hospital Pharmacists Association (NVZA), the Vereniging Innovatieve Geneesmiddelen (VIG), and delegates from the Expert Group Regulatory Affairs, all of whom are members of the companies associated with the VIG.

The Medicines Evaluation Board (CBG), the Dutch Health Inspectorate (IGJ) and the Ministry of Health (MoH) are involved for advice and review in relation to this pilot.

2. Process

The derogation to supply hospital packages without a paper leaflet has been granted on 11 November 2024 by the European Commission.

In contrast to the Belgian/Luxembourgian project, outreach for participation will be conducted by VIG rather than the competent authority CBG. Therefore, initially, only VIG members will participate in the pilot. The derogation requested will allow partnership with companies throughout the duration of the pilot.

In 2025 (Q2), non-VIG members will be able to join the pilot, provided they comply with the established rules of the pilot.

2.1 Request

Companies can submit a request to participate in the pilot by completing the template for participation. This template, part of an informational starting package, will be provided upon request.

The list of medicinal products received as candidates for the pilot project will be checked by the hospital pharmacists in the working group based on the preset criteria. Subsequently, the list of potential candidates will be provided to the CBG for confirmation of participation before inclusion in the pilot project.

2.1.1 Criteria for medicinal products to be included in the pilot project & call for candidates

For the scope of this pilot, only intramural medicinal products are eligible to participate in the pilot.

The criteria are as follows:

- The medicinal product should be used solely in hospitals. In some cases, medication is administered from the hospital at home, but these may only participate if they have been prepared for administration in the hospital pharmacy beforehand and are no longer dispensed in the original packaging.
- The packages may not contain information leaflets in several languages, so-called 'shared packs'. An exception applies to Benelux packages participating in the pilot in the Netherlands, Belgium, and Luxemburg because a similar pilot is running in Belgium and Luxemburg.

Products that have not yet received a Marketing Authorization need to be submitted via mail, not via this form, and will be assessed separately.

2.2 Release

Once confirmed by the National Competent Authority in the Netherlands (CBG), batches of medicines without the patient information leaflet printed on paper can be released.

The list of approved medicine will be posted on the VIG website and on the CBG website.

Production of packaging without leaflets may commence. Upon release,

1. IGJ will receive the batchnumber(s) by date of release
2. CBG will receive a compiled list of batchnumbers and products quaterly, drawn up by the VIG after notification from companies

These batches will then be distributed to hospitals in the Netherlands by the marketing authorization holder via their usual supply channel.

There is no deadline before when the batches must be released without a paper leaflet.

Of note: Some medicine will be released with a blank paper because these products are vulnerable to damage during transport without a paper insert or because of regulatory issues.

2.2.1 Source of electronic PIL for the pilot

The MEB-CBG website: www.geneesmiddeleninformatiebank.nl will be the trusted reference source during this pilot.

2.3 Closure

The pilot in the Netherlands has been granted by the European Commission until the end of December 2026. The final release of the batches of the medicines without a paper PIL in the packaging should occur before that date. The Ministry of Health (MoH) has been advised that the pilot should remain open until the new EU pharmaceutical legislation will become effective and to have a system of extension already pre-agreed.

Of note: Ending the pilot before EU regulation is implemented and reverting to the "old" situation with paper leaflet in the packages for products involved in the pilot is discouraged. It would present a logistical challenge for MAHs to revert packaging line setting etc. It will take at least 9 months to return to packages with paper leaflet.

2.4 Milestones

The following analyses are proposed:

- A survey for hospital pharmacists will be conducted: At the start (t=0) of the project to establish the baseline and after 12- and 18-months intermediate analysis will be done to evaluate access to, use of and reading of the electronic PILs.
- A survey for participating pharmaceutical companies after 9- and 15-months intermediate analysis will be done to evaluate the (medical) questions received and the amounts of paper saved due to the absence of paper PIL in the packaging of the concerned hospital medicines.

- To ascertain that patient information is not in any way impaired, interviews with patient engagement groups will be held at 0 and 12 months.

Additional survey(s) might be considered at a later stage of the pilot.

2.5 Communication

The NVZA will inform all hospital pharmacist about the general principles of this pilot, the organization and implementation in the Netherlands. Also provided is the reference to access the electronic version of the PIL.

The list of participating medicinal products is shared on CBG site. Addition of products will also be included quarterly by the MEB on their website until the end of the pilot.

Overall communication, including information for participants, will be shared on the site of the VIG, ePIL pilot - Vereniging Innovatieve Geneesmiddelen

Upon first delivery of paperless packages, the Dutch authorities (CBG, IGJ and MoH) will be informed by the VIG. MoH will inform Dutch Parliament and the European Commission (EC). In addition, the evaluation plan and reports, including the list of medicinal products and the therapeutic areas that will be included in the pilot project, will be shared with the EC.

2.6 Experiences from the Belgian/Luxembourgian pilot

The Dutch pilot is inspired by the combined Belgian/Luxembourgian pilot which has started in 2018. This pilot has concluded so far that the majority (98%) of hospital pharmacists have reported that the absence of the paper PIL has not caused any inconvenience in their daily practice.

Due to positive results in Belgium and Luxembourg, the pilot has been extended to August 2025. The results can be viewed here: e-PIL (electronic patient information leaflet) | pharma.be. The pilot will stop after this date.

While awaiting the new legislation, a request to extend the status of participating medicines and to allow companies to continue issuing medicine without a paper PIL has been made to the European Commission, until the new EU pharmaceutical legislation will become effective.

We will continue to monitor other European pilots in this field.

3. Future endeavors

In the strive to fully replace all paper patient information leaflets, the ultimate aim is to include non-hospital products as well. Currently, only products administered in the hospital setting are suitable to participate in the pilot. A possible extension of the pilot could be to include a selection of medicines. This extension of the pilot will be evaluated towards the end of 2025 and upon positive results from the ongoing pilot.

To achieve such, it is essential that pharmacists and patient organizations will join the working group as additional stakeholders. Also, as clear and easy access to the digital product leaflet is essential, it is advised to further identify the properties of a website for the best convenience of the users. Added value could be personalized and/or spoken information and a search feature beside the sustainability goal.

We will also explore the possibilities to refer to the product leaflet by using a QR-code. This code will be found on the packaging of the drug, linking to a website where the e-PIL is listed. Starting from mid-2026, a prerequisite is that there must be the prospect of a permanent situation.

We will advocate for a permanent situation through the acceptance of the new EU Pharma Legislation and strive to ensure that pilots will prepare us before the new EU Pharma Legislation comes into force. A uniform approach to pilots in Europe is our goal.