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Review Article

Free Trade Agreements and Intellectual Property Rights: An Impact on Access to Essential Medicines: Overview of the Global Trade Negotiations, in the Context of Developing Countries

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Introduction

Globally the policies are well placed to address the major issues of access to essential medications to meet the global humanitarian crisis. Major concern across the global health community, for making the provisions of the safe and essential medicines are the challenges, in negotiating with various regulatory agencies, with respect to their trade policies and priorities.[1] Free trade agreements and intellectual property rights are of the most important issues the global health community needs to address, to push the agenda of countries essential medicines, within the policy sphere. Public policies are the back bone of one's own countries political and administrative mechanisms to make provisions of the essential services, including the health care services. Trade agreements and negotiations needs to happen within the ambiance of the public policy sphere. The policies or agreements ideally needs to be formulated within the context of country's emerging markets, economy and diseases. Polices does not fit into the framework and may have a little impact on health outcomes, if they are not contextualized.[2]

Access to health care is possible when individuals or families can mobilize the resources they need to preserve or improve their health At the simplest level, having access to health care may be judged in terms of the availability of services, and resources this may include the geographical proximity or physical accessibility of services and financial resources. There may be considerable barriers to the uptake of services even when these are available. Obstacles to utilization include affordability with financial barriers, such as the costs to individuals or households of utilizing care, physical barriers including distance or difficulties of travel. The health outcomes is the terminal outcomes of health and non health sectors. It depends on the quality of health care services, and seriousness with which barriers to access are dealt with. Globalization and industrialization are bringing a rapid transition in the disease patterns and also the demand for the health care services including those requiring at tertiary health care level, apart from the essential medical services at the primary level. Policy development and changes should happen on the basis of underlying beliefs about both the cause of a problem and the potential effect of proposed interventions. These beliefs contribute to the policy making process and final policy direction along with the social and political context in which the decisions is made. The ability to interpret the root causes of a problem and identify effective solutions that enable public health practitioners to influence policy decisions.[3] Public health is inherently a global challenge and thus assumes high priority for international cooperation. The interaction between health and non health issues and various other policy domains such as human rights, development, intellectual property (IP) and international trade is very crucial. WHO should provide an open forum for intensified debate and discussions

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which creates a strong rationale for cooperation and coordination with other Global financial institutions, such as the World Intellectual property Organization (WIPO) and the World Trade Organization.

Objectives: To assess the impact of global trade negotiations, in the context of developing countries for commissioning the life saving treatments and medicines and to enlight on issues of trade agreements and intellectual property rights. **Methodology:** Cross sectional study

Results

This section discusses various key issues, which influences access to essential medicines. The elaborate discussions have been made under the sub themes of global trade negotiations, regulating the medications, market regulations and emerging markets, intellectual property rights issues and finally concepts of essential package of care approach. The three critical ingredients to public health policy formation are the development of evidence base, the political will to act and the identification of sustainable strategies. The evidence based public health policy poses the challenges in bridging research and policy. The free trade agreements and the trade negotiations needs to be analyzed as it has immense repercussions on the health service provisions. Switching over to the generic medicines by lifting the patents, proved highly beneficial in case of treating the HIV infection in the sub Saharan Africa for an instance. The same was attempted to replicate in various other countries of low and middle economies The literature showed the accessibility to the essential antiretroviral drugs has shooted up to 98 percent.[4]

The change in the system of granting patents is of utmost priority, which helps in bringing rapid reformation in the service delivery in these countries. Though enhancing the access to essential medicines will contribute to the provision for the universal health coverage there are various other challenging aspects. The lancet commission on essential medicines, largely advocates for the patent based solutions for the provision of essential medicines, as lifting the patents may prove beneficial in reduction of the costs of the medicines, by switching over to the generic versions. The pharmaceutical companies has a different versions of arguments, which largely emphasizes in the non-patent based solutions, as most of the essential medicines are patent protected. The world trade organizations largely advocates for the amendment on changes in the existing patent systems, which has complicated mechanisms in granting the patents. The TRIPS agreement was amended through the protocol of 6 December 2005 that entered into force on 23 January 2017. These provide the legal basis for WTO members to grant special compulsory licenses exclusively for the production and export of affordable generic medicines to other members that cannot domestically produce the needed medicines in sufficient quantities for their patients. The growing public policy concerns add significantly towards the attainment of declared policy goals. The expansion of the public policy agenda largely influence the regulatory interventions addressing market failures and international spillovers with inevitable consequences for trade flows and investments. The increased role of public policy becomes very important in international economic relations as globalization intensifies interdependency among nations. Effective international cooperation is a key challenge facing the multilateral trading system in the future.[5]

