



**Statement of Knowledge Ecology International: WHO 20th Expert Committee on the Selection and Use of Essential Medicines, with specific focus on expanding access to new cancer drugs, when available at affordable prices**

20 April 2015

Dear members of the WHO Expert Committee and the WHO secretariat,

Thank you for providing Knowledge Ecology International (KEI) the opportunity to address this Committee.

In April 2002, the World Health Organization (WHO) made history by its inclusion of antiretrovirals into the WHO Essential Medicines List (EML). In the words of then Director-General, Dr. Gro Harlem Brundtland,

*[t]he designation of ARVs as essential are vital steps in the battle against the AIDS pandemic. They should encourage both industrialized and developing country governments to make HIV treatment more widely available.<sup>1</sup>*

This week, the 20th Expert Committee is asked to consider the inclusion of new drugs for cancer, hepatitis C (HCV) and tuberculosis (TB), and to change the methodology for the EML.

KEI wants the WHO to create a category in the EML for products that would be essential, if available at affordable prices. We have been making this proposal for several years, and we elaborate on the reasons today, highlighting the case of new drugs for cancer.

Historically, the WHO has excluded drugs to treat cancer than have been on the market less than 15 years, and are protected by patents. The exclusion is primarily due to the high prices for cancer drugs. It is also the case that many of the new drugs for cancer are targeted therapies, and some, such as imatinib or dasatinib, are useful for treat fairly small populations. In 2014, the USA approved 10 new cancer drugs. All 10 were super expensive. Nine of the 10 new cancer drugs were approved as orphan drugs, for small

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<sup>1</sup> WHO takes major steps do make HIV treatment accessible, 22 April 2002, <http://www.who.int/mediacentre/news/releases/release28/en/>

client populations. As we learn more from genetic and big data, the use of targeted therapies will grow.

New drugs are expensive in some parts of the world, like North America, or in Europe, due to policies, not physics, chemistry or biology. A policy to grant an IPR monopoly, through patents, data or other IPR mechanisms, is designed solely to induce investments in R&D.

Countries can regulate or eliminate monopolies, and some do. India has broken the monopoly for sorafenib, because of excessive pricing, and several countries broke the imatinib monopoly, also over pricing concerns.

Several countries and several health and innovation experts have proposed the elimination of monopolies for cancer drugs, and the creation of new ways of funding and rewarding investments in the development of new cancer drugs and diagnostics devices, relying upon combinations of grants and large, robust inducement prizes. The innovation prize funds would be funded by the same entities tasked with reimbursing drug purchases today.

IPR enforced monopolies, created to induce investments, are only one way to stimulate R&D,<sup>2</sup> and they are the wrong way, when it comes to cancer drugs, particularly for developing countries, if that means a generation of cancer patients is excluded from the benefits of new drugs that are used in high income countries.

By creating a category in the EML for drugs (and diagnostics) that are essential, if available at affordable prices, the WHO will send a signal to governments and cancer patients, that they have policy options that can provide for more equal and more fair access to new drugs.

One of our employees has stage 4 HER2+ breast cancer. She is alive today and leading a good life because she has had several years of treatment with trastuzumab, a drug under consideration today that is finally losing its patent and data protection, but which has had very limited access outside of high income countries. She has recently switched to T-DM1, a drug that so far is very effective in prolonging her life. Why would the WHO have a policy that effectively endorses inequality? Why would the WHO only legitimize the grant of an access restricting monopoly on a cancer drug, and not recognize the possibility and the benefits of the alternatives that expand access by delinking R&D funding from the prices of drugs, or policies to address excessive pricing in other ways, such as through the grants of compulsory licenses?

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<sup>2</sup> See: 2014. James Love, Alternatives to the Patent System that are used to Support R&D Efforts, Including both Push and Pull Mechanisms, with a Special Focus on Innovation-Inducement Prizes and Open Source Development Models, World Intellectual Property Organization, CDIP/14/INF/12, September 19.