Promoting the Quality of Medicines

Product Information Reports (PIRs)

A new series summarizing key technical considerations for the production of priority essential medicines

What are PIRs?

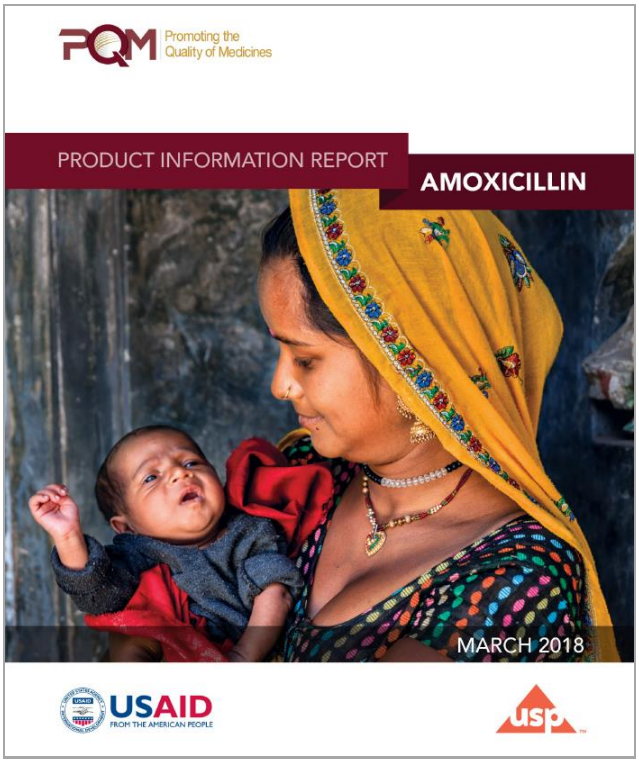
The Product Information Reports (PIRs) are documents that have been developed to provide critical technical information and guidance related to the manufacture of medicines that are of global public health importance. Each PIR synthesizes the available literature for a given product and summarizes relevant information on the product's physicochemical, biopharmaceutics, pharmacokinetics, and toxicological properties; the active pharmaceutical ingredient; analytical methods; and formulation development. The PIRs also provide an analysis of key manufacturing, packaging, labeling and stability considerations and challenges.

Who can use them?

PIRs are intended to guide manufacturers to make informed decisions regarding product development, scale-up, and manufacturing by proactively identifying and addressing potential manufacturing issues. The PIRs may also be used by donors and other stakeholders involved in expanding the supply of and access to essential medicines to understand how product development and manufacturing challenges impact the availability of these products.

Why were PIRs developed?

The continuous supply of safe, effective, and quality-assured medicines is paramount to ensuring and sustaining long-term progress against major global health threats such as tuberculosis, malaria, and HIV/AIDS. Access to essential medicines also promotes the health of children and mothers and their families. However, the supply of some essential medicines is stifled by the limited number of manufacturers. In some cases, life-saving medicines are being produced by only a handful of manufacturers or, in some instances, by only one manufacturer. Manufacturers often lack the economic incentive to produce essential medicines, may lack the technical capacity to meet international quality standards (such as those set forth by the World Health Organization Prequalification Program), or may deem the manufacturing process for some medicines too complex or resource intensive to undertake.



PIRs seek to demystify key manufacturing challenges associated with producing certain essential medicines, and potentially stimulate interest from manufacturers to include these medicines as part of their product pipeline. It is expected that the PIRs will also help spark open dialogue among global stakeholders about the manufacturing challenges related to the supply of essential medicines.

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