Trade negotiations

Essential medicines and its access largely depends on the negotiations and resolutions which have been amended from time to time by the regulatory agencies. The trade negotiations and agreements are very important from the public polices perspectives at bilateral and multilateral governmental and intergovernmental levels for the provisions of the life saving essential medicines. The global financial institutions and development agencies always look for the better polices so as to have better impact within the short span of time.[6] The concept of defining essential medicines and establishing a list of them was aimed to improve the availability of affordable medicines for the world's poor. Access to essential

medicines is a major determinant of health outcomes. Several countries have made substantial progress towards increasing access to essential medicines, but access to essential medicines in developing countries is not adequate. To enhance the credibility of healthcare system, procurement and delivery systems of essential medicines have to be strengthened through government commitment, careful selection, adequate public sector financing, efficient distribution systems, control on taxes and duties, and inculcating a culture of rational use of medicines in current and future prescribers. [7] World Health Organization (WHO) defines essential drugs or medicines as "those drugs that satisfy the healthcare needs of majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford". This is the basis of the Essential Medicine Concept that was launched in 1977, and became one of the eight pillars of WHO's "Primary Health Care" strategy. This concept is intended to be flexible and adaptable to many different situations and it is a national responsibility to determine the essential medicines.

Global trade negotiations

The global trade negotiations deals with the issues related to the international trade theory, trade policies, trade agreements, and government trade regimes. One of the main motivating factors to the world trade organization's commitment to the trade liberalization is the notion that free trade is integrated to the economic growth. However the success of the trade liberalization has been ambiguous in some developing countries. Commitment to reduce trade barriers can be difficult to implement, and opening domestic sectors can cause massive displacement of workers because some industries fail to be competitive on the global market. Some developing countries are also concerned that the trade liberalization will make them more vulnerable to price fluctuations and recessions on other parts of the world. In response to the necessary criticism that trade negotiations are not sensitive enough to the countries of developing economies. The world trade organization therefore very keen to build the capacity on trade negotiations primarily with the World Bank, united nations, and the IMF. It also provides the financial assistance to developing countries participants to enhance the negotiating skills. The WTO initiated the DOHA development round as the first trade round to focus specifically on the rate of trade in development. The DOHA agenda is very lengthy, the US has been major influencer for initiating the negotiations on the four issues, they are investment, competition, transparency and government procurement. Developing countries objected to negotiate with these issues. While the policy makers, analysts and observers paint a global economic recovery, the numbers are very discouraging.

Regulating the medications

The adoption of the global strategy and plan of action on public health (GSPA-PHI) was a major step towards a global consensus on political action on public health, innovation and Intellectual property rights. The overarching objectives of GSPA- PHI are to promote new thinking as innovation and access to medicines. It helps in formulating a framework for securing an enhanced and sustainable access to essential medicines. Govt. have to ensure that the manufacturer distribution and use of medical products are regulated effectively to protect and promote public health. The objective of medicine regulation is to ensure that the manufacturer distribution and use of medical products are regulated effectively to protect and promote public health. The objectives of medicine regulation is to ensure that ,Products of required quality ,safety and efficiency, Products are appropriately manufactured, illegal manufacturing and trade are detected and adequately sanctioned.

