

A Request for Clarification Concerning the Proper Scope of the IGWG's Work to Improve Access to Patented Medicines

Submission to the WHO IGWG
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The IGWG document, Elements of a global strategy and plan of action A/PHI/IGWG/1/5 (8 December 2006) contains many interesting features that will draw significant commentary. This submission will focus only on one phrase:

“diseases which disproportionately affect developing countries”

This phrase or similar formulations is found throughout the document:

- “As a first step, the plan of action will need to set out ways to identify gaps in research on diseases that disproportionately affect developing countries.” (at 3, par. 2)
- “A plan of action could include steps to secure such financing for developing and making accessible products to combat diseases that disproportionately affect developing countries, for underpinning public-private partnerships and local research and development institutions, and for boosting resources channeled to research organizations in developing countries in both the public and private sectors.” (at 8, par. 8)
- **“Meeting public health needs.** The challenges and opportunities for achieving this objective include:
 - the growing burden of diseases and conditions disproportionately affects developing countries, particularly women and children (*resolution WHA59.24*)” (at 10, par. 3)
- “the development of safe and affordable new products¹ needs to be continued for such communicable diseases as AIDS, malaria and tuberculosis, and for other diseases or illnesses disproportionately affecting developing countries (*resolution WHA59.24*) (at 11)

- additional funding is needed for research and development for new vaccines, diagnostics and pharmaceuticals, including microbicides, for illnesses, including AIDS, that disproportionately affect developing countries (*resolution WHA59.24*) (at 11)

These appearances are not surprising; as India points out, on behalf of South-East Asia Region, the phrase was part of the World Health Assembly Resolution that established the IGWG, WHA 59.24, and was prominently discussed in the *Public health, innovation and intellectual property rights report* (WHO Commission Report 2006).

The phrase is best understood when limited to a particular innovation market failure: the lack of commercial research into *neglected (Type II) and very neglected (Type III) diseases*. No substantial market in high-income countries exists for these diseases, necessitating various non-market mechanisms such as product development public-private partnerships and advance purchase commitments in order to facilitate innovation.

But the innovation gap is not the only problem facing this IGWG. Your terms of reference also include ensuring equitable access to patented innovations treating all diseases, including Type I, II and III diseases. WHA 59.24 urges member states:

“to work to ensure that progress in basic science and biomedicine is translated into improved, safe and affordable health products – drugs, vaccines and diagnostics – to respond to all patients’ and clients’ needs, especially those living in poverty, taking into account the critical role of gender, and to ensure that capacity is strengthened to support rapid delivery of essential medicines to people;” WHA 59.24 par. 2(3).

The WHO Commission Report (2006) clearly identified the needs in this area, giving the example of cervical cancer as a Type I disease of great importance in low- and middle-income countries (at 12-15). Focusing more resources on neglected diseases is entirely appropriate; but we cannot overlook the fact that chronic conditions in the high-income and low-income worlds are converging. Non-communicable disease accounted for 47% of the global burden of disease in 2001 (WHO 2004a) and about 49% of the global DALYs in 2001. (Mathers, Lopez & Murray 2006, Annex 3C). The global disease list includes many of the major chronic conditions associated with wealthy countries — including cardiovascular disease, stroke, mental illness, diabetes, and arthritis. These “wealthy country” diseases are also the leading causes of adult disease burdens throughout the world. (WHO Commission Report 2006; WHO 2004b; Outtersson 2005, at 244-46).

Many of these Type I conditions disproportionately affect the poor. Take the example of cervical cancer. In high-income countries, deaths from cervical cancer are relatively rare due to expensive population screening and treatment. Deaths from cervical cancer in low- and middle-income countries totalled 218,000 in 2001, exceeding the deaths from all diseases in the tropical-disease cluster. (Mathers, Lopez & Murray 2006, Table 3B.1)

One bright point concerning Type I diseases is that the innovation problem is frequently addressed by high-income markets, such as existing patented treatments for cancer, heart disease, depression, diabetes and hypertension. In these situations, innovation is not a barrier to adoption in the developing world. Price, however, can create an access gap for Type I disease innovation.

For example, a highly effective vaccine is now available to prevent most cases of cervical cancer (Harper, Franco, Wheeler, Moscicki, Romanowski, et al. 2006), but the price – US\$360 per person – exceeds the per capita annual health budgets for most of the women worldwide that need it. New models are needed in order to create robust generic markets for patented medications without undermining innovation. In an upcoming paper, we examine how a Type I vaccine (HPV vaccines for cervical cancer) might be distributed in order to improve access while fully supporting innovation. (Outtersen & Kesselheim 2007). Clearly, the IGWG needs to consider access-related issues for all types of diseases.

The concern that prompts this submission is certain language and actions by the United States government that might lead to an inappropriate extension of the phrase “disproportionately affecting developing countries” from the innovation gap to other issues, including the access gap. For example, in its comments to the Draft Global Strategy, the United States claims that the phase necessarily limits the scope of the IGWG’s mandate to Type II and III diseases:

“The IGWG should not consider Recommendation 2.4 as the focus of its work should be on diseases that disproportionately affect developing countries, more commonly referred to as Type II and Type III diseases.” (US Comments 2007)

Recommendation 2.4 emphasizes the need to address all types of disease in developing countries, including Types I, II and III. (WHO Commission Report, at 48). Is the US Government arguing that developing countries don't need access to medicines for Type I diseases?

Other actions by the US Government may lead to some confusion on this point. For example, while the WHO Commission Report (at p. 22) and WHA 59.24 (at par. 2(4)) supported the use of TRIPS flexibilities by developing countries, the United States Trade Representative’s Office elevated Thailand to the Special 301 Priority Watch List when Thailand issued compulsory licenses on clopidogrel (Plavix), a patented drug which treats heart disease, in addition to two AIDS drugs, efavirenz and lopinavir/ritonavir. (USTR 2007). Some observers might think that the US Government hopes to restrict compulsory licenses to Type II and III conditions. This idea is not without foundation, as the USTR reacted with particular swiftness against Thailand’s use of a compulsory license on a drug for a Type I condition, heart disease. Nothing in TRIPS or Doha limits compulsory licenses to Type II and III diseases. A clarification to that effect, by the IGWG or the US Government, would be helpful.

References

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