

# IAPO's response to the Draft Global Strategy



## WHO IGWG Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property

The International Alliance of Patients' Organizations (IAPO) strongly supports the World Health Organization's (WHO) efforts to develop a global strategy to address the lack of safe and effective medications for many patients around the world and especially those suffering from diseases and conditions that have been "neglected" by pharmaceutical research and development for a variety of reasons. IAPO agrees with WHO's identification of two main barriers to effective treatment for many patients: lack of innovative therapies and lack of access to therapies that have been developed. Finally, we concur that the former barrier must be addressed by providing incentives to stimulate research and development into treatments for neglected diseases, while the second barrier must be addressed by reducing the gap between the costs of therapies and the funds available to purchase them.

### General Comments

IAPO is committed to engaging in the discussion on this issue; however, we must express our significant disappointment that patients and patient groups have not been actively encouraged to participate and offered the necessary support to do this effectively from the outset of this process. Now, given the announced timeframe of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, there is insufficient time for patient groups to inform themselves and consult with each other regarding the important and complex issues and potential measures outlined in the strategy.

The draft plan does not specifically refer to patients or patient groups amongst the key stakeholders yet patients are a key stakeholder and there are many patient groups, including IAPO, that are committed to actively participate in health policy issues, at international, national, and regional levels. A fundamental premise of patient-centred healthcare is that patients and patient groups are involved in all stages of healthcare decision-making, including setting of international policy. Patients and patients' organizations deserve to share the responsibility of healthcare policy-making and performance monitoring through meaningful and supported engagement in all levels and at all points of decision-making, to ensure that they are designed with the patient at the centre.

IAPO's comments on the global strategy are necessarily broad and general, given the limited time that we have had to consider these issues and consult with patient groups around the world to receive their opinions on these issues, at this time. However, the content of this paper has been shared with IAPO's members and reflects their comments and has been approved by IAPO's Governing Board, made up of nominated member representatives. IAPO's comments are organized around three key themes that we believe are at the centre of the issue of IGWG's draft on public health, innovation and intellectual

# IAPO's response to the Draft Global Strategy



property. These are: innovation and access, safety and neglected diseases. Our comments are founded on IAPO's vision that patients throughout the world are at the centre of healthcare and the principles that IAPO and its membership believe are essential to achieve this vision, as illustrated by the IAPO Declaration on Patient-Centred Healthcare (available online at [www.patientsorganizations.org/declaration](http://www.patientsorganizations.org/declaration)).

## **Innovation and Access**

IAPO believes that access and innovation are inseparable. Without access, innovation generates no benefit, without innovation, access leads to limited outcomes.

Patients must have access to the healthcare services warranted by their condition. This requires:

1. Continuing to foster an environment that provides strong incentives to innovate
2. Providing support to those patients that need medicines to access them, and
3. Addressing the issues preventing patients accessing medicines anywhere, including basic off-patent medicines in developing countries

## **Safety**

Patients have a right to access safe, quality and appropriate services, treatments, preventive care and health promotion services. To this end, the draft strategy must ensure that all medicines, wherever they are developed or produced, must pass through a stringent regulatory framework that guarantees:

1. The quality of the manufacturing process
2. The security of the supply chain, and
3. High quality information is provided to patients, e.g. information to help patients take their medicines correctly and hence safely and to help patients identify counterfeit medicines.

Moreover, as discussed below, to assure patient safety, medicines must be made available to patients within a healthcare environment that includes appropriate diagnostic, monitoring, and supportive treatment and care.

## **Neglected Diseases and Neglected Patients**

As mentioned above, IAPO believes that patients must have access to the healthcare services warranted by their conditions. As identified by the draft global strategy, many of the neglected diseases are concentrated in developing countries, where lack of innovation and research and development (R&D) is not the only barrier to access. Therefore, it is imperative that any solution does not focus only on supporting and encouraging R&D but that a number of strategies are focussed at tackling the range of issues that affect health, including health system infrastructure, poverty, government policy, health awareness, and moral and business ethics if there is to be a chance of success. National and local jurisdictions must invest in appropriate healthcare infrastructure, including medical personnel, equipment, and institutions.

# IAPO's response to the Draft Global Strategy



However, it should be underlined that research must be encouraged into conditions which, for whatever reason, are not focused on by pharmaceutical companies. These conditions include "rare diseases" in addition to neglected diseases. In fact, the market is so narrow for each rare disease that the pharmaceutical industry is reticent to invest in the research and development of treatments for these conditions. While rare diseases affect the lives of patients in both developed and developing countries, being affected by a rare disease while living in a developing country exacerbates existing health, social and economic vulnerabilities.

## Conclusions and Recommendations

IAPO is concerned that debate around these issues has become polarised by different stakeholders as developed versus developing economies or, more versus less stringent intellectual property regimes. This has the potential to create conflict between patients with chronic illnesses and patients with infectious diseases when, in fact, what should operate to the benefit of all patients, is access to good healthcare, including safe and effective treatments. These different interests have neglected the perspective of the key stakeholder: "*patients*". We urge the WHO and all stakeholders to show leadership and take meaningful action to ensure that patients and patient groups are given a central role in future discussions while recommending that member countries should consult with patients' organizations and patients and include their opinions in their own responses.

Across these areas, we would like to see studies into the impact on patients of the measures proposed in the draft global strategy conducted in order to inform all stakeholders particularly patients and patient groups to make better quality decisions on this important issue. The results should be made available to patients and patient groups in an appropriate format according to health literacy principles, as outlined here: [www.patientsorganizations.org/healthliteracy](http://www.patientsorganizations.org/healthliteracy)