I. Medical technologies: the fundamentals

Against the background of the global burden of disease (GBD) and global health risks, this chapter outlines the fundamental imperative for collaboration. It demonstrates the need for a coordinated approach, taking into account health, intellectual property (IP) and trade variables, to ensure coherent decision-making in the area of public health at the international, regional and domestic levels.

Contents

A. Public health and medical technologies: the imperative for international cooperation

Key points

- The WHO, WIPO and the WTO each have distinct, but complementary, mandates to work on issues relating to public health, IP and trade.
- Although this study focuses on relevant developments relating to medicines, it also covers other medical technologies, such as vaccines and medical devices, including diagnostics, due to their importance for achieving public health outcomes.
- Public health and IP policy-makers are faced with the challenging task of identifying the right mix of policy options to best advance their national objectives. Governments are therefore seeking more coherent, comprehensive and accessible information for policy debate.
- This study is designed to serve as a background reference for policy-makers in the widest sense – lawmakers, government officials, delegates to international organizations, non-governmental organizations (NGOs) and researchers.

Health is a fundamental and universal human right. The attainment by all peoples of the highest-possible level of health is the foundational objective of the WHO. The Preamble of the WHO Constitution emphasizes that international cooperation is essential for the promotion of health:

> "The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States. The achievement of any State in the promotion and protection of health is of value to all. Unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger."

This central objective of the WHO, the essential logic of international cooperation, and the responsibility to take practical action have compelling implications for the international community. Accordingly, public health outcomes are also of importance to both WIPO and the WTO. In this regard, WIPO and the WTO focus on the social and developmental dimensions of innovation and the transfer and dissemination of technology, as well as access to these technologies. WIPO and WTO policy discussions and technical cooperation activities, including a range of programmes conducted in partnership with the WHO, have focused increasingly on public health matters. WTO members have stressed the need for a positive link between public health and the global trading system. In the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration),[1] trade ministers recognized "the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, TB, malaria and other epidemics", and articulated "the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of wider national and international action to address these problems".

"Our three organizations, together with other stakeholders, share a responsibility to address these challenges so that innovative technologies come to the market, in affordable, sustainable and accessible form."[2]

Roberto Azevêdo, *Director-General, WTO*

1. Policy coherence

The WHO, WIPO and the WTO each have distinct, but complementary, mandates to work on issues relating to public health, IP and trade. The three organizations therefore share a responsibility to strengthen practical dialogue between themselves and other partners in order to fulfil their mandates more effectively, to ensure the efficient use of resources for technical cooperation and to avoid duplication of activities.

Coherence is vital in international action to address public health problems. Such coherence has never been more important for the technical cooperation work of the

three organizations than it is at the present time. The WHO brings vast expertise in all areas of public health, including medicine and vaccine policies, medical devices, regulatory questions, pricing and procurement, in addition to other factors affecting access to medicines. WIPO is uniquely positioned to help work towards creating a truly global view and understanding of the IP system, including the flexibilities in implementation of the patent system at the national level, to provide information on patents, including information on the patent status of key medicines and vaccines in developing countries, and to lend its expertise on patent law and its interplay with public policy. The WTO works on several aspects of trade policy that have direct relevance to public health, including IP rules and flexibilities within the international legal system, as they affect both the access and innovation dimensions.

The Doha Declaration has served as a catalyst for developing coherence at the international level. In conjunction with its role of making public health issues a central focus of work carried out by the WTO on IP and international trade, the Doha Declaration has been taken up in a series of World Health Assembly (WHA) resolutions on ensuring accessibility to essential medicines and public health, innovation and IP. Notably, the Doha Declaration was a point of reference in the negotiations that led to the adoption of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI)[3] in 2008. The 2007 WIPO Development Agenda (WIPO, 2007) deals extensively with flexibilities in international IP law, including the health-related flexibilities specifically identified in the Doha Declaration.

These mandates and competencies have been at the centre of policy debates. The UN 2030 Agenda for Sustainable Development, adopted in 2015, calls for cooperation to support sustainable development (target 17.16) and emphasizes the importance of research and development and access to medicines in accordance with the Doha Declaration (target 3.b).

