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General Comments

- The Irish Patients' Association (IPA) is very supportive of the efforts being made by the World Health Organization (WHO) to address the issue of research and development for diseases that disproportionately affect developing countries.
- We affirm many of the proposals made in the Draft Global Strategy and Plan of Action on public health, innovation and intellectual property.
- We reaffirm the moral responsibility that those with resources have towards those in need who do not have the necessary resources to provide for their needs.
- We decry the current situation that allows 18 million people to die prematurely every year from diseases for which medical cures exist.
- We see as a violation of the ethical principle of justice the current situation called the 10/90 gap whereby roughly 10 percent of healthcare research and development is directed towards the needs of 90 percent of the world's population.
- The existence of diseases with massive disease burden for which vaccines, treatments, and diagnostic tools are not available must be addressed as part of the global strategy to combat poverty.
- We believe that the WHO's inter-governmental working group is a prime opportunity for governments to join together and tackle the important and complex issues surrounding treatments for those in developing countries suffering from neglected diseases.
- We remind everyone that this initiative is primarily about neglected people, not just neglected diseases.
- Failure to address the needs of those in developing countries will impact people around the world. Recent outbreaks of SARS and avian flu demonstrate the global impact of communicable diseases that originate in poorer regions.
- We recognize that illnesses that predominantly affect people in developing countries are different from those that affect people in developed countries. However, the disease profile of developing countries is becoming more like that of developed countries. It is

important to ensure that actions aimed at addressing problems faced by one group of patients do not inadvertently create problems for any other group of patients.

- While we believe the goals of the WHO are laudable, we are disappointed with the process applied to the consultation. Patients, both in developing and developed countries, need to be at the table from the beginning and at all stages for discussions that affect their health. As the saying goes “*Nothing About US – Without US*”
- We believe that the action plan should focus on addressing issues related to delivery and access to necessary medicines and services, rather than issues related to trade. While issues of trade are involved, focusing here shifts attention to commercial and financial interests, while this issue should remain primarily focused on people. These initiatives are ultimately about the people who are neglected because of the current situation.
- The WHO deliberations provide an ideal opportunity to address key issues related to delivery and access. At the same time, the IPA is also concerned with the safety of people living in developing countries – especially if more generic drugs are produced.
- A greater emphasis is required on good manufacturing practices and appropriate regulatory oversight to directly benefit patients in developing countries while also reduce the risk for those in other countries.
- Manufacturers in all countries must follow internationally accepted good manufacturing practices as this will serve patients living in developing countries and could mitigate the risk associated with a key issue for IPA – counterfeit pharmaceuticals.
- We strongly urge the WHO to include combating counterfeit pharmaceuticals in their plan of action.
- Counterfeit drugs pose a significant danger to public health and safety. In developing countries, people and organizations are using the few resources they have to purchase what they believe are life-saving medications. They grasp at the opportunity to get an affordable product. When they obtain a fake product, the consequences are often fatal. Many report the problem as one of wholesale murder. Some of the most vulnerable people in the world are being exploited because of their great need. This is a humanitarian crisis of such huge proportions that it deserves greater attention.
- A number of measures in the plan appear to encourage production and use of generic drugs in developing countries. We are concerned that this may increase the risk of unscrupulous operators producing and illegally exporting ineffective or dangerous counterfeit products to other markets.
- As noted in our position paper on counterfeit pharmaceuticals (available from www.dcu.ie/nursing/counterfeit_drugs.shtml), there exists a perception that counterfeit drugs are only a problem for developing countries.

- Although this may have been the case in the past, the impact of this problem is growing in developed countries. For instance, in 2005, law enforcement authorities uncovered a counterfeit operation in Switzerland worth approximately 12 million Euros. In another incident, authorities intercepted a shipment of AIDS drugs from Africa that was illegally being diverted into the European market.
- We believe that the WHO's inter-governmental working group has an excellent opportunity to tackle the problem of counterfeit drugs. This is a problem that requires a coordinated approach by several stakeholders using numerous strategies. We urge the WHO to use this opportunity to bring together governments, the pharmaceutical industry, healthcare professionals, police, customs, distributors, patients' organizations, and those concerned about people's rights to address this important issue.
- It is also important to monitor the unintended negative consequences of measures proposed in the draft action plan. For instance, the plan calls for compulsory licensing for export which could put patients at risk. At the same time, it could also lead to unnecessary confrontation and stand-offs between parties who should be working together to reduce disease burden.
- Ireland has benefited greatly from the presence of the research-based pharmaceutical industry. The IPA is proud of the fact that Ireland is one of the world's largest exporters of pharmaceuticals and that among the world's top selling drugs, 12 out of 25 are produced in Ireland. Irish patients and Ireland as a country has benefited both in terms of economic and health status. (Lest there be any perception of a conflict of interest, the IPA declares that it receives less than ten percent of its core funding from the pharmaceutical industry.)
- Regarding the research-based pharmaceutical sector we recommend that any action taken by the WHO not undermine this industry's ability to discover, develop and manufacture their innovations for patients everywhere. To accomplish this, a key objective of the strategy must be to find ways to align the motivations and interests of those with the resources and expertise necessary to conduct needed research and the needs of patients around the world.
- The current patent protection system has serious deficiencies when applied to research and development for neglected diseases, especially those associated with poverty. Almost by their nature, patients with these diseases will never be able to afford the very high prices of innovative healthcare products. We applaud the WHO's inclusion of actions to explore and promote complementary incentive schemes for research and development. Much progress has been made through public-private partnerships that combine researchers from industry and academia with private and public funders and the WHO's Tropical Disease Research program (TDR). These initiatives have already produced dozens of novel compounds for treating neglected diseases. However, the resources for these initiatives have been small compared to the needs. The involvement of the WHO in promoting such initiatives is welcomed.