Health professionals and patients have the necessary information to enable them to use products (particularly medicines) in a rational manner. Promotion and advertising is fair, balanced and aimed at rational use of medicines. Access is not hindered by unjustified regulatory barriers (such as applying different standards for imported and locally manufactured products, lengthy processing time for registration and marketing authorization

applications, and duplication of the work of other regulators without delivering added value) side-effects. Convergence of regulatory procedures across countries is a challenge. National and sub-national registration authorities follow their own administrative rules and technical requirements, and they have established their own processes and procedures for medicines registration. Even within countries, there is often no clear indication at a national level of the length of time registration takes or the maximum period of time permitted for regulators to assess and register medicines. Furthermore, limited transparency may apply before or during the registration process. Different national-level technical requirements for registration set out in international guidelines are often due to factors such as different governmental structures, cultural norms, levels of technical competence and availability of human resources, and the business environments. In addition, there is often a time lag between the publication of international/ regional/sub-regional technical regulatory guidelines and their implementation by individual countries. Regional differences still exist in terms of how individual countries go about ensuring compliance with current international good manufacturing practices (GMPs), as well as numerous other regulatory requirements for ensuring quality, safety and efficacy of products. Such distinctions can influence costs and the speed with which a company obtains marketing approval. Immediately after the TRIPS Agreement came into effect, member states in the WHO discussed its potential impact on public health and requested the WHO Director-General "to report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate". Since then, the interface of public health, IP and trade has been subject of many debates and many resolutions passed by the WHO reflect a growing consensus on access to medicine issues. The 52nd World Health Assembly (WHA) provided the WHO Secretariat with a mandate to work with WHO member states on the monitoring of the impact of the TRIPS Agreement and other trade agreements and to help member states develop adequate health policies to, if necessary, mitigate the negative impact of trade agreements. The implementation of the resolution included the establishment of a WHO network for monitoring the implications of the TRIPS Agreement on public health. The series of resolutions

1996 WHA49.14 :	Revised drug strategy
1999 WHA52.19:	Revised drug strategy
2000 WHA53.14:	HIV/AIDS: confronting the epidemic
2001 WHA54.10:	Scaling up the response to HIV/AIDS
2001 WHA54.11:	WHO medicines strategy
2002 WHA55.14:	Ensuring accessibility of essential medicines
2003 WHA56.27:	Intellectual property rights, innovation and public health
2003 WHA56.30:	Global health sector strategy for HIV/AIDS
2004 WHA57.14:	Scaling up treatment and care within a coordinated and comprehensive response to HIV/ AIDS
2006 WHA59.24:	Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action 2006 WHA59.26: International trade and health
2007 WHA60.30:	Public health, innovation and intellectual property
2008 WHA61.21:	Global strategy and plan of action on public health, innovation and intellectual property
2009 WHA62.16:	Global strategy and plan of action on public health, innovation and intellectual property
2011 WHA64.5:	Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits
2011 WHA64.14:	Global health sector strategy on HIV/AIDS,
2012 WHA65.22:	Follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

passed by World Health Assembly are listed as below,

World Health Assembly Resolutions.[10]

In spite of the efforts by the Global Health and financial institutions in making the medicines and technologies accessible, through the various trade negotiations and resolutions, the global market regulations matters a most, and plays a vital role. The global market regulations are very important to keep track of while achieving the objectives of access to the life saving essential medicines to the most vulnerable populations in medical humanitarian crisis situations. It is highly impossible to harmonize the regulatory issues across the globe, to make the access to medicines smoother, passing through the public policy sphere of the both developed and developing nations.

Market regulation

Global markets are highly volatile and this volatility leads to uncertainties in health care service delivery. The global health care markets encounter fluctuations in many different ways, and depends on the state of the economies. The economies of the countries are classified in to different categories. The World Bank classifies economies according to gross national income (GNI) per capita, calculated using the World Bank, Atlas method. The cut off points are updated every year using purchasing power parities (PPP) at current international dollars. For 2011, the groups are low income, $1025 or less; lower-middle income, $1026-4035; upper middle income, $4036-12,475 and the high income, $ 12,476 or more. The World Bank changed its terminology from gross national product, or GNP, in previous publications to the GNI (World Bank 2012b) However, the definitions and groupings of transition economies and emerging economies in the literature have so far been hazy.

