

The quality of medicines varies greatly, particularly in low- and middle-income countries. The use of ineffective, poor quality, harmful medicines can lead to therapeutic failure, exacerbation of disease, resistance to medicines and sometimes death. It also undermines confidence in health systems, health professionals, pharmaceutical manufacturers and distributors. Money spent on ineffective, poor quality medicines is wasted – whether by consumers or governments. Governments need to establish strong national regulatory authorities to ensure that the manufacture, trade and use of medicines are regulated effectively, to protect and promote public health.

Effective medicine regulation and quality assurance are fundamental to public health. WHO provides technical support to countries to:

- improve the effectiveness of national medicine regulatory agencies
- develop national quality assurance capacity
- improve implementation of good manufacturing practices and capacity to inspect medicine distribution channels
- combat counterfeit and substandard medicines.

WHO prequalification programme

The WHO prequalification programme was launched in 2001, driven by global public health needs, to achieve universal access to quality priority medicines, especially to those in need. The programme strives to achieve its vision through close collaboration with national medicines regulatory authorities and partner organizations.

The programme facilitates access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria, tuberculosis and reproductive health. It is supported by UNAIDS, UNICEF, the United Nations Population Fund (UNFPA) and the World Bank as a concrete contribution to the United Nations (UN) priority goal of addressing the problem of widespread diseases in countries with limited access to quality medicines.

Prequalification was originally intended to give UN procurement agencies, such as UNICEF, the choice of a range of quality medicines. With time, the growing list of products (i.e. medicines) that have been found to meet the set requirements has come to be seen as a useful tool for anyone bulk-purchasing medicines, including countries themselves and other organizations. For instance, the Global Fund to Fight AIDS, Tuberculosis and Malaria disburses money for

medicines that have been prequalified by the WHO process.

The availability of quality, safety and efficacy of medicines is a major concern of WHO. To ensure that quality pharmaceuticals are available, WHO sets norms and standards, develops guidelines and advises Member States on issues related to quality assurance of medicines in national and international markets.

These activities have been endorsed and supported by Member States through numerous World Health Assembly resolutions. The prequalification programme is part of these activities and WHO's mandate. It does not intend to replace national regulatory authorities or national authorization systems for importation of medicines, however, prequalification draws from the expertise of some of the best national regulatory authorities to provide a list of prequalified products that comply with unified international standards.

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