A number of UN high-level meetings have called for cooperation and policy coherence as being central to tackling urgent health issues. For example, the 2016 Political Declaration of the High-Level Meeting of the General Assembly on Antimicrobial Resistance[4] called for enhanced "capacity-building, technology transfer on mutually agreed terms and technical assistance and cooperation for controlling and preventing antimicrobial resistance (AMR), as well as international cooperation and funding to support the development and implementation of national action plans". Similarly, the 2017 Moscow Declaration to End TB and the 2018 UN High-Level Meeting on Non-Communicable Diseases called for increased collaboration among stakeholders and technical partners.[5]

"[U]niversal health coverage is one of the targets the nations of the world have adopted in the Sustainable Development Goals. And it's also our top priority at WHO. But we're aware that achieving universal health coverage is not the job of WHO alone, or of the health sector alone. It will take cooperation between all of us."[6]

Tedros Adhanom Ghebreyesus, *Director-General, WHO*

2. Scope of the study

This study focuses on issues relating to access to medical technologies and innovation. Besides medicines and vaccines, the study addresses other medical technologies, such as medical devices, including diagnostics, due to their importance for achieving public health outcomes. Some of the lessons learned about access and innovation with respect to medicines may be useful with respect to these other medical technologies. While there are significant differences regarding the role of IP for innovation and access, other important determinants for public health, such as health promotion, lifestyle modification, access to adequate and nutritious food, health infrastructure, human resources, health financing and health systems (except where these directly relate to medicines and medical technologies), do not fall within the scope of this study.

3. The need for this study

Governments have choices to make regarding the appropriate implementation of policy instruments in their domestic systems and practices. Even though international standards apply to most of the main policy instruments – in particular, IP – there is "policy space" within and around those standards. Public health and IP policy-makers are faced with the challenging task of identifying the right mix of policy options to best advance their national objectives. Governments are therefore seeking more coherent, comprehensive and accessible information for policy debate. The aim of the technical cooperation activities of the WHO, WIPO and the WTO is to facilitate understanding of the full range of options and their operational context. This study draws together the materials used in technical cooperation and addresses emerging needs for information in an accessible, systematic format, to support ongoing collaborative efforts.

"[I]nnovation exists to improve the quality of life, the foremost basis of which is health, without which nothing really matters. This recognition opposes a humanitarian imperative to economic rationalism."[7]

Francis Gurry, *Director General, WIPO*

The Doha Declaration recognized that "intellectual property protection is important for the development of new medicines". At the same time, it also recognized the concerns about IP effects on prices. The challenge for governments is to use the policy instruments at their disposal to address both aspects in a mutually reinforcing manner. Since the early 2000s, policy-makers have sought effective ways to strengthen the positive linkages between, on the one hand, the private sector's capacity to finance research and development (R&D) and, on the other hand, the public policy goals of selecting, supplying and using medicines in the most rational way.

"Universal health coverage is not a dream for the future. It is a reality now. Countries at all income levels are proving that universal health coverage is achievable and affordable, with domestic resources."[8]

Tedros Adhanom Ghebreyesus, *Director-General, WHO*

Rising health-care costs have led to increased national public health budgets and higher public expectations for health care. In difficult economic times, there is even more reason to evaluate the efficiency and fairness of health services, including expenditure on medicine and medical technology. Effective delivery of health care also means adapting technologies to diverse local needs and priorities. The world is facing an increased burden of non-communicable diseases (NCDs). The increased availability of patents for medicines has implications that pose a further challenge in a wider range of countries, notably in key low-cost exporting countries that have traditionally specialized in generic medicine production. The evolving disease burden, the lack of appropriate medicines required for treating neglected diseases and the challenges of AMR and emerging pathogens with pandemic potential all require the development of new treatments, vaccines and diagnostics. Innovation needs to be encouraged – in terms of both inventing new products and providing effective systems to bring them through very complex product development stages, and to market and deliver them to patients. Policy-makers have recognized the need to look beyond conventional approaches to R&D to address the innovation gap – particularly in the area of neglected diseases, pathogens such as Ebola virus and resistant bacterial infections.

"Trade and the multilateral trading system can help in creating a more favourable global environment for public health policies and the implementation of a balanced and effective intellectual property system."[9]

Roberto Azevêdo, *Director-General, WTO*

4. Who should read this study?

This study is designed to serve as a background reference for policy-makers in the widest sense – lawmakers, government officials, delegates to international organizations, non-governmental organizations (NGOs) and researchers who seek a comprehensive presentation of the full range of issues, including institutions and legal concepts with which they may be unfamiliar. It is also designed to serve as a factual resource for the three organizations' technical cooperation activities. Nothing in the study should be taken as a formal position or the interpretation of rights and obligations by any of the three organizations, or by any of their respective members. Actual policy choices and interpretations of member states' rights and obligations remain exclusively a matter for governments.

