#### ITALY

**

***Ministry of Foreign Affairs and International Cooperation***

***Inter-ministerial Committee for Human Rights***

***Italy’s contribution in relation to the request of the United Nations High Commissioner on Human Rights on the Human Rights Council Resolution*** ***'RIGHT OF EVERYONE TO THE ENJOYMENT OF THE HIGHEST ATTAINABLE STANDARD OF PHYSICAL AND MENTAL HEALTH IN THE IMPLEMENTATION OF THE 2030 AGENDA FOR SUSTAINABLE DEVELOPMENT'***

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Further to your query, Italian Authorities are in a position to provide the following information.

**Paragraph 13 Resolution A/HRC/35/23**, regarding the **2030 Agenda for sustainable development with its 17 goals and targets: “contributions of the right to health framework to the effective implementation and achievement of the health-related Sustainable Development Goals, identifying best practices, challenges and obstacles thereto”**.

At the time of the launch of the 17 Sustainable Development Goals (SDGs) in 2016, the Italian Medicines Agency (AIFA), with the support of the Ministry of Health, had undertaken initiatives aimed at promoting and protecting the right to health, highlighting access to treatments as a human right, enshrined in the Constitution and in numerous international legal instruments.

AIFA has long been aware of the fact that timely access to medicines, especially essential medicines, as well as therapeutic continuity, can save lives. AIFA guarantees its support to initiatives aimed at creating a solid active collaboration between Institutions and with actors involved in the pharmaceutical supply chain and non-profit organizations, for the purpose of intervening, with ethical and social responsibility and in compliance with current legislation, in support of people in state of need.

Access to medicines is a fundamental part of the broader issue of the right to health, which in turn is part of the global debate on equity and human rights. However, it is interesting to note that while health is mentioned as a fundamental human right in at least 135 national constitutions and in numerous international treaties, only five countries expressly recognize access to essential medicines as part of the realization of the broader right to health.

On 14 September 2016, the United Nations Secretary-General's High-Level Panel on Access to Medicines has published a report entitled "Promoting innovation and access to health technologies". The key message of the report is that nobody has to suffer because they cannot access medicines, diagnostic tools, medical equipment or vaccines.

**BEST PRACTICES**

Cooperation in terms of sharing information about medicinal products and in the area of **Health Technology Assessment as a mean to contribute to sustainability and access**. The relevance of constructive dialogues between stakeholders - including patients, government and pharmaceutical industry- aimed at fostering R & D and balancing the value of innovation with patients access and affordable prices, is increasingly appearing on the global agenda. The current imbalance within the pharmaceutical system, whereby prices to be paid by healthcare systems for acquiring new/innovative drugs are increasingly not sustainable and sometimes even not aligned with their value, given the limited body of evidence, poses challenges to public health systems.

1. Cooperation and actions for exploring **alternative pricing and reimbursement**. Changes in approaches to drug development and marketing require reflection on the appropriateness of traditional systems, which are not deemed adequate to ensure sustainability and access to innovative drugs.
2. Reinforcement of international guidance with regards to the **use of HTA in decision making processes** and the mapping and monitoring of countries’ needs could support the establishment or preservation of systems, informing the pathway to the achievement of robust and sustainable systems for UHC also through capacity building. A critical element of the renewed global commitment to health is the acceleration of progress on attaining universal health coverage (UHC). In light of rising costs associated to health, the possibility of resorting to the HTA methodology plays a significant role in the decision making process towards the strengthening of health systems and the achievement of UHC, as recognized in the WHO Resolution on Health Intervention and Technology assessment in Support of Universal Health Coverage (WHA67.23, May 23rd 2014). HTA presents an opportunity for improving systems' performance, particularly in cases of lack the capacity to assess merits of health interventions, ensuring access to quality healthcare services, whereby it contributes to optimise health expenditure by providing analysis of interventions, which are useful for the purpose of efficient resource allocation.
3. Strengthening collaboration among different stakeholders involved in the pharmaceutical chain - recalling the concept of corporate social responsibility - for the purpose of defining a series of initiatives to increase awareness towards **medicines donations** for poorer populations and good donation practices.
4. Strengthening inter-institutional collaboration among health agencies and police forces both at national and international level for the purpose of **monitoring and combatting the phenomenon of counterfeit medicines**, also through capacity building initiatives. Figures from a new research conducted by the WHO estimate that 1 in 10 medical products circulating in low- and middle-income countries is either substandard or falsified, which means that people are taking medicines that fail to treat or prevent disease. Such a phenomenon not only represents a waste of resources but also a threat, as substandard and falsified medical products can cause serious illness or even death.
5. Including in the health institutions agenda the **promotion of the public scientific research** in the strategic sectors of medicines especially in areas not covered by private research. This recommendation is intended to stimulate the conduction of no-profit clinical studies with the aim to generate outcome that impact positively on the regional health system and on the health and well-being of the citizens.
6. Strengthening awareness on the appropriate use of vaccines and medicines (such as antimicrobials) **through improvement of information campaigns** intended for citizens with a view to encouraging empowerment of patients which involves capacity to make informed decisions about their health care.
7. Collaboration to address the issue of **environmental risks to achieve more environmentally sustainable use and disposal of pharmaceuticals**.

**CHALLENGES**

* Socio-economic determinants represent an important risk factor for many diseases, probably even higher than that of ethnicity and migration. It is therefore essential to **combat social exclusion and poverty** as a mean of improving the state of health of the most disadvantaged people.
* Significant intervention on the demand for illegal drugs. The deadly implications of falsified medicines are a direct threat to public health and to the well-being of individuals. Given the difference between regional regulatory frameworks efforts should be exerted to effectively **combat the phenomenon of drug counterfeiting**.
* Changes in disease patterns, demographic factors and migration can have repercussions on progresses made in the health sector and require better management and governance. The rapid expansion of chronic diseases and mental disorders, the lack of social cohesion and financial uncertainty make health improvement and access to treatments increasingly difficult, threatening the **sustainability of the healthcare system**.
* Encourage the **adoption of legislation that foresees the effective and dissuasive prosecution of falsification of medicines**, for example in the European region, among others, through the national implementation of the MediCrime Convention. The implementation of the Medicrime Convention, signed by Italy in 2011, would allow to incriminate i.e the "cyber- pusher" who operates on the Internet sites on which the counterfeit medicines are sold. The current Italian legislation system does not consider the falsification of drugs as a specific criminal behavior, and therefore the penalties do not take into account the risks that this activity causes to public health.
* **OBSTACLES**
* The **online purchase of falsified medicines is a serious obstacle to the protection of public  health**. The Commodities and Health Unit of the Italian Carabinieri force (Nucleo Antisofisticazioni e Sanità, NAS) found that most of the drugs purchased online might be counterfeited, less than 1% of online sellers are authorized to sell.
* The **difference between regulations** in neighboring countries is certainly an **obstacle** to be overcome in order **to effectively combat the phenomenon of drug counterfeiting**.
* Difficulties arising from frequent conditions of **socio-economic discomfort**, do not allow patients to follow medical prescriptions.
* The existence of **different cultural approaches to illness and treatment** as well as linguistic differences can make it very difficult for patients to properly understand the usefulness of the drug and its proper use.