"Fighting poor quality health products in times of Covid-19 and beyond: the need for a multi-stakeholder approach"

A side event at the 30th Commission on Crime Prevention and Criminal Justice

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Background

World Health Organization (WHO) estimates from 2017 indicates that 10.5% of medical products available in low- and middle-income countries (LMICs) are "substandard or falsified" (SF). Substandard health products are approved by the national regulators, but they do not comply with adequate standards due to undetected errors, negligence, or poor practice in manufacturing, transportation, or storage. In some cases, they may be linked to corruption. Conversely, falsified medical products always result from criminal fraud. Current analyses from Oxford University suggest that the Covid-19 pandemic has seen a surge in SF health products, and particularly for vaccines.

Universal access to quality-assured health products, including for vulnerable communities in LMICs, is a priority for Belgium. For instance, the implementers of Belgium-funded medical programs overseas are explicitly required to ensure the quality of procured products, and Belgium is now actively promoting a similar approach for other European donors. In 2020, Belgium promoted a resolution, approved by the Tenth Conference of State Parties (COP10) of the United Nations Convention on Transnational Organized Crime (UNTOC) that aims at preventing and combatting the manufacturing of and trafficking in falsified medical products.

The Belgian side event

Belgium sponsored on 17th May 2021 a side-event at the thirtieth session of the Commission on Crime Prevention and Criminal Justice, with title "Fighting poor-quality health products in times of COVID19 and beyond: the need for a multi-stakeholder approach". The event was co-organized by the Antwerp Institute of Tropical Medicine and by ENABEL (the Belgian Development Agency).

Speakers from academia and from regulatory agencies in Africa stressed the importance of tackling SF through both regulatory and law-enforcement approaches.

Raffaella Ravinetto, a researcher at the Institute of Tropical Medicine, underlined the need of a public health–informed legal and regulatory environment, to prevent and detect SF health products. She reminded that SF health products arise from the interplay between societies,

economies, and behaviors: thus, we need to disincentivize the production and supply of SF health products, while supporting health systems to ensure access to affordable, quality-assured health products to all levels of society.

Paul Newton, a professor at the Centre for Tropical Medicine & Global Health, Oxford University, described the current knowledge about SF health products in the field of COVID19, including cases of falsified remdesivir, contamination of hand sanitizer with methanol, and 94 reports of diverted or SF COVID-19 vaccines from 32 countries. He underlined that inequitable access is highly likely to fuel an increase in such incidents, and that vaccine falsification using harmful adulterants could cause outbreaks of unexpected side effects with dire consequences for vaccine hesitancy.

Mojisola Christianah Adeyeye, the Director General of the Nigerian National Agency for Food and Drug Administration and Control, reminded that while a reliable and well-developed health infrastructure is vital for every country, ensuring access to quality-assured health products is just as important. She presented the way Nigeria has been addressing the problem of SF health products for about twenty years now, by reinforcing the national regulation and regulatory oversight within the country and in the countries from where about 70% of drugs are imported, and by promoting coordination across regulatory authorities, international organisations, manufacturers, public health and enforcement agencies.

Daphney Mokgadi Fafudi, Head of Regulatory Compliance at South African Health Products Regulatory Authority (SAHPRA - South African Health Products Regulatory Authority), presented the national statistics on SF medical products, and the stakeholders involved in tackling them. She stressed the need of live stream electronic system to detect warnings; the need for timely prosecutions of SF medical products (including online sales); and the need of international collaboration, including timely sharing of lifesaving resources, information and associated skills transfer. She reminded that access to quality-assured health products is a moral requirement for humanity.

Aboubacry Amadou Ba, Director of Pharmacy and Laboratories in Mauritania, reminded that SF health products are harmful to individuals, communities and health systems, and that people in resource-limited countries are the first victims, due to lack of resources and limited international coordination to combat them. He wished that the side-event could be an opportunity to address the question of multi-stakeholders collaboration, as a way to find jointly

sustainable solutions to the issue of poor-quality health products in times of COVID-19 and beyond.

There was overall agreement that a stronger legal and regulatory framework is needed to mitigate the impact of SF health products, by enhancing the national and international capacity to prevent, detect and respond to them. However, regulatory authorities and law enforcement bodies should not act separately: while they have different mandates, skills and field of interventions, there are also overlapping and complementarity in their work concerning SF health products. Information sharing and cooperation should be encouraged and promoted.

It is also hoped that the COVID19 crisis can trigger greater international collaboration and collective action on SF health products. This involves stronger regulation, including via harmonization initiatives through African Medicines Regulatory Harmonization and the evolving African Medicines Agency; rigorous prosecution of falsified health products; greater coordination between international and UN agencies; and enhanced information-sharing (e.g. concerning medical alerts or evidence-based research for policy-making purposes).