"Health, innovation and trade are, in the present configuration of the world, inextricably connected and mutually dependent. We will not be able to enjoy relative health security unless we continue to innovate and bring on new technologies to improve health outcomes."[10]

Francis Gurry, *Director General, WIPO*

B. The cooperating agencies: the WHO, WIPO and the WTO

Key points

- The WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends.
- WIPO is the specialized agency of the United Nations dedicated to developing a balanced and accessible IP system that rewards creativity, stimulates innovation and contributes to economic development in the public interest.
- The core mission of the WTO is to open trade, based on a rules-based, inclusive international trading system. It provides a negotiating forum to its members, monitors the implementation of trade agreements, settles disputes upon request by its members and builds capacity, including as regards the TRIPS Agreement protection and enforcement standards and related policy options.
- Partnership is crucial for an effective international response to the ever-evolving challenges at the interface of public health, IP and trade. For this purpose, the WHO, WIPO and the WTO collaborate with other international and regional organizations, as well as with civil society and the private sector.

This section provides a brief overview of the specific roles, mandates and functions of the WHO, WIPO and the WTO, which cooperate within the general international framework on issues related to the interface between public health, IP and trade concerning innovation in, and access to, medical technologies.

1. World Health Organization

The WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends.

Monitoring the impact of trade and intellectual property rights (IPRs) on public health is one of the strategic areas of the work of the WHO. Following the adoption of the TRIPS Agreement, the Forty-ninth World Health Assembly (WHA), in May 1996, adopted the first mandate of the WHO to work on the interface between public health and IP.[11] In subsequent years, many more resolutions were adopted, continually broadening and reinforcing the WHO mandate to work on issues related to public health, IP and trade.

In May 2003, WHO member states decided to establish the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) to examine the interface between IPRs, innovation and public health.[12] Its 2006 report (WHO, 2006a) contained 60 recommendations aimed at fostering innovation and improving access to medicines. It concluded that:

> "Intellectual property rights have an important role to play in stimulating innovation in health-care products in countries where financial and technological capacities exist, and in relation to products for which there are profitable markets. In developing countries, the fact that a patent can be obtained may contribute nothing or little to innovation if the market is too small or scientific and technological capability inadequate. [...] Where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding."

Following CIPIH recommendations, WHO member states adopted in 2008 and 2009 the GSPA-PHI, which was a major step forward in the process of achieving global consensus on practical action on public health, innovation and IP. The GSPA-PHI reaffirmed and extended the mandate of the WHO to work at the interface of public health and IP. A comprehensive evaluation and an overall programme review of the GSPA-PHI were published in 2016 and 2017, respectively (Capra International, 2016; WHO, 2017e).

In 2019, the WHO Secretariat developed a new, comprehensive Access Roadmap, which outlines the programming of the WHO's work on access to medicines and vaccines for the period 2019–2023, covering implementation of the GSPA-PHI as well as other relevant strategic documents, such as the WHO Global Strategy on Human Resources for Health: Workforce 2030.[13]

The WHO has produced a large body of material to provide evidence-based guidance to its member states in order to support them during the process of shaping their policies on public health and IP. Examples of such guidance include patent landscape analyses for key hepatitis C medicines (WHO, 2016d), a range of detailed analyses of opportunities and challenges in local production[14] and a technical background document on intersections in trade and health (WHO, 2015d).

The WHO also fulfils technical functions outside the scope of the GSPA-PHI that are of significant relevance to the intersection of medicines, IP and trade. For example, the Model List of Essential Medicines (EML),[15] reviewed every two years, comprises the medicines that satisfy the priority health-care needs of the population,[16] and is used by many countries as a basis for developing national formularies (lists) to guide procurement, among other purposes. As another example, the WHO provides a quality assurance mechanism through its Prequalification platform.[17] Hundreds of medicines and other health products have been quality assured through WHO prequalification, without which, in many cases, quality assurance would have been difficult or impossible (see Chapter IV, section A.11(a)).

2. World Intellectual Property Organization

WIPO is the specialized agency of the United Nations dedicated to developing a balanced and accessible IP system which rewards creativity, stimulates innovation and contributes to economic development in the public interest.

The core activities of WIPO include:

- administering multilateral treaties and supporting the evolution of the international legal IP frameworks
- providing global IP services for a fast, efficient and more cost-effective route for IP protection across borders, and also to facilitate alternative dispute resolution services
- cooperating with governments, intergovernmental and non-governmental organizations, and with public and private-sector stakeholders to assist in developing and implementing national IP and innovation strategies, developing appropriate regulatory frameworks and building the infrastructure and human capacity needed to harness the potential of IP for economic development
- developing technical platforms to facilitate cooperation among IP offices
- developing free databases of patents, trademarks and industrial designs to facilitate access to knowledge
- building awareness, understanding and respect for IP
- working in partnership with the United Nations and other organizations to identify IP-based contributions to climate change, food security, public health and other global challenges.

