WMA STATEMENT IN SUPPORT OF ENSURING THE AVAILABILITY, THE QUALITY AND THE SAFETY OF MEDICINES WORLDWIDE

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INTRODUCTION

Over the past decade, pressure on supply has led to shortages of certain medical products, including vaccines. In many situations, these shortages result from putting economic objectives before public heath. These shortages are detrimental to patient care, to maintaining public health and to the organisation of healthcare systems.

The world is going through rapid change; technological progress, radical progress in matters of communication and access to information as well as the increasing power of multi-nationals are transforming the global landscape, including the pharmaceutical industry. Unfortunately, some of these developments have encouraged the production and sale of medical products which do not meet the required safety standards, whether due to the manufacturing process or inappropriate storage, or due to the criminal manufacture and fraudulent distribution of sub-standard or falsified medicines.

According to the WHO's Global Surveillance and Monitoring System (GSMS) for sub-standard and falsified medical products, around one out of ten medicines is either of a sub-standard quality or falsified in countries with low or medium income. This observation is not limited to the most expensive medicines or the most well-known brands, but also concerns patented and generic products. The medicines most often flagged are the antimicrobials and antimalarials.

The WMA reiterates its position on biosimilar medicines, its resolution on prescribing medicines, its position on the substitution of medicines and resistance to antimicrobials.

The rational use of medicines implies ensuring that research, regulation, production, distribution, prescription, financing, delivery and proper administration of these medicines comply with coherent and rational scientific, professional, economic and social criteria.

From a healthcare point of view, a shortage of medicines is unacceptable, as it has a negative impact on confidence for patients, doctors, pharmacists and the healthcare system, it leads to insecurity and uncertainty and compromises treatment continuity; with all the risks that this implies.

With the objective of combatting the intolerable missed opportunities that such shortages represent for patients, undermining public trust in the healthcare system, the WMA is calling for the implementation of the following recommendations:

RECOMMENDATIONS

Availability of medicines

1. As a public health issue and out of concerns for safety, the WMA urges national governments to improve the availability of medicines.

2. National governments and regulatory authorities should:

    - Create a national entity responible for gathering and communicating information relative to demand and offer for medicines under their jurisdiction. Establish standards and mechanisms guaranteeing the continuity and the supply of medicines and thus avoid shortages.

    - Improve the monitoring of medical product supply chains, as the weakness of regulatory structures make the application of good medical product distribution particularly difficult.

    - Design contingency strategies to counter the dependence of States on foreign medicine production due to the delocalisation and centralisation of the majority of structures which produce the main pharmaceutical components used in the composition of major medicines.

- Encourage national healthcare authorities to maintain stocks of essential medicines in order to minimise the risk of shortages. Indeed, the Covid-19 health crisis has demonstrated the limits of stocks held by States and has constrained them to reorganise and restrict access to certain medicines.
- In the case of global epidemic, to pool scientific research and clinical trials with the objective of accelerating the development of vaccines and/or treatments to eradicate the pandemic.
- Support legislative and regulatory initiatives which guarantee an appropriate national capacity to produce pharmaceutical products, in the interests of the well-being of the populace and national security.
- Identify and create sustainable mechanisms which will guarantee sufficient stocks and sufficient access to necessary medicines.
- Promote co-operation between governments in the prevention and the management of medicine and vaccine shortages.
- Encourage governments to be more directive in their dealings with the pharmaceutical industry, notably in terms of adjusting quotas, of accelerating approvals and of importing substitute medicines when pharmaceutical companies are not able to ensure a continuous and adequate supply of medicines.
- Consider demanding that medicine producers establish a continuity plan for the supply of vital and necessary medicines and vaccines in order to avoid production shortages wherever possible.
- Ensure the transparancy, sharing and availability of quality information coming from reliable sources in order to establish a trustworthy flow of communications between all stake-holders and healthcare professionals and to the patients. In the case of shortages, governments should divulge and detail the causes to all stake-holders.
- Enable WMA member states to acquire, via common supply contracts, healthcare and vaccine products in sufficient quantities during a pandemic and thus to have greater influence in negotiations with laboratories.
- Avoid the 'first come, first served' approach, notably during a pandemic, leading to counter productive competition acting against the safeguarding of public health.
- Allow an industrial level of security of supply in line with the deployment of Interpol's programme combatting pharmaceutical criminality.

Safety of medicines

3. The objective is to set up active supply processes to ensure the continuity of quality medical supplies while guaranteeing their safety.
4. Elements of a high-quality, active supply process comprise:

- Improvements in quantification, including forecasting.
- Direct communication between supply agents and the manufacturers on the question of sustainable capacity.
- Deliberate and well-considered approaches to a specific situation for each product (long term, short term, split contracts, etc.)
- Responsible pricing with the emphasis on quality
- Rational and necessary contracts.
- Establish frameworks which limit the excessive accumulation of medicines and the useless scrapping of unused medicines with the objective of preserving the quality of their pharmaceutical properties.
- Encourage governments to promote the sharing of public information on the real price of medicines. The authorities must regulate and limit the possibility of reaching agreements on price and discounting

confidentiality in the medicine evaluation process. The system must be made more transparent in all areas, including the evaluation of new medicines.

