Wilton Park

Report

Pathways to safe medicines

Wednesday 7 – Friday 9 June 2023 | WP3188

In association with:

THE WORLD BANK
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THE GLOBAL FUND

Gavi
The Vaccine Alliance

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Almost ten years ago to the day, experts and key stakeholders gathered at Wilton Park to discuss the threat of illicit medicines. Today, substandard and falsified medicines, in Sub Saharan Africa and beyond, continue to pose an acute threat to the health and wellbeing of millions of individuals. In partnership with USAID, GAVI, The World Bank and The Global Fund, this Wilton Park dialogue identified areas of weakness, explored opportunities for collaboration, and reinvigorated the fight against substandard and falsified medicines.

Key points

- Enhanced coordination is essential among diverse partners including medicines regulators, law enforcement, private sector, customs and health financing agencies.
- Nationally owned and driven efforts comprised of national interagency task forces can demonstrate strong results.
- Consensus built around the multifaceted benefits of national traceability systems based on GS1 global standards.
- The threat of falsified and substandard medicines together with widespread diversion and theft of health commodities severely impact the integrity of health systems and undermines health outcomes.
- Additional public and private resources must be deployed to raise awareness and deploy practical solutions, including stronger prosecutions for crimes related to illicit pharmaceuticals.

Introduction

Access to quality health commodities is a basic part of a functioning national health system. Challenges for health commodity supply chain integrity, equitable access and system failures that existed well before the COVID pandemic were accentuated during a period of global crisis and scarcity. Supply chain theft or ‘leakage’ may represent criminality and corruption on a large scale, which ultimately deprives patients of access to medicines and other health products. Furthermore, the transparent and effective delivery of safe health products is undermined by the persistent problems of illicit medicines that may take the form of deadly falsified or substandard quality products (SF), especially in lower- and middle-income countries. In those countries, an estimated 1 in 10 medicines is substandard or falsified. However, what was once considered a problem limited to developing and low-income countries has now become an issue for all. Both generic and innovator medicines can be falsified, ranging from products for cancer to treatments of pain. In addition, with the exponential increase in internet connectivity those engaged in

the manufacture, distribution and supply of substandard and falsified medical products have gained access to a global marketplace. This means that substandard and falsified medical products contribute to antimicrobial resistance and drug resistant infections.

Despite policy dialogue, programmatic expenditure and national engagement, sustainable supply chain integrity solutions continue to elude stakeholders. Practical and widely used solutions, such as health commodity traceability, are widely deployed in developed countries, yet similar approaches are making only slow progress in most less developed regions. Despite significant investments in regulatory harmonization and strengthening, many countries remain vulnerable to supply chain challenges. There is a need for sustained public and private sector support.

1. Coordination across diverse stakeholders

Inter-agency collaboration (both within governments and across international stakeholders) will produce a more robust and multifaceted approach to combatting falsified medicines or diverted/stolen health commodities. No single agency has adequate tools or expertise to tackle pharma crime on their own. A regular coordination mechanism is required to ensure public and private sectors exchange ideas, avoid duplication of efforts and strategically allocate limited resources. Additionally, parties unaccustomed to working together need to move out of siloed activities. Routine collaboration among medicines regulatory authorities, development partners, the private sector, customs and law enforcement must be prioritized.

The Global Steering Committee for Quality Assurance (GSC) was repeatedly mentioned as the existing and effective coordination platform as it already has buy-in and trust among the public and private sectors. The addition of international law enforcement entities will further build up strategic coordination among stakeholders focused on lower- and middle-income regions.

Recommendations

- The Global Steering Committee (GSC) should serve as an ongoing voluntary coalition of medicines regulatory authorities, development partners, private sector and law enforcement to help coordinate across organisations combatting illicit pharmaceuticals.
- Meetings should be regular and ongoing to provide routine coordination opportunities and help stakeholders avoid duplication of efforts.
- International and national agencies must coordinate more effectively with entities outside of their normal network in order to effectively disrupt the trade in illicit medicines.

2. Awareness of the threat posed by falsified and diverted medicines

Falsified and substandard quality medicines occur in every country in the world and represent a threat to public health of pandemic proportions in some lower- and middle-income regions. Greater public awareness of the deadly threat can help save lives and build integrated national responses. UNODC, Interpol and WHO have created joint training materials for national authorities. This is a great example of collaboration across organisations and sectors that can be replicated. Enhanced regional coordination and information sharing can help address the transnational nature of the criminal networks behind the trade in illicit health products. The public and private sectors can improve information sharing both as a means of informing the public and to better prosecute cases of pharmaceutical crime.

Recommendations

- All parties (national medicines regulatory authorities, international agencies, pharmaceutical companies and law enforcement) should prioritize coordinated public awareness of the threat posed by falsified health products.

- Additional training resources are needed to equip national agencies to better pursue illicit pharmaceutical activities.
- National medicines regulatory authorities, working with national law enforcement, need support from international agencies to build appropriate regional information sharing capabilities.

3. Nationally owned solutions

In order for solutions to be the most sustainable and lasting, local actors need to actively build and expand national level efforts to fight pharmaceutical crime. National authorities can draw upon and adapt global best practices, but each country will have unique circumstances. In many situations, new or strengthened legal frameworks are required to enhance prosecutions and better deter pharmaceutical crimes. Country driven interagency approaches that include a 'whole of government' task force comprised of appropriate regulatory and law enforcement agencies promotes more effective responses. National authorities also benefit from regular coordination and support from international organisations.

Recommendations

- Solutions should be nationally owned and driven, vetted by countries themselves in order to be most effective.
- Legal frameworks should be reviewed, updated and strengthened. The trade in illicit medicines should be treated as a serious crime so that the criminal justice system can prosecute appropriately.
- Countries should establish dedicated national task forces that are made up of all government agencies, including law enforcement, required to detect, disrupt and prosecute pharmaceutical crime.

4. Consensus on traceability for health products

Global standards (GS1) for health product traceability enhance supply chain visibility and integrity in more developed regions and should be prioritized for lower- and middle-income regions. The ability to track and trace a product from its manufacturer, through the supply chain and to the patient offers multifaceted benefits, but most importantly patient safety. Public and private sectors agree to prioritize GS1 traceability as a key component for patient safety. The Lagos Call to Action signed by 25 African countries will form the basis for a continent-wide push for national traceability systems in Africa. New momentum in the post pandemic era must promote globally interoperable and nationally owned traceability as a key tool to combat falsified and diverted medicines.

Recommendations

- The Lagos Call to Action for the adoption of nationally developed medicines traceability systems must be prioritized across Africa as a leading solution for patient safety.
- Global standards (GS1) will enable countries to work together to protect supply chain integrity and therefore must form the basis for national level systems.
- Development partners and health financing institutions should work closely with national authorities, led by medicines regulatory authorities, to implement medicines traceability as a high public health priority.

Falsified, stolen and diverted medicines represent a pandemic level threat to public health and undermine health outcomes in every region. The threat disproportionately impacts lower- and middle-income regions. Medicines regulatory authorities, health financing institutions, the private sector and law enforcement agencies must coordinate their work better. Proven solutions for health commodity supply chain integrity such as medicines traceability using GS1 global standards represent a consensus priority in lower- and middle-income countries but require concerted efforts and additional resources to

implement. Law enforcement agencies, though unaccustomed to working within the public health sphere, must be fully integrated as key partners. National authorities must own and vigorously pursue action against illicit health products with support from international funding partners as well as the private sector. Ongoing stakeholder coordination is a high priority and will be maintained under the Global Steering Committee for Quality Assurance.

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