In 2007, the WIPO General Assembly established the WIPO Development Agenda[18] to ensure that development considerations form an integral part of the work of WIPO. Development is considered to be a cross-cutting issue that impacts various sectors of the organization. The 45 Development Agenda recommendations guide the work of WIPO.

Several areas of the work carried out by WIPO have particular relevance for public health.

The WIPO Global Challenges Program addresses innovation and IP as they relate to global and interconnected issues, such as climate change, public health and food security. The Program seeks to raise awareness and understanding of the interplay among innovation, technology transfer and the dissemination of technology, among other things, as they relate to health innovation and access to medicines. WIPO Re:Search, a public–private partnership (PPP), aims at enabling the sharing of IP and expertise to promote the development of medicines to treat neglected diseases (see Chapter III, section C.8).

WIPO facilitates discussion among member states on the identification of issues in patent law that require multilateral attention and actions, with a view to keeping pace with the rapidly evolving technological, economic and social environments.[19] The continuing growth in the number of patent applications worldwide and the constant development of technologies present a challenge for the effective and efficient handling of patent applications, for the achievement of high quality in patents that are granted, and for the role of patents in contributing to innovation and the dissemination of technology. WIPO advises its member states not only on establishing and implementing the requisite legal framework but also on how to assess options and to develop coherent policy strategies. In 1995, WIPO and the WTO established an agreement as a basis for collaboration in the provision of legal and technical assistance relating to the TRIPS Agreement.[20] WIPO member states have been engaged in discussions in the Standing Committee on the Law of Patents (SCP)[21] on issues related to patents and health since 2011 (see Box 2.10).[22]

The WIPO Traditional Knowledge Program aims at achieving more effective use of IP principles and systems for the legal protection of traditional knowledge, including traditional medicine.[23]

The WIPO Program for Building Respect for IP facilitates international policy dialogue on IP, notably through the work of the Advisory Committee on Enforcement (ACE) (see Chapter II, section B.1(f)(iii)) and provides technical and legislative assistance to member states on IP law enforcement and awareness-raising.

In line with its goal of fostering international policy dialogue on IP and public health, WIPO also engages substantively with other relevant stakeholders – UN and intergovernmental organizations, governments of member states, civil society and NGOs, as well as the private sector and academia.

3. World Trade Organization

The core mission of the WTO is to open trade, based on a rules-based, inclusive international trading system. It provides a negotiating forum for its members, monitors the implementation of trade agreements, provides assistance to build capacity, including as regards the TRIPS Agreement protection and enforcement standards and related policy options, and resolves disputes upon request by its members. International trade and trade rules intersect with public health objectives in various areas and in many different ways. Most directly, integration into the world economy can enhance access to the most basic requirements for good health, such as the safe supply of food or access to health-related products and services. Trade also offers the opportunity for economies to grow and thus contributes to the alleviation of poverty and ill health.

The importance of public health has been recognized in the rules of the multilateral trading system since 1947. The General Agreement on Tariffs and Trade (GATT), adopted in 1947 and subsequently incorporated in the GATT 1994, contains an exception in Article XX(b), which explicitly recognizes the right of governments to enact trade-restricting measures that are necessary to protect human life and health. The right to take measures for the protection of health is recognized in a number of provisions in other WTO agreements, including the TRIPS Agreement.[24]

The implementation of the rights and obligations established under the covered agreements is overseen by the Ministerial Conference and subsidiary WTO bodies. Ministers have recognized that under WTO rules no country should be prevented from taking measures for the protection of human, animal or plant life or health, or of the environment, at the levels it considers appropriate, subject to certain requirements.[25]

In the area of IP, the search for a balance between the need to protect IPRs to provide incentives for R&D on the one hand and, on the other hand, to address concerns about the potential impact of such protection on the health sector – in particular its effect on prices – has been an important consideration in the WTO's work. A number of provisions in the TRIPS Agreement are directly relevant to public health. WTO members have the flexibility to interpret and implement these provisions in a manner supportive of their right to protect public health. The importance of creating a positive, mutually reinforcing link between the IP system and access to medicines was recognized in the Doha Declaration in 2001. In 2003, the General Council of the WTO adopted an additional flexibility in the form of a special compulsory licensing system for export of medicines. This system is designed to deal with the difficulties of WTO members lacking sufficient manufacturing capacities to make effective use of compulsory licensing when they have to import the medicines needed from third-country suppliers where patents have been granted.

