Policy paper on traceability of medical products

World Health Organization

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Key points

This policy paper outlines the features of existing traceability systems and provides guidance on developing workable traceability regulation. In the light of the widely varying needs, capacity, and resources of Member States, the risk mitigation and sustainability strategies embedded in implementation efforts will vary. Given the range of possible implementation pathways, a set of guiding principles will assist Member States in establishing systems best suited to their needs and constraints.

For this purpose, Member States are encouraged to:

- establish a suitable governance process for their traceability system based on the analysis of national specificities (e.g. regulatory environment, supply chain management), taking into account the impact of the different forms of governance on interoperability, cost, security, regulatory control and access to safe, quality medical products;

- include a costing analysis as well as a sustainability mechanism in their traceability system planning to prevent costs from negatively impacting patients, government, supply chain stakeholders, and ultimately, access to medical products; and

- use global standards for product identification, production identification, automatic identification, and data capture and data exchange to reduce set-up and operating system costs and maximize national and international interoperability.

Glossary

This glossary was developed in consultation with the International Coalition of Medicines Regulatory Authorities. It is not intended to be an exhaustive list.

Aggregation	The documented parent/child relationships between uniquely identified items and the uniquely identified outer container that they are contained within for the purposes of improving the efficiency of serialization business processes involving data exchange and/or regulatory requirements.
Authentication	The act of determining the authenticity of a product or a system user.
Authenticity	The quality of a product and labelling, establishing that they are unquestionably genuine.
Automatic identification and data capture	The processes used to automate the assignment, marking and capturing (reading) of product identification, through the use of carrier technologies such as barcodes and radio frequency identification tags.
Barcodes	A symbol that follows a data carrier standard that allows it to encode a finite amount of data, which may be read repeatably and reliably to extract the data it contains. There are generally two types of barcodes used in commercial supply chains around the world: linear and two-dimensional.
Batch number/lot number	An identifier assigned to a homogeneous quantity of a product that has identical manufacturing and packaging characteristics, including raw materials, manufacturing processes and timing. The batch or lot number associates an item with production information that the manufacturer considers relevant for the traceability of the trade item. The data may refer to the trade item itself or to items contained in it.

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