5. The WMA is clear on the fact that the quality of medicines is a public health priority and is recommending national medical associations and doctor members to:

    - Increase awareness among the public and medical practitioners of sub-standard and fake products.
    - Create a list of 'essential' medicines meeting a country's healthcare needs.
    - Create an early alert system, based around vital medicines and those intended to treat a debilitating pathology, in particular those for which no alternative therapeutic options are available. The activation of such a system would trigger a sequence of measures for all the stake-holders (licensed manufacturers, wholesalers, hospital pharmacists) alongside reporting obligations and a close monitoring of corrective actions.
    - Create a scenario and emergency programmes, including a stress test for manufacture and inspection systems at regular intervals, with appropriate communication strategies adapted to the different stake-holders.
    - Persue efforts to harmonise regulatory standards between the countries and beyond regions.
    - Set up proactive and productive collaboration between all the essential stake-holders in order to prevent medicine shortages and mitigate the harmful effects these have on patient care.
    - Work with healthcare user associations to fight against the growing culture of ill-advised self-diagnosis, self-prescription and self-medication, which could make the supply chain vulnerable to the introduction of non-approved or counterfeit products.
    - Restrict the prevalence of low quality medicines by implementing and applying current good practices in manufactuting, storage and distribution which respect the environment (cGMP) and by preventing the deterioration of medicines.
    - Encourage the pharmaceutical sector to undertake to guarantee the continuity of supply of medicines, in order to avoid any interruptions in treatment.

6. The WMA is insisting that national governments, in tandem with healthcare user associations and other stake-holders, do everything possible to ensure awareness of medicine safety for all patients.

    - At an international level and working together, Health Ministers and Medical Regulators should recommend that national medical associations actively oppose the illegal misappropriation of medicines, the illegal sales of medicines on the internet, the illegal importing of medicines and the counterfeiting of medicines.
    - Improve regulation and monitoring of the online pharmaceutical market through national regulation of e-commerce activities.
    - Regulations and mechanisms should be adopted to immediately close all websites illegally offering medical products not controlled by state authorities.
    - Improve the identification and the revelation of counterfeit medical products all over the world.
    - Launch international campaigns warning of the health risks linked to the use of counterfeit medical products, informing people about the dangers of buying medicines, or products offered as such, on the internet (counterfeit or fake medicines, etc.).
    - Improvement in detecting falsified and sub-standard medicines, including vaccines and other medical products, and their reporting worldwide. Falsified and sub-standard medicines, including vaccines and other other medical products, should be reported to the appropriate authorities whenever they are discovered. Pharmacies, hospital pharmacies and patients must be prevented by whatever means from

being supplied with falsified or sub-standard medicines. All adverse side-effects of a falsified or sub-standard medicine must be immediately highlighted via an efficient and adapted reporting system.

- Strengthen and align international rules against conterfeit medical products, allowing an efficient fight against the growing challenges of the systems of governance caused by the globalisation of manufacturing processes and supply chains.

Covid-19 health crisis

7. The Covid-19 health crisis has highlighted the fundamental problems of availability, quality and safety of medicines.

8. The already significant problems of availability, quality and safety of medicines have been starkly brought to light by the Covid-19 health crisis. The importance of these questions is even bigger, on a global scale, and the Covid-19 pandemic has created unprecedented challenges for the authorities of every State. A pandemic leads to a sharp increase in demand for certain medicines and major expectations of specific medicines and vaccines, creating the conditions for multiple tensions.

9. The problem of **medicine availability** is particularly apparent for anesthetics and curares in life support, which are subject to closely monitored delivery in order to avoid any break in supply. The prescription and delivery of certain other medicines have been closely supervised in order to maintain supply for chronic illnesses.

10. As a response to the unequal access to vaccinations, the implementation of the COVAX mechanism must be developed in the future so as to promote access to and distribution of vaccines, with the objective of protecting the people of all countries.

11. The WHO warns and cautions consumers, healthcare professionals and health authorities about **medicine safety**: the growing offer of falsified medical products in the context of the Covid-19 pandemic is aided by the possibility of shortages.

12. Concerning the **quality of medicine**, the health crisis has highlighted the risks of self-medication and the need for the States to set up information systems aimed at the general population. False hopes of possible cures for or prevention of Covid-19 by scientifically unproven methods have been known to have serious consequences for the health of the individual.

13. Economic and/or political interests must not be in competition with the health of the public. Pooling of public health interests must be developed in order that economic and/or political interests are not the cause of failure to manage the situation, of stock shortages or of anti-competitive behaviour.

14. The evolution of the current health crisis and notably the arrival of new variants show that States must be able to respond scientifically to this evolution without being hampered by overly-restrictive international regulations.