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EDITORIAL
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Start-up first electronic leaflet (ePIL) project for medicines used in hospital environment in Spain

Puesta en marcha del primer proyecto piloto "prospecto electrónico" (ePIL) en medicamentos del ámbito hospitalario en España

Ana Herranz-Alonso[1], Olga Delgado-Sánchez[2], Ana Santamartina-Conde[3], Ana López de la Rica-Manjavacas[4]

[1] Hospitals Division of the Consejo General de Colegios Oficiales de Farmacéuticos. Spain. [2]Sociedad Española de Farmacia Hospitalaria. Spain. [3]Agencia Española del Medicamento y Productos Sanitarios. España. [4]Farmaindustria. Spain.

Author of correspondence
Ana Herranz Alonso
Servicio de Farmacia
HGU Gregorio Marañón
Dr. Esquerdo, 46
28007 Madrid. Spain.
Email:
aherranza@salud.madrid.org

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Digitalization is a trend that impacts all aspects of society, and medicines are no exception. The widespread use of the Data Matrix code on the outer packaging of medicines has helped many healthcare providers in the European Union (EU) become familiar with this technology. By making it possible to easily capture important data on a given medicine, the code provides up-to-date information on the drug without having to review the paper-based patient information leaflet (PIL).

In Spain, the Spanish Medicines and Medical Products Agency (AEMPS), the Spanish Society of Hospital Pharmacy (SEFH) in collaboration with the Hospitals Division of the General Council of Official Pharmacists' Associations, and a group of pharmaceutical companies (most of them members of Farmaindustria trade association) have vowed to gradually implement, from 1 January 2022, a pilot project aimed at suppressing paper-based PILs from a series of exclusively hospital-provided medicines and including a Data Matrix code on the primary container of these drugs. When scanning the code, users will directly access the medicine's official PIL, based on the information on the drug registered with AEMP's online Approved Medicines Information Center (CIMA).

As regards the methodology and the implementation criteria used in the project, it was established that the project would last at least two years, notwithstanding potential extensions agreed by the parties.

Moreover, the unserialized Data Matrix code printed on the primary container will have to comply with the Global Standard (GS1) and contain a specific national trade item number/global trade item number (NTIN/GTIN) that will allow access —through a correspondence table— to the medicines' register number (dose and formulation) registered in the AEMPS' official formulary.

Furthermore, hospital pharmacy departments that wish to access the drug identifiers hosted in the AEMPS' official formulary must develop their own system, which should be able to scan the Data Matrix code. A URL (https://cima.aemps.es/cima/publico/home.html)[1] has been made available where hospitals can insert a drug's GTIN/NTIN primary container identifier to consult the medicine's PIL. This new development should allow access to the latest versions of PILs and may also be used by hospitals to facilitate integration of the different medicines into their archive systems.

Finally, hospital pharmacies will be asked to fill out a feedback form, which they should forward to SEFH, which will be used to analyze the performance of the pilot project.

It should be noted that exclusively hospital-provided drugs are not usually delivered with their paper-based PILs. Such PILs are often disposed of together with the outer packaging, leaving only the drug in its primary container.

At the same time, hospitals will have to ensure that they have the required digitalization capabilities to be able to use the new system, which will undoubtedly be highly beneficial to them. Indeed, the automatic scanning of a code that corresponds to a specific drug will reduce the margin of error when reconciling prescription with dispensing and administration, and when compounding the complex formulations that patients require. Assigning an identifier to drug packages is associated with many benefits for all kinds of hospitals, which are demanding that pharmaceutical companies assign medicine unit packs a code that identifies them. This is particularly important in areas such as oncology[2,3].

Both the authorities and the different hospitals in Spain have the technology required to make specific queries about a particular drug. In this regard, the AEMP's online Approved Medicines Information Center (CIMA) is a highly useful tool, whose implementation was welcome by all the parties involved. As far as hospital-provided drugs are concerned, internet queries are the usual way in which official information on medicines is obtai-

ned, and an identifier on the primary container of the drug may constitute an appropriate vehicle to facilitate these queries as well as some internal hospital processes.

At the same time, the initiative could greatly contribute to addressing the needs of both patients and healthcare providers as it would provide up-to-date information about medicines at the time when it is needed during the treatment.

The goal of this pilot project, set within the European context, is to analyze the impact of suppressing paper-based PILs in Spain and generate data that may guide experts in future changes to pharmaceutical regulations, particularly in view of the rapid development of new technologies and their implementation in the pharmaceutical arena[4].

Similar projects have been conducted at a European level such as the one implemented in Belgium and Luxembourg, whereby PILs have been suppressed for all hospital-provided drugs[5].

The European pharmaceutical strategy has emphasized that "better use of product information in electronic format (ePI) 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 European Commission (EC) is collaborating with Member States and the pharmaceutical industry to "develop and implement electronic product information (ePI) for all EU medicines" and "evaluate and revise relevant provisions in the legislation in 2022". The need for greater flexibility was manifested by the use of ePI in the context of the development of COVID-19 vaccines.

Multiple initiatives are being deployed to support the digital transformation of healthcare across the EU. The EC has also undertaken to prioritize innovations that may contribute to building a healthier society.

The foregoing is testament to the efforts being made by different stakeholders to promote digitalization in order to harness the available resources to prepare for the challenges of the future. Today it is more important than ever to create a global industry-governments-hospital pharmacy collaborative framework to spearhead activities that contribute real value to the healthcare system and to patient safety.

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