Hidden Hunger, Hidden Danger

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The latest estimates are that over two billion people in the world suffer some micronutrient deficiencies, often referred to as 'hidden hunger'. The main sustainable solution is to ensure adequate public health interventions, including clean water, sanitation and hygiene as well as healthy, diverse diets for all.

In the short term, however, it will be necessary to provide supplements of vitamins, minerals and trace elements to those especially vulnerable, e.g. due to displacement and emergency situations. There is a general consensus that such needs of pregnant and lactating mothers should be especially prioritized due to the intergenerational consequences of child stunting for such reasons.

Developing countries should be able to affordably access locally produced or imported generics of the vitamin and mineral supplements they require. Many current options associated with public-private partnership will instead strengthen the vested interests of the lucrative, large and fast-growing industry for nutrition supplements.

The need for supplementation to address urgent, short-term micronutrient deficiencies should qualify as part of the public health exception to the Trade-Related Aspects of Intellectual Property Rights (TRIPs) rules of the World Trade Organization (WTO).This has not been fully recognized ostensibly because people do not drop dead immediately due to 'hidden hunger'.

TRIPS and generics production for developing countries

Under the TRIPS agreement, intellectual property rights (IPRs) -- for copyright, trademark, geographical indication, industrial designs and patents-- are extended to all signatory countries. Patents, most relevant to public health and access to medicines, give twenty years of protection to inventions.

In the current language, there are no explicit provisions for generic production of patented nutrition supplements. However, there is supposed to be a great deal of flexibility on the basis of public health needs, which could be extended to minerals and vitamins for supplementation.

The TRIPS Agreement provides space for countries taking measures to protect public health. Under Article 31, countries can issue compulsory licenses allowing firms or individuals to produce generic copies of patented products or processes for the domestic market without the owner's consent in "case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use". The government can also determine adequate payment to the IPR holder.

At the Doha WTO conference in 2001 launching the Doha Development Round of trade negotiations, the Declaration on the TRIPS Agreement and Public Health affirmed the right of countries to protect public health, enable access to medicines, and determine the criteria for issuing a compulsory license. It emphasized that each country "has the right to grant compulsory licenses" and "the right to determine what constitutes a national health emergency or other circumstances of extreme urgency".

This new text corrected the false impression that some health emergency was needed to justify compulsory licensing. It also spelt out that "public health crises, including those

relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency".

Technology transfer

Under Article 66.2 of TRIPS, developed country governments are obliged to actively promote technology transfer in establishing manufacturing capabilities for patented processes in developing countries. The 2001 Declaration also reaffirmed the developed countries' commitment to provide incentives to their corporations to enable technology transfer to the least developed countries. This was part of the original bargain for developing countries to provide protection of IPRs.

Developing countries also have the right to import generics if they lack manufacturing capabilities. A 2003 waiver allows countries unable to domestically produce pharmaceuticals to import them instead. Hence, under compulsory licensing, such countries can import externally produced patented drugs. Thus, while compulsory licensing allows countries to import cheaper generics from countries already producing them, to take advantage of TRIPS Agreement flexibility, countries need to legislate accordingly.

However, exemptions to pharmaceutical patent protection to the least developed countries, enabling them to import without issuing a compulsory license, were only extended until 2016. The upcoming Nairobi WTO ministerial should extend this exemption beyond next year.

While there appears to be legal space under TRIPS for developing countries to use compulsory licensing, they have effectively been prevented from doing this by complicated rules and procedural requirements. Consequently, use of compulsory licensing by developing countries has been largely limited to HIV/AIDS medicines, and almost exclusively used by middle-income countries. LDCs have not issued any compulsory licenses while the total number of applications has declined significantly in the last decade.

Needed actions

Existing TRIPS texts do not preclude compulsory licensing for local generic production in developing countries. However, extension of the right to use compulsory licensing and other such flexibilities to vitamin and mineral supplements is not explicit. While explicit permission is given to AIDs, malaria, tuberculosis and epidemics, even this is rarely used.

In light of the foregoing, the following revisions to WTO provisions to protect developing countries' right to produce generic vitamin and mineral supplements should be introduced. This will also be in line with the July 2015 Addis Ababa Action Agenda's commitment to facilitate technology transfer:

- Developing appropriate model legislation to facilitate development of the national legislation needed for compulsory licensing, etc.

- Provide free legal services to developing country governments interested in accessing TRIPS facilities

- Identify and investigate relevant national vitamin and mineral supplement production needs in partnership with other governments to enable developed countries to meet their technology transfer obligations

Developing countries need to act to overcome three major constraints to issuing compulsory licenses and bypassing patent legislation for public health. First, the governments must be strong enough to withstand business and political pressures. Second, it is necessary to have

enabling legislation in place. Third, these countries need to have production capacity and distribution arrangements in place.

Also, the UN system should offer appropriate technical expertise to advance progress.