Ministry of Health, Welfare and Sport

> Return address P.O. Box 20350 2500 EJ The Hague

European Commission
Commissioner Stella Kyriakides
Rue de la Loi / Wetstraat 200
1049 Brussels
Belgium

Directorate-General Curative Care
Department of Medicines and Medical Technology

Address for visitors:
Parnassusplein 5
2511 VX The Hague
T 070 340 79 11
P.O. Box 20350
2500 EJ The Hague
www.rijksoverheid.nl

Reference
3854567-1067779-GMT

Information

Date

Subject Request for permission to start a pilot project of electronic package leaflet for medical products in hospitals

Dear Commissioner Kyriakides, dear Stella,

The Netherlands hereby requests permission to start a pilot project of electronic package leaflet (e-PIL) for medicinal products to be used within the hospital setting, referencing to the European Commission's report[1] on shortcomings in the summary of product characteristics and the package leaflet and how they could be improved in order to better meet the needs of patients and healthcare professionals.

In recommendation 4.5 of the report, it is recommended "*to explore the use of electronic media to provide the information included in the SmPC and PL in the future. It should be further explored what opportunities new technologies offer to optimize the presentation and design of SmPC and PL. In this context the opportunities for the information included in the SmPC and the PL to be more easily used as an integrated part of the care process should be explored. For example, developing mechanisms through electronic tools to inform patients and healthcare professionals on changes in other SmPC and PL should be considered.*"

Within the pilot project, specific approved medicinal products to be used within a hospital setting would not be accompanied by their leaflet. Instead, the information on the leaflet can be consulted online via the website of the national competent authority. The goal of the pilot project is to demonstrate whether the electronic package leaflet, in lieu of a paper version, has no (negative) effects on the proper use of medicinal products in a hospital setting and the provision of information to patients.

We envision a pilot project within the following conditions:

- Only medicinal products used in a hospital setting can be included. The products need confirmation by the national competent authorities to be included in the project;
- The medicinal products are administered by trained healthcare professionals in participating hospitals;

[1] Report from the Commission to the European Parliament and the Council in accordance with Article 59(4) of 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, COM(2017) 135 final.

Directorale-Generaal Curative Care
Department of Medicines and Medical Technology

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- Websites containing the information leaflet are set up or approved by the competent authorities and shall be communicated to the participating hospitals by the relevant associations;
- Our national authorities, i.e. the Medicines Evaluation Board and the Health and Youth Care Inspectorate, are in close contact with each other and with the Ministry of Health, Welfare and Sport to ensure the quality and safety of the health care provided during this pilot. In addition, a project team will be instated with representatives of the participating companies, hospital pharmacists and the Dutch hospital pharmacists' association (NVZA);
- We propose a pilot project for the duration of two years, with mid-term and end evaluations.

Such a pilot would, in principle, be contrary to Article 58 of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use, which states: "The inclusion in the packaging of all medicinal products of a package leaflet shall be obligatory unless all the information required by Articles 59 and 62 is directly conveyed on the outer packaging or on the immediate packaging."

We therefore ask for the Commission's permission to derogate from the provision of Article 58 of Directive 2001/83/EC and start a pilot project within the aforementioned conditions.

We are, of course, at your full disposal to discuss this pilot project if needed.

Yours sincerely,

Pia Dijkstra
Minister for Medicalcare