- We recommend that the WHO monitor the impact of any new measures related to intellectual property on disease burden, but also on the innovative pharmaceutical industry and the global quality of health care products.
- The IPA suggests that further research is needed to examine fully the question, “Why is health care so expensive?” Simple answers are often given, but reality is more complex. However, much effort is needed to understand this issue before effective answers will be found.
- Given that the innovative pharmaceutical industry is the primary source for discovery and development of new medicines, a proactive due diligence exercise should be conducted by an independent body prior any final decisions on this policy.
- We recommend that that the WHO also considers including actions directed at providing more information and education to patients. Many of the neglected diseases of developing countries will require more than new treatments. For example, Chagas disease infects 16-18 million people, with about 50,000 dying annually, primarily in Latin America. The infection is spread by insects that live in the thatched roofs of sub-standard housing. People become infected when the insects’ feces drops onto food or skin and is then rubbing into the eyes or cuts. No effective, safe and affordable treatment currently exists. However, tackling the disease will require public education about housing, food storage and cooking, and skin care.
- Governments should be encouraged to invest in health-delivery infrastructure and measures should be taken to put in place mechanisms to effectively regulate in all regions of the world, the safety, quality, and effectiveness of medicines and health products.
- It is imperative that patients are informed and involved in programs aimed at modifying aspects of their health care system. The reasons why people cannot access available treatments are multiple and complex. Financial issues are important, but many other issues need to be examined, including cultural, social, and political factors. A broad range of types of research is needed to understand all the factors involved in the current global situation.
- We recommend that moving forward, the WHO adjusts its time frames and consultation plan, to ensure that all interested and affected parties have their fair say on these important global issues. Governments all around the world are taking steps to include patients in the healthcare decision-making process. For example, the Irish Department of Health and Children invited the IPA to give our views on this subject. We believe that the WHO can set a prime example globally by actively engaging patients in their deliberations on this topic.
- Involving patients’ organizations is vital to provide the patient’s perspective. In any healthcare system, the patient is the *Key Person*. Including this important perspective will ensure a greater degree of success and acceptance of any plan put forward to the World Health Organization Assembly in 2008. The IPA has seen the fruit of this approach as

when we provided a platform for informed debate among all stakeholders in Ireland on action against counterfeit medicines.

- The IPA is willing and able to be a partner in representing patients' views and bringing forward solutions that can benefit patients in both developed and developing countries.
- Finally, we restate that the challenge for WHO is to create "a domain of trust" among a diverse group of stakeholders. We would suggest that a key value is partnership. We need a plan that will benefit *all* patients.

Summary

- The current situation that allows millions of patients, primarily women and children, to die needlessly every year is a moral outrage that requires urgent attention.
- We believe that it is crucial that patients living in developing countries gain access to the medicines and treatments that they need to live healthy productive lives.
- We believe that the focus must be kept on people (patients) and the amelioration of their needs.
- We recognize that sustained health investment in any State depends on continued economic and political stability in civil society. However we believe that the WHO action plan should focus on addressing issues related to delivery and access to necessary medicines and services, rather than focus primarily on issues related to trade.
- Patients living in developing countries share a host of issues to a greater or lesser degree when trying to gain access to appropriate health care: political instability, corruption, poverty, the inability to get to a hospital, the lack of appropriate infrastructure and access to health care workers, to name but a few.
- We are concerned for the safety of patients living in developing countries if those countries are encouraged to produce targeted de-patented medicines when they do not have the appropriate manufacturing capability or infrastructure in place or quality assured regulatory bodies. Compulsory licensing for this reason must be used with caution if that is the only option.
- The incentives for health care innovation must be brought into alignment for the different stakeholders. Current intellectual property regulation promotes one approach for all situations. A variety of approaches maybe are needed based on the immense differences in the circumstances of different patients without prejudice to the current IP owner.
- A key feature of the WHO strategy must be the aligning of the concerns of all stakeholders. The current situation sometimes brings the interests of patients and researchers or inventors into conflict as well as economic ideologies. We do not wish to see the plan polarize patients in developed and developing countries or societies.
- Patients' Associations often do not have the resources to process and respond to large-scale consultations such as this in a short time frame. It is imperative that everyone be given adequate time to consult on these issues to allow our input into the process.