The Global Language of Business

Considerations on 2D barcodes on healthcare products offered for sale directly to the patient and without a prescription for sale.

Scope and purpose of this paper

This paper aims at supporting decisions made by manufacturers on the type of 2D barcodes to be applied on healthcare products (medicines or medical devices) offered for sale directly to the patient and without a prescription for sale.

Issue statement

Depending on the country, healthcare products offered for sale directly to the patient and without a prescription for sale are supplied through healthcare supply chains and/or through the retail supply chain. These products are regulated healthcare products and are covered by relevant regulations on distribution mode, labelling, dosage, market authorisation, etc.

For example, the US FDA recently reinforced their requirements due to the risk posed to patients in case of overdose and in combination with other medicines. Likewise in the UK, the MHRA is maintaining a database compiling patient information leaflets related to regulated healthcare products, including to those offered for sale directly to the patient and without a prescription for sale. A last example could be regulations, in the UK and in the USA, requiring that adverse events or side-effects for healthcare products sold without prescriptions are reported.

The considerations above are important to provide as some of these products may pose a risk to the patient, if misused, and are usually a “grey zone” not always managed in a similar way depending on the countries where they are supplied. Some differences between prescribed healthcare products and those directly offered for sale without a prescription can be for example the quantity in a pack of medicines (e.g. a pack of 7 pills is not submitted to prescription but a pack of 14 pills is), or the need for a healthcare professional to dispense a medical device to the patient whereas bandage can be directly sold to the patient.

Another important point is that not all countries have prescriptions as a pre-requisite for healthcare products to be sold but in all countries patient safety must be ensured.

2D barcodes on healthcare products

Driven by regulatory requirements, and endorsed by the WHO, the **migration to 2D barcodes in healthcare started 20 years ago with GS1 DataMatrix** being used as the only recommended 2D barcode for identification and traceability of healthcare products.

Healthcare products offered for sale directly to the patient and without a prescription for sale may pose a risk for patients when wrongly used (e.g. interaction with other medication, wrong dosage, side effects). Alignment to the regulatory framework for identification of healthcare products is therefore critical. For medical devices, the unique device identification of the device using global standards, such as GS1 standards, is recommended. For pharmaceuticals, the use of the GS1 DataMatrix encoding the product code, lot number, expiry date and serial number is recommended. This not only enables authentication of the healthcare products, but also facilitates usage of the data about the healthcare products in supply chain and clinical processes. For this reason, retailers should plan to also scan GS1 DataMatrix at point of sale along with other 2D barcodes.

The use of the GS1 DataMatrix is also recommended to access digital content on healthcare products, including on healthcare products directly sold to the patients without prescription, when there is a need to ensure data integrity and/or patient safety.

The GS1 DataMatrix currently requires the use of an App to access digital content via a mobile device. The App ensures that the brand owner keeps control of the data and its integrity, whereas a QR Code contains a URL that directly links the product with online

information. The ongoing discussions with Google, on accessing digital content by scanning a GS1 DataMatrix with a mobile device, includes this requirement for data control and data security.

Maintaining one barcode on the pack is important to avoid confusion and risk at the point of scan and more importantly at point of care.

It is acknowledged that the global program for migration to 2D in retail may result in applying a GS1 DataMatrix on a pack while keeping the existing linear barcode until all scanning capabilities will enable scanning of the GS1 DataMatrix at point of sale. This must be a temporary solution, and the same identification information (i.e. Global Trade Identification Number - GTIN) must be captured in both barcodes, to ensure unambiguous identification of the healthcare product.

Conclusion:

The GS1 DataMatrix is the only recommended 2D barcode to be applied on healthcare products, including those sold directly to the patient without a prescription, as this ensures consistency on the marking of healthcare products and as the GS1 DataMatrix enable the capture of the information required to facilitate supply chain and clinical processes critical to ensure patient safety.

About GS1 Healthcare

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards, enhancing patient safety, and operational and supply chain efficiencies.

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefit to all stakeholders. Global members of GS1 Healthcare include more than 100 leading healthcare organisations worldwide.

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