The emerging markets influence the access to the essential medicines. The emerging markets depends on the emerging economies. The term emerging economies corresponds to various and often blurred groupings, sometimes it is used in relation to the fourth BRICs (Brazil, Russia, India, and China) or group of fast growing economies, while on other occasions, if refers to all developing countries. The term emerging economies implies not only a rapid growth of gross domestic product (GDP) per capita or an increasing presence in world markets, but also entails several important ingredients of political economy. These countries' have pursued a process of economic liberalization, promoted market orientation and opened up to international flow of goods, service and capital. Various classifications of emerging economies include the countries which have a level of income below the threshold set by the World Bank. Have been able to increase their share in world markets of manufactured goods or services by at least 0.05 per cent points between 1995 and 2005.This group includes Brazil, India, Indonesia, China, South Africa, and Mexico. Similarly the organization for economic cooperation on development describes Brazil. Russia, India, Indonesia, China and South Africa, together known as the BRIICS, as the six largest non-OECD economies rapidly integrated in to world markets during the past decade (OECD2009).[6] Growth rates in emerging market countries have significantly outpaced those of more developed economies in recent years. Poverty has fallen; standards of living have improved. But with this rapid expansion comes the danger that the gap between the rich and the poor in those countries will widen. Several research studies show that most people are optimistic about the future in emerging markets such as India, Nigeria, and other countries that are progressing toward advanced economy status. One must ensure that growth remains inclusive in these economies so that this optimism is justified. By inclusive growth, it means a more equitable sharing of the benefits of increased prosperity, decent-paying jobs, equal employment and education opportunities, and improved access to and provision of health care and financial services. In comparison to advanced economies, emerging markets experience greater income disparity and higher poverty, and lag behind in access to key social services like health care and finance. One can attain the health inclusion by good regulatory measures and initiatives by national and sub-national governments. The regulatory affairs

must be a well-planned function and not just improvised as the need arises the key strategy and implementation must be addressed from the very beginning. The regulatory affairs play a key role in the global markets in the access to the essential medicines. The global health care markets are well controlled by the regulatory agencies. Some of the important regulatory agencies which control the access to the essential medicines and the medical devices are listed here. The regulatory agencies form a vital role in addressing the issues of accessibility issues. Medical device regulation in Asia has gained more importance than ever. Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones. A registered product requires a lot of technical documentation to prove its efficacy, safety, and quality. A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government, testing centers, and hospitals and among doctors. Government bodies, the medical device industry, and academics needs to be sensitized about the global regulatory environment and their research and development capacities. The clinicians and the non-clinicians and the administrative authorities needs to be enlightened in the areas of medical device regulatory system in different countries, ISO standards for medical devices, and need to be providing substantial background materials to have a better understanding of regulatory affairs.[7] There are many regulatory agencies, which have a control over the cost, quality and other standards. Some of the key regulatory agencies are shown as under

Table 1. List of regulatory agencies in providing an access to essential medicines and medical devices

Regulating agencies
Food and Drug Administration (FDA)
DOHA ministerial declaration
Hong-Kong Ministerial declaration

Intellectual Property Rights

Intellectual property rights are divided into two categories: industrial property – which includes patents, utility models, trademarks, industrial designs and geographical indications of source – and copyright, which includes literary and artistic works such as novels, poems, plays, films, musical works, drawings, paintings, photographs, sculptures and architectural designs. International Patent Classification (IPC) Provides for a hierarchical system of language-independent symbols for the classification of patents and utility models according to the different areas of technology to which they pertain. The symbols contain information relating to sections, classes, subclasses and groups. There are various systems of registration for the patents and trademarks throughout, the world. Some of the most prominent registration systems being are

Madrid international application

Madrid System for the International Registration of trade marks, established under the Madrid Agreement and the Madrid Protocol and administered by WIPO. The Madrid System makes it possible for an applicant to register a trademark in a large number of countries by filing a single application at their national or regional IP office if it is party to the System. The Madrid System simplifies the process of multinational trademark registration by reducing the requirement to file separate applications at each office. It also simplifies the subsequent management of the mark, since it is possible to record changes or renew the registration through a single procedural step. Registration through the Madrid System does not create an international trademark, and the decision to register or refuse the trademark remains in the hands of each national or regional office. Trademark rights are limited to the jurisdiction of each office. Patent A set of exclusive rights granted by law to applicants for inventions that are new, non-obvious and commercially applicable. A patent is valid for a limited period of time (generally 20 years), during which patent holders can commercially exploit their inventions on an exclusive basis. In return, applicants are obliged to disclose their inventions to the public in a manner that enables others skilled in the art to replicate the invention. The patent system is designed to encourage innovation by providing innovators with time-limited exclusive legal rights, thus

enabling them to appropriate the returns from their innovative activity.

