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EMA endorses global facilitation of track and trace systems in pharma supply chain

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The European Medicines Agency has endorsed ICMRA recommendations to facilitate the use of track and trace systems for medicinal products at a global level.



EMA has endorsed recommendations developed by the International Coalition of Medicines Regulatory Authorities (ICMRA) to facilitate the use of track and trace systems at the global level.

The paper published identifies common technical denominators that allow different systems to exchange and use the available information on medicines and their supply chains in order to protect public health.

Production and distribution of medicines are the globalized and rapid exchange of information among regulatory authorities is integral to the protection of supply chain integrity and patient safety. Track and trace systems are considered to be a useful tool to mitigate the risk of shortages and fight production and marketing of falsified medicines. They provide visibility into the supply chain of medicines at any given time. However, until now, traceability systems have been designed and implemented with a local or regional focus, without taking into consideration whether they can exchange information with other systems at the global level.

In this paper, international regulators emphasize that the interoperability of track and trace systems helps to protect public health by improving information sharing in case of quality defects, reducing shortages, contributing to the fight against falsified medicines, and supporting pharmacovigilance activities. A common understanding of these potential benefits of interoperability is fundamental to promoting global planning and implementation of interoperable systems for medicines.

The ICMRA paper was open for public consultation from November 2020 to February 2021. The extensive and helpful feedback was carefully analysed and reviewed in order to refine and finalise the recommendations on common technical denominators for track and trace systems. ICMRA developed the recommendations in consultation with the World Health Organization (WHO), representatives from international medicines regulatory authorities and experts from the private sector.