The WTO serves as a useful and effective forum for discussions regarding the interface between IPRs and public health, for example, through discussions at the TRIPS Council.

The WTO Secretariat aims to enhance the participation and informed decision-making of its members and observer governments through awareness-raising, capacity-building and the provision of factual and technical information. To achieve this objective, the WTO regularly engages in technical assistance activities, which comprehensively cover the relationship between trade, IPRs and public health.[26]

A core function of the WTO is to resolve disputes among its members concerning their compliance with their commitments under the Marrakesh Agreement Establishing the World Trade Organization (WTO Agreement). The WTO has developed extensive jurisprudence concerning the intersection between public health and trade rules under the GATT 1994, the Agreement on Technical Barriers to Trade (TBT Agreement), the TRIPS Agreement and other agreements.

4. Trilateral cooperation

Since 2001, the principles enshrined in the Doha Declaration have shaped the framework for multilateral cooperation in this area and have guided the WHO, WIPO and the WTO, including for the provision of technical and policy support requested by members, joint publications and mutual participation in training programmes.

WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat (WHO and WTO, 2002) examined the linkages between trade and health

policies in general, to enable trade officials and health officials to better understand and monitor the effects of their work on each other's areas of responsibility. The study remains a useful resource on many issues, such as health services, infectious disease control, food safety and tobacco.

The 2007 WIPO Development Agenda – specifically, Recommendation 40 – requested the WIPO Secretariat to intensify its cooperation on IP-related issues with relevant international organizations, in particular with the WHO and the WTO, in order to strengthen the coordination for maximum efficiency in undertaking development programmes.[27] In the WHO, the GSPA-PHI adopted in 2008 requested the WHO "to coordinate with other relevant international intergovernmental organizations, including WIPO, WTO and UNCTAD, to effectively implement the global strategy and plan of action".[28]

Given that partnership is crucial for an effective international response to the ever-evolving challenges facing public health, the WHO, WIPO and WTO Secretariats have intensified interagency collaboration on matters related to public health, IP and trade.[29] Within their respective mandates and budgets, common activities are planned and carried out jointly to ensure that data, experiences and other information are exchanged, and to ensure that the best use is made of the available resources (Krattiger et al., 2015).

This collaboration relies on cooperation with other international and regional organizations, as well as with civil society and the private sector. The WHO, WIPO and the WTO have therefore broadened the base of their collaborative and consultative networks dealing with public health issues. In their capacity-building activities, the three organizations regularly include speakers from relevant international organizations, industry and civil society.

Since 2010, the WHO, WIPO and the WTO have organized a series of joint technical symposia (see Box 1.1).[30] These are designed to improve the flow of practical information to guide and support technical cooperation in the future. Similarly, the launch of the initial version of this trilateral study has been a further milestone on the road towards stronger cooperation. The study also laid the groundwork for a distance learning course, Promoting Access to Medical Technologies and Innovation, on the intersections between public health, IP and trade, which commenced in 2016.[31]

5. Other international key stakeholders

The period since 2001 has seen dramatic growth in the number and diversity of participants in international policy debates concerning innovation in, and access to, medical technologies. Consideration of these issues necessarily entails a multidisciplinary and pluralistic approach. A distinctive feature of the debates has been the range of perspectives during discussions, coupled with the depth of expertise and practical experience that has been drawn from international and intergovernmental organizations, procurement and product development initiatives, and NGOs such as public health advocates and industry associations. The study recognizes and values the work of many others, and no suggestion is made about the relative importance of any organization, whether mentioned or not.

Box 1.1: WHO–WIPO–WTO technical symposia

2010	Access to Medicines: Pricing and Procurement Practices[32]
2011	Access to Medicines: Patent Information and Freedom to Operate[33]
2013	Medical Innovation – Changing Business Models[34]
2014	Innovation and Access to Medical Technologies: Challenges for Middle-Income Countries[35]
2015	Public Health, Intellectual Property and TRIPS at 20: Innovation and Access to Medicines: Learning from the Past, Illuminating the Future[36]
2016	Antimicrobial Resistance – How to Foster Appropriate Use of Antibiotics, Access and Innovation[37]
2018	Sustainable Development Goals: Innovative Technologies to Promote Healthy Lives and Well-Being[38]
2019	Cutting-edge Health Technologies: Opportunities and Challenges[39]

C. The global burden of disease and global health risks

Key points

- Understanding the patterns and trends of the global burden of disease (GBD) is important in order to develop effective strategies to improve health and identify the range of medical technologies that are needed.
- Longer life expectancies and population ageing have resulted in an increased focus on non-communicable diseases (NCDs) in low- and middle-income countries, in addition to high-income countries. NCDs caused 60 per cent of the burden of disease (measured by DALYs) in 2016.

