EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medicines: Policy, Authorisation and Monitoring

Brussels
SANTE.D.1/KS/am(2024)5699492

Dear Ms Dijkstra,

Thank you for your letter with the request for permission to start a pilot project of electronic package leaflet (e-PL) for medicinal products to be used within the hospital setting. The request is based on the report from the Commission to the European Parliament and the Council (COM(2017)135 final) on current 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.

According to your request the pilot project will include only specific medicinal products to be used within the hospital and administered by trained healthcare professionals in participating hospitals. The medicinal products included in the pilot project will be approved by the national competent authorities. These medicinal products would not be accompanied by the package leaflet in paper format in the packaging. Instead, the information on the package leaflet can be consulted online via the website containing the information leaflet that will be set up and approved by the competent authorities and shall be communicated to the participating hospitals by the relevant associations.

The goal of the pilot project as defined in the request is to demonstrate whether the electronic package leaflet instead of a paper version has no negative effects on the proper use of medicinal products in a hospital setting and providing of information to patients. The competent authorities, i.e. the Medicines Evaluation Board and the Health and Youth Care Inspectorate, will supervise the pilot project and will be 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).

The European Commission is actively facilitating the development of electronic tools to improve access for patients and healthcare professionals in the form of electronic product information (ePI). The Pharmaceutical Strategy for Europe recognises that better use of product information in electronic format could facilitate the delivery of information on the medicine to healthcare professionals and patients in the EU’s multilingual environment and support wider availability of medicines across Member States. The experience that will be acquired from this pilot project together with experience from similar pilots in other Member States is a valuable source of empirical evidence to support policy initiatives in this area, including the reform of the pharmaceutical legislation.

Ms. P. Dijkstra,
Minister for Medicalcare
Ministry of Health, Welfare and Sports

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We hereby confirm the European Commission's support for the envisioned pilot project for a period of two years. We would appreciate if you could, once available, inform us the starting dates of the pilot and provide the evaluation plan and annual evaluation reports, including the list of medicinal products and the therapeutic areas that will be included in the pilot project.

We hope for a fruitful collaboration between all the stakeholders involved in this pilot project - Medicines Evaluation Board and the Health and Youth Care Inspectorate, the Ministry of Health, Welfare and Sport, the Dutch hospital pharmacists' association (NVZA), representatives of the participating companies and hospital pharmacists.

We are looking forward to continuing learning from the pilot project of electronic package leaflet and wish you a successful implementation of this valuable initiative.

Yours faithfully,

Electronically signed

Olga SOLOMON
Head of Unit