OP-42 IMPACT OF GLOBAL POLICY REFORMS ON EQUITY IN ACCESS TO MEDICINES IN INDIA

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Background India is one of the largest producers of generic medicines in the world. Yet, low cost generic medicines remain inaccessible and unaffordable to many Indians. The 2011 World Medicine Situation Report states that 65% of all Indians lack access to essential medicines. In an era of increasingly globalised trade, not only the national health policies but also global pharmaceutical policies play a key role in the availability and affordability of medicines. This study aimed to find out the impact of global policy reforms on equity in access to medicines in India.

Methods A scoping review was done sourcing literature from Pubmed (MEDLINE), Embase and CINAHL databases. The keywords used included 'equity', 'access', 'medicines', 'policies', 'pharmaceutical policy', 'global health', 'India' and 'intellectual property'. Abstracts were reviewed and studies having any three

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out of the first four keywords in the title and/or in the main body were included for further review. Total 41 studies were included for review. Policy and declarations documents of various international organisations like World Health Organization (WHO), United Nations (UN) and World Trade Organization (WTO) were reviewed to find out commitments and agreements held by various international agencies post TRIPS (Trade Related Aspects of Intellectual Property Rights) era (post 1994), and progress made so far corresponding to these commitments.

Findings In 1994, when agreement on TRIPS was adopted, many low- and middle-income countries resisted the inclusion of an intellectual property regime in the WTO system because they feared that it might obstruct development goals and access to important goods such as essential medicines. Ultimately however, they were constrained to accept the 'TRIPS package' as an indivisible component of the WTO system. At the fourth WTO ministerial conference held 2001 in Doha, WTO adopted a declaration on TRIPS and public health (the 'Doha declaration'), which affirmed the sovereign right of governments to take measures to protect public health and urged member nations to use flexibilities under TRIPS, especially compulsory licensing under article 31. However, it failed to take into account the difficulties faced by the countries that lack manufacturing capacity.

After a long battle of wealth versus health, WTO in August 2003 provided a waiver to TRIPS agreement and allowed countries to issue compulsory license to import medicines. Although these countries may issue compulsory licenses to import generic versions of patent-protected medicines, TRIPS rules constrained the ability of countries that have the capacity to manufacture generics, such as India to export such products. Later, in December 2005, WTO allowed non-producing countries to issue a compulsory license to import medicines in accordance with a special compulsory license for export issued in the exporting country. However, making use of this flexibility remained complex, as both importing and exporting countries are required to pass the legislation to make it possible. As a result, the accession is pending and only 45 out of 155 WTO countries have made changes in legislations. Out of these, only Rwanda and Canada have used it.

Recent disputes about intellectual property and access to cancer medicines (imatinib and sorafenib) in India demonstrates the conflict between commercial interest and public health concerns. India is facing pressure from its global trade partners for its attempt to use safeguards against patents. In 2005, India included strict patentability criteria in its patent law to address the ever greening of patents. This provision was challenged by a pharmaceutical company in the Madras High court alleging that it was a violation of TRIPS and of the constitutional equality provision.

Discussion The evolving regime of intellectual property rights has many implications for access to medicines in low- and middle-income countries where 50–90% of the population have to pay for medicines themselves, rendering treatment unaffordable for many. Geographically, lack of access to essential medicines is severe and concentrated in Africa and India. One overarching and crucial challenge to promotion of access to essential medicines is how to address conflicts of interest, i.e when commercial concerns take precedence over public health interests. Global policy reforms are required that promote knowledge transformation and sharing, favour export as well as regional production and encourage technology transfer among the countries to save millions of lives.

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