

Summary of Comments of the American Autoimmune Related Diseases Association (AARDA) on the World Health Organization's (WHO) draft of a Global Strategy on Public Health Innovation and Intellectual Property

Patients are primary stakeholders and should be included in healthcare policy development. This approach encourages patients to define and articulate their needs, participate in decision making, and guide care to improve quality, cost-effectiveness and outcomes. This approach demands that policy makers take into account the interests of patients above other interests.

The current WHO draft needs to recognize that the patient must be the cornerstone of any initiative. The draft neglects to recognize that patients must be involved in all aspects of setting health care policy including international policy

The need for development of more effective treatments for autoimmune disease must be recognized. Although some autoimmune diseases have benefited from the introduction of new therapies, most autoimmune diseases continue to be treated with therapies introduced over 40 year ago. A robust pipeline of innovative therapies is fundamental for patients residing in both developing and developed nations.

The needs of patients in developing countries demand a long-term solution. By focusing solely on patent protections, the WHO proposal fails to address fundamental issues that significantly contribute to the lack of access to treatments and medical care in developing countries.

Any sustainable solution must address the need for increased innovation in treatments for infectious diseases. It also must consider fundamental issues such as inadequate health workforce and facilities, lack of government support for a health care delivery system, and general symptoms of poverty.

We do not absolve the pharmaceutical industry of its responsibility for finding solutions for the humanitarian issues surrounding the lack of access to lifesaving drugs for patients in resource poor countries. Finding these solutions needs to be incorporated into each company's business plan.

Developing countries need to be engaged in research and development, clinical trials and pharmaceutical manufacturing. But they first must create the infrastructure to support and implement best practices and quality assurance and to train health care personnel to ensure patient safety, effective treatment and prevention education.

AARDA urges the WHO to undertake a comprehensive study of many possible initiatives to improve access for those with infectious diseases. New initiatives should build on the success of recent efforts by the private-public projects that have resulted in significant improvements in access and reduction in market barriers to many therapies.

We need to develop incentives to support research into neglected diseases such as tropical diseases and rare disorders where it has been difficult for pharmaceutical companies to recoup their costs. However, such a discussion should not overlook the fact that universal diseases such as cancer, diabetes and cardiovascular disease actually cause more morbidity and mortality in developing countries than tropical diseases.

We urge the WHO not to lose sight of its original mandate to boost research and development, build capacity and improve access, all the while making sure that the agenda is driven by patients' needs and interests.

Because of the importance of patient input AARDA joins with the member states who have requested that the decision postponed until all stakeholders have had input into the plan.