PCT international application

A patent application filed through the WIPO-administered Patent Cooperation Treaty (PCT). The PCT, an international treaty administered by WIPO, facilitates the acquisition of patent rights in a large number of jurisdictions. The PCT System simplifies the process of multiple national patent filings by reducing the requirement to file a separate application in each jurisdiction. However, the decision whether to grant patent rights remains in the hands of national and regional patent offices, and patent rights remain limited to the jurisdiction of the patent-granting authority. The PCT international application process starts with the international phase, during which an international search and possibly a preliminary examination WIPO IP FACTS AND FIGURES 50 ADDITIONAL INFORMATION are performed, and concludes with the national phase, during which a national or regional patent office decides on the patentability of an invention according to national law. Key terminologies in Intellectual property rights.

Resident

For statistical purposes, a resident application refers to an application filed with the IP office of, or acting for, the state or jurisdiction in which the first-named applicant in the application has residence. For example, an application filed with the JPO by a resident of Japan is considered a resident application for the JPO. Resident applications are sometimes referred to as "domestic applications". A resident grant/registration is an IP right issued on the basis of a resident application.

Trademark

A sign used by the owner of certain products or the provider of certain services to distinguish them from the products or services of other companies. A trademark can consist of words and combinations of words (for instance, slogans), names, logos, figures and images, letters, numbers, sounds and moving images, or a combination thereof. The procedures for registering trademarks are governed by the legislation and procedures of national and regional IP offices. Trademark rights are limited to the jurisdiction of the IP office that registers the trademark. Trademarks can be registered by filing an application at the relevant national or regional office(s) or by filing an international application through the Madrid System.

Utility model

A special form of patent right granted by a state or jurisdiction to an inventor or the inventor's assignee for a fixed period of time. The terms and conditions for granting a utility model are slightly different from those for normal patents (including a shorter term of protection and less stringent patentability requirements). The term can also describe what are known in certain countries as "petty patents", "short-term patents" or "innovation patents".[8] About 2.9 million patent applications were filed worldwide in 2015, up 7.8% from 2014. Driving that strong growth were filings in China, which received about 174,000 of the nearly 208,000 additional filings in 2015 and accounted for 84% of total growth.

Essential package of care approach

The World Bank's world development report for 1993 (World Bank 1993): Investing in health emphasized in application of innovative tools for the need assessment, health technology assessment, and cost effectives analysis to model potential solutions to a range of health problems in middle and low income countries. The motivation behind the report was summarized in it title, Investing in health. A healthy population is a major resource that

Table 2. Showing the intellectual property rights negotiated by global institutions and the inter-governmental agencies.

Intellectual property rights
Trade related intellectual property rights
Madrid Declaration
Hague Declaration
Patent cooperation treaty

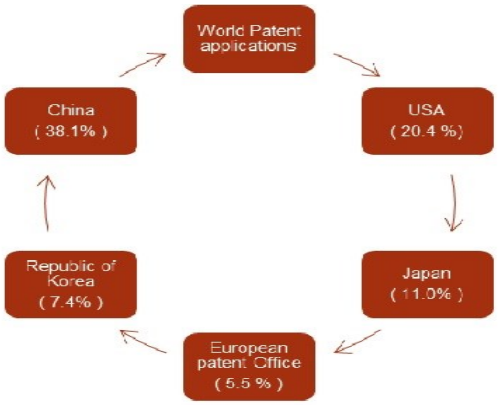

Fig 1. Patents and utility models: Pictorial representations of patents filed world wide Source: WIPO Statistics Database, October 2016

can contribute to stronger economic growth and improving standards of living. On average each 10 percent increase in life expectancy at birth in a country is associated with an increase in economic growth of (0.3-0.4) per cent per year**.** Improved health can lead to greater productivity because there are more economically active adults; fewer dependent adults affected by illness, children who are better able to participate in education to foster the future economies northern and southern parts of the globe. An essential health package in low income countries often consist of the limited list of public health and clinical interventions which should be provided at primary and or secondary level care. In developing countries the packages are often designated based on the convenience and often disease specific, among various population groups.[9] There are various determinants and dimensions to access to essential health care services including medications and the technologies. Some of the key dimensions are illustrated in the table below.

