Agenda item 11 19 February 2023

Substandard and falsified medical products

The First Global Model WHO World Health Assembly,

Having considered the resolution WHA 65.19, recognizing the need to enhance support for national and regional regulatory authorities to protect public health and promote access to affordable, safe, efficacious and quality medical products;

Noting the definition of substandard and falsified medical products as adopted by the World Health Assembly in 2017[1];

Recognising the multidimensional impact that substandard and falsified medical products have on health, health systems, economy, socio-economic factors and society at large;

Alarmed by the spread of antimicrobial resistance, increase of disease prevalence such as malaria, tuberculosis, and HIV/AIDS due to the use of substandard and falsified medical products;

Alarmed by the increase of substandard and falsified medical products, especially in personal protective equipment and vaccines during the Coronavirus Disease (SARS-CoV-2) pandemic;

Affirming WHO's focus of safeguarding public health and promoting access to affordable, safe, efficacious and quality medical products;

Concerned about the economic impact of substandard and falsified medical products, related to increased out-of pocket costs and health system spending on health care and economic loss for patients, health systems and manufacturers of quality medical products;

Expressing concern about data reported in the first report of the WHO Global Surveillance and Monitoring System that highlights low- and middle-income countries are bearing the greatest burden of substandard and falsified medical products;

Aware of the need to gather data that can produce reliable estimates related to substandard and falsified medical products, thereby gaining a better understanding of their impact on health and the economy;

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[1] World Health Organization, document WHA70/23, appendix 3, para. 7 (c), as endorsed by the World Health Assembly in its decision 70(21), reads as follows: "Medical products that deliberately/ fraudulently misrepresent their identity, composition or source."

Acknowledging the work already accomplished by the Member State Mechanism as well as the Global Focal Point Network towards the elimination of substandard and falsified products;

Acknowledging also the Member State Mechanism's eight point work plan currently in place to increase cooperation, collaboration coordination, capacity and awareness and encourage surveillance and information sharing to fight substandard and falsified medical products;

Acknowledging further the efforts made by the United Nations Office on Drugs and Crime, the Council of Europe with the Medicrime convention, the World Customs Organization and INTERPOL towards the prevention, detection and response of substandard and falsified medical products,

1. URGES Member States:

(1) to educate hospitals, clinics, healthcare workers and pharmacies through the creation of curricular units, and to strengthen risk communication as well as the development and implementation of public awareness campaigns;

(2) to work together with Ministries of Health as well as health and safety authorities in their respective countries in order to enhance the surveillance of substandard and falsified medical products and their origin, and adopt post-market surveillance where regular monitoring and testing of medical products are conducted;

(3) to implement multi-sectoral, government-led regulatory reforms for medical products and form strong legislative and regulatory frameworks;

(4) to continue the efforts made to reach SDG 3 "good health and well-being" including working towards Universal Health Coverage;

(5) to strengthen development of broader pharmaceutical manufacturing capacities in low- and middle-income countries;

(6) to provide access to reliable and accredited laboratories and analytical services to fight substandard and falsified medical products through National Laboratory systems;

(7) to develop a stronger supply chain management system while working with the WHO Global Surveillance and Monitoring System to prevent the introduction of substandard and falsified medical products into the market;

(8) to establish cooperation mechanisms between health authorities and shipping companies, postal service providers, internet service providers and providers of other online services to inspect bonded warehouses and free-trade zones to ensure the possibility that all medical products are being identified before entering the supply chain;

(9) to improve the understanding and uptake of technologies to screen and detect substandard and falsified medical products and the implementation of national traceability systems;

(10) to recognize the distribution of substandard and falsified medical products via the Internet and develop strategies to ensure legitimate online vendors of medical products can be easily identified;

(11) to introduce global standards on end-user authentication and to encourage members of society to actively contribute to the detection of substandard and falsified medical products;

2. CALLS UPON relevant international, regional organizations and national partners alongside other stakeholders, especially the healthcare and pharmaceutical industry:

(1) to increase access to safe and affordable medical products;

(2) to enhance transparency, traceability, and reporting for product labeling and supply chain methods;

(3) to support local governments to raise alerts on substandard and falsified medical products and to establish a comprehensive system for monitoring and detection;

(4) to work together with Member States to increase participation in mutual recognition agreements with low- and middle-income countries to share the cost of inspecting substandard and falsified medical products;

(5) to implement a process known as pre-qualification to provide a strict review of safety and efficacy data;

(6) to develop strategies to mitigate public health risks posed by the distribution of substandard and falsified medical products and adopt education, media and awareness programmes for the general public and non-health professionals on substandard and falsified medical products;

3. REQUESTS the Director-General:

(1) to strengthen the operation and development of the Global Surveillance and Monitoring System for substandard and falsified medical products;

(2) to encourage the use of initiatives to detect substandard and falsified medical products where resources are limited;

(3) to strengthen coordination, cooperation, information flow, and intelligence sharing between Member States to increase the prevention, detection and response of substandard and falsified medical products;

(4) to dedicate an international day on the issue of substandard and falsified medical products to increase education and awareness;

(5) to increase the availability and accessibility of quality-assured medical products to the public;

(6) to support local subsidization of medical products that are most frequently substandard and falsified, or that have the highest morbidity and mortality rates, as relevant to each Member State eligible for additional funding.