This section introduces the GBD concept and explains trends related to it.

International efforts to address public health issues need to be grounded in a clear understanding of GBD, and future efforts should be guided, as far as possible, by best estimates on the evolving disease landscape. The GBD measurement methods were developed in order to generate comprehensive and internally consistent estimates of mortality and morbidity by age, sex and region. The burden of disease studies aim to summarize overall loss of health associated with diseases and injuries. The key feature of this concept is a summary measure called the disability-adjusted life year (DALY), which is now widely used to measure the burden of ill health. The DALY concept was introduced as a single measure to quantify the burden of disease, injuries and risk factors (Murray and Lopez, 1996). The DALY is a measure that combines years of life lost due to premature death, and years of life lived in less than full health (see Box 1.2).

1. Current estimates of global and regional burden of disease

Globally, the average burden of ill health in 2016 was 358 DALYs per 1,000 people, a reduction of 22 per cent since 2000.[40] Global life expectancy at birth has increased from 67 years in 2000 to 72 years in 2016.[41] The WHO African Region bore the highest burden of ill health per person in 2016, with an average of 587 DALYs per 1,000 population. This is more than twice the burden of disease in the region with the lowest DALY rates (270 per 1,000 population) in 2016, the WHO Western Pacific Region.[42]

2. Trends: major cause groups contributing to the total disease burden

The proportional contribution of the three major cause groups to the total disease burden has changed substantially since 1990, as part of the so-called "epidemiological transition" (Jamison et al., 2013). Globally in 2000, communicable, maternal, neonatal and nutritional (CMNN) conditions grouped together contributed 43 per cent of the total disease burden in terms of DALYs, and NCDs contributed 47 per cent. By 2016, the share of NCD burden had increased to 60 per cent, more than double the burden caused by CMNN diseases, which represented 29 per cent of burden in DALYs. The share of injury burden has changed little, from 10 per cent of DALYs in 2000 to 11 per cent in 2016.[43]

The three leading contributors to overall DALYs in 2016 globally were ischaemic heart disease, stroke and lower respiratory infections (see Figure 1.1). The leading causes of death in 2016 were ischaemic heart disease, stroke and chronic obstructive pulmonary disease (see Figure 1.2).

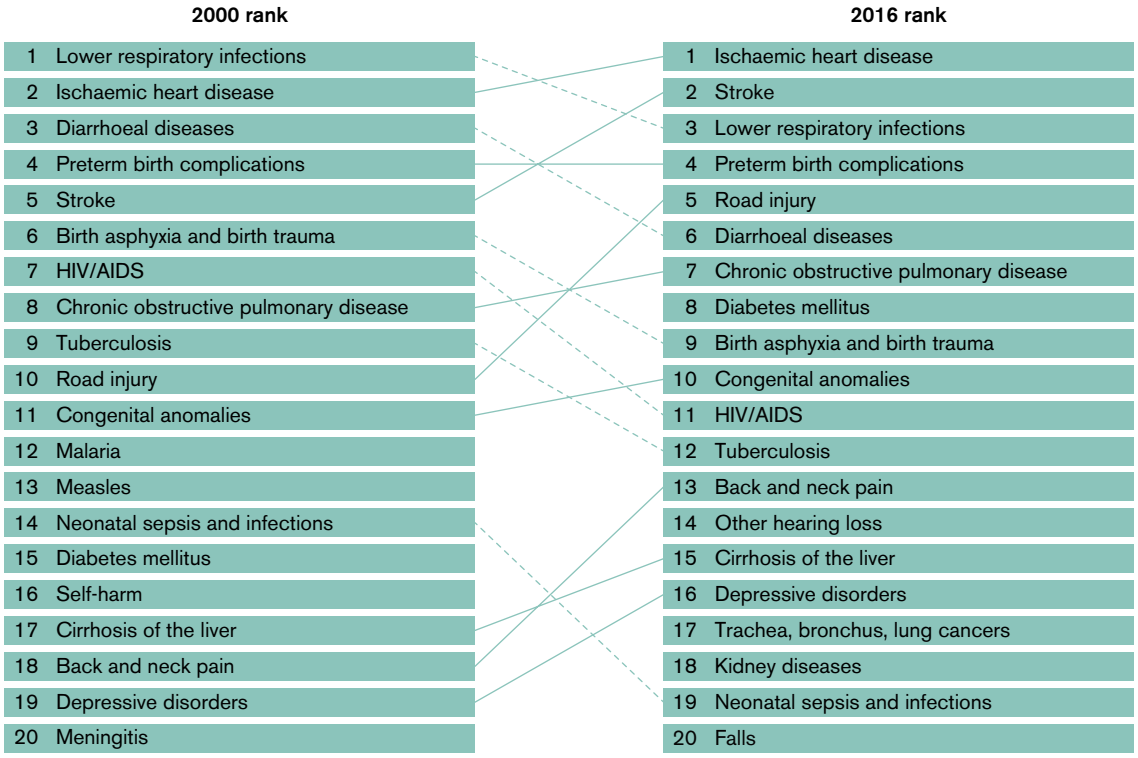
Box 1.2: The disability-adjusted life year (DALY)