Conclusion

The concept of essential medicines is not very familiar with the medical fraternity, in the developing countries nor do they perceive the importance of prescribing and dispensing the medicines rationally. The problems in judicious use of the medicines is many folds, one side the physicians are not following the standard protocol for dispensing the medicines rationally and on the other side there is acute shortage of the medicines to treat the life threatening diseases in various parts of the world. The funding which goes in to the research in addressing these issues are unevenly distributed. The 10/90 gap, as stated by the global forum for health research, where the 90 percent of the research funds goes only to the 10 percent of the countries to address the burning issues, in health research including the implementation research.

Table 3. Dimensions of access to health care

Dimensions of access	Meaning	Potential indicators
Availability	Whether there is an adequate supply of health services in an area	• Number of physicians or nurses per 1000 population • Number of hospital beds per 1000 population • Distance to nearest primary care provider • Distance to nearest hospital
Utilization	Whether health services are utilized	• Primary care consultations per 1000 populations • Hospital admissions per 1000 populations
Relevance to need	Whether appropriate services are received by people who need them	• Proportion of births attended by trained health care professional • Proportion of subjects with elevated blood pressure who receive antihypertensive therapy
Outcomes	Whether achievable health outcomes are realized.	• Eg. Maternal mortality rate • Mortality rate from appendicitis

Though the concept of funding the health systems research is very old, still in the era of rapid transition, economically and epidemiologically, it makes sense in funding the health systems research , so as to make the health systems conductive and perceptive for the issues such as the in- adequate medicines and health infrastructure for providing better health care service delivery. Trade and commerce plays very important role in making the provisions of the essential medicines, to the vulnerable population groups. The practice of medicine, largely confined to the clinician and patient interactions rather than the systems approach. WHO largely advocates for the systems approach to derive the best solutions to optimize the treatment protocols and the access to the essential medicines. Public health professionals are often frustrated because the public health evidence and a population based perspective on health do not adequately influence the development of public policy, particularly in sectors other than health. An improved understanding of the policy making process and how to influence it, will enable public health practitioners and researchers to engage more effectively in the development of healthy public policy. Public policies with in the context of the global public health, in providing access to the essential medicines needs to be relooked. Thinking like an economist is very essential for understanding the novel concepts of essential medicines and making provisions for the affordability issues.

The gains from specialization and trade are used do-not on absolute advantage but on comparative advantage. When each person specializes in producing the good for which he or she has a comparative advantage, total production of the economy rises. The increase in the size of economic pie can be used to make every one better off.[9] The principle of comparative advantage establishes that there are gains from specializations and trade, particularly in the context of Global public health as trade negotiations and rights, determines the many of the access and affordability issues for commissioning the essential life saving treatments and medications at the health care facilities.

References

1. Drugs, patents and WTO, Symptomatic Relief. Economist, Sept 4, 2003 .
2. Public health policies to protect against the falsified medicines: A systematic review of international , national and local policies. Health policy and planning; 31(10)1448-66.
3. Millio N. Making healthy public policy: developing the science by learning the art. Health promotion International 1987;2: 263-74.
4. Essential medicines for universal health coverage: www.lancet.com, 2007; 389.
5. World Trade Report 2012; Trade and public policies: A closer look at non-tariff measures in the 21st century.
6. Hoosen Coovadia, Irwin Friedman. Reducing health inequalities in developing countries. Oxford text book of Global Public Health.
7. Theodore R. Kucklick. The Medical Device R&D Handbook. 2nd Edition.
8. World IP facts and figures 2016: World Intellectual Property Organization.
9. Essential health packages, what are they for? What do they change: Catriona Waddington: June 2013; HLSP Institute
10. World trade report- 2016, World Trade organization
11. Essential medicines. Indian J Community Med. 2015; 40(4): 223–32.
12. Don nutbeam. Developing healthy public policy. Oxford hand book of public health practice.
13. Commission on health research and development (COHRAD) : A report (1990)
14. Promoting access to medical technologies and innovation: Intersections between pubic heath, intellectual property and trade: 2012, World Health Organization, World Intellectual Property organization, and world trade organization reprinted with index, 2013.