



Promoting and Ensuring Public Health through Regulatory Support in the Democratic Republic of the Congo: Medicines Registration

Effective medicines regulation is key to promoting and ensuring public health. Medicines regulation incorporates several mutually reinforcing activities and includes licensing of the manufacture, import, export, distribution, promotion and advertising of medicines. Licensing of medicines helps to ensure that substandard medicines, genuine drug products which do not meet the quality specifications set for them, do not enter national markets. In 2015, in the Democratic Republic of the Congo (DRC), the failure to regulate medicines took a toll on the health of more than 1,000 people who were hospitalized in a remote area of the country after suffering toxic effects from mislabeled drugs.

Medicines regulation demands the application of sound technical knowledge and skills. In the DRC, the Directorate of Pharmacy, Medicines and Traditional Medicine oversees this activity and is responsible for keeping the National Medicines Registry up-to-date. The national regulatory staff are also responsible for ensuring that the country is compliant with the requirements of the World Health Organization's Prequalification of Medicines Program. This program helps ensure that medicines supplied by international procurement agencies for distribution in resource-limited countries meet acceptable standards of quality, safety and efficacy. Strengthening the capacity of the national medicine regulatory authorities is key for promoting and ensuring public health.

In December 2017, the Global Health Supply Chain Technical Assistance Francophone Task Order provided technical and financial support to the Directorate of Pharmacy, Medicines and Traditional Medicine of the DRC to review the Registry of Medicines authorized for use in the country. The revision identified that half of all the authorizations (2322) issued in the period of January 2010 to September 2017, expired. Additionally, 109 market authorizations were identified to expire within the next three months after the review.

The identification of expired medicines authorizations will help the health authorities of the DRC ensure that the 2015 incident is not repeated. Following this review exercise, the Directorate of Pharmacy, Medicines and Traditional Medicine will comply with the WHO prequalification commission requirement to publish the list of registered medicines every quarter. Quarterly updates of the Medicines Register will provide relevant data for the customs services to track authorized products at the point of entry. Together this represents remarkable progress toward a health supply chain system in the DRC that ensures quality pharmaceuticals are available for its citizens.