The DALY extends the concept of potential years of life lost due to premature death to include equivalent years of "healthy" life lost by virtue of being in states of poor health or disability (Murray and Lopez, 1996). One DALY can be thought of as one lost year of "healthy" life, and the burden of disease can be thought of as a measurement of the gap between the current health status and an ideal situation where everyone lives into old age, free of disease and disability. DALYs for a disease or injury cause are calculated as the sum of the years of life lost (YLL) due to premature mortality in the population and the years lost due to disability (YLD) for prevalent sequelae associated with the disease or injury. YLL is calculated from the number of deaths at each age multiplied by a global standard life expectancy of the age at which death occurs. YLD for a particular cause in a particular time period is estimated as follows:

$$\text{YLD} = \text{prevalence} \times \text{disability weight}$$

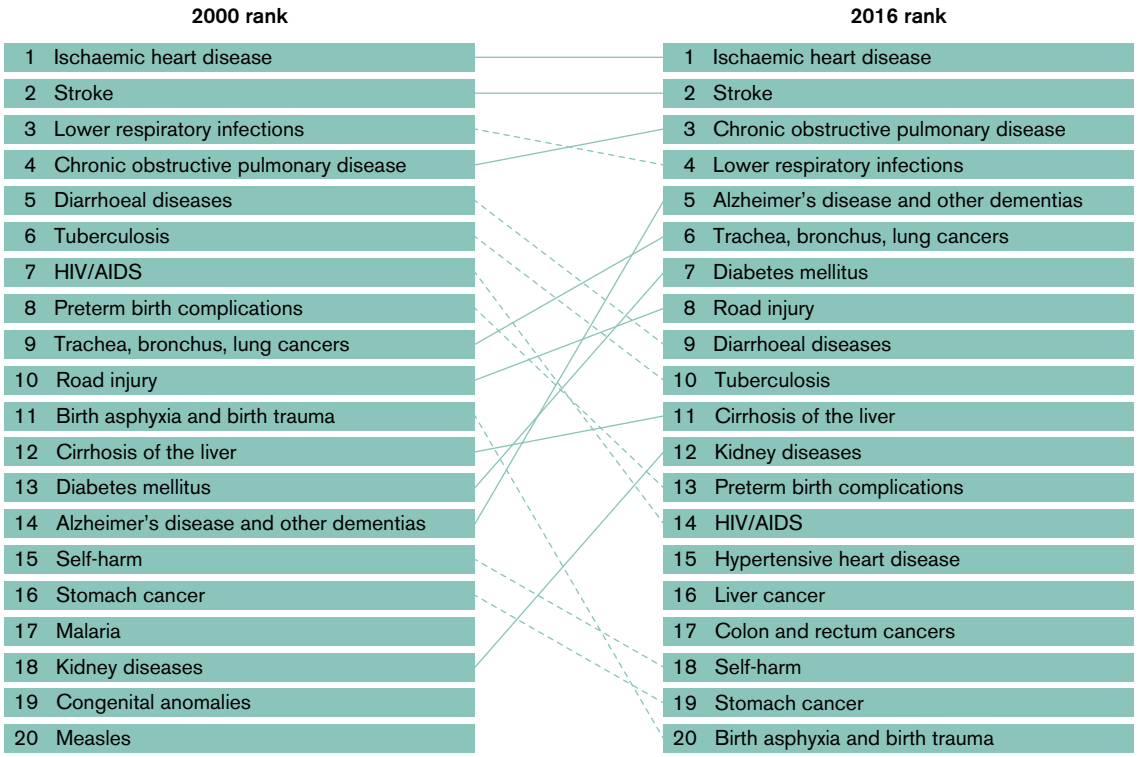
The weight factor reflects the severity of the disease on a scale from 0 (perfect health) to 1 (death).

Figure 1.1: Leading causes of disease burden in DALYs in 2000 and 2016 globally



Source: World Health Organization. Disease burden and mortality estimates, available at: https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates.

Figure 1.2: Leading causes of death in 2000 and 2016 globally



Source: World Health Organization. Disease burden and mortality estimates: Cause-specific mortality, 2000–2016, available at: https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates.

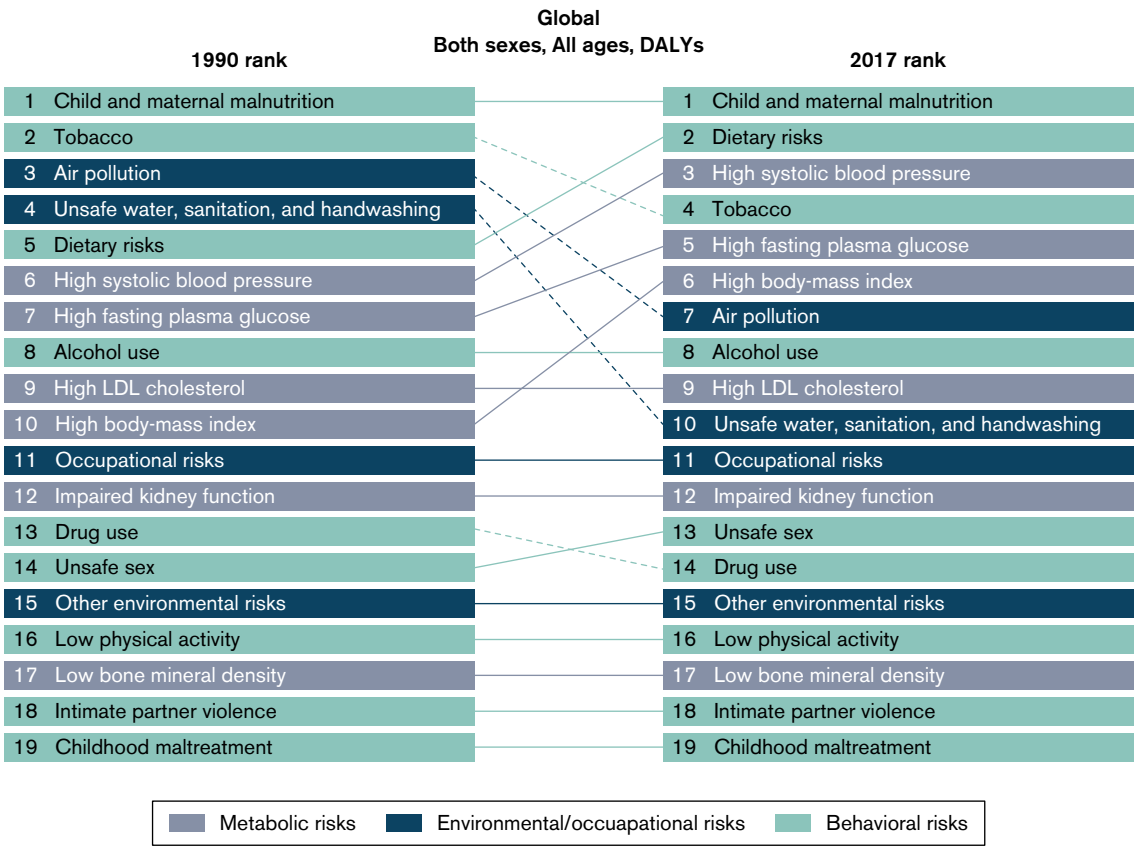
3. Trends in global health risks

Mortality and burden of disease can be attributed to selected major risks. In this context, the WHO defines "health risk" as "a factor that raises the probability of adverse health outcomes" (WHO, 2009). In 2017, the leading global risks for mortality were dietary risks (responsible for 19 per cent of deaths globally), high systolic blood pressure (19 per cent), tobacco use (14 per cent), high fasting plasma glucose (12 per cent), air pollution (9 per cent), high body-mass index (8 per cent), high LDL cholesterol (8 per cent), child and maternal malnutrition (6 per cent), alcohol use (5 per cent) and impaired kidney function (5 per cent) (Level 2 risk groups).[44]

The leading global risks for burden of disease as measured in DALYs (see Figure 1.3) are child and maternal malnutrition (13 per cent of global DALYs), dietary risks (10 per cent), high systolic blood pressure (9 per cent), tobacco (9 per cent), high fasting plasma glucose (7 per cent), high body-mass index (6 per cent), air pollution (6 per cent), alcohol use (4 per cent), high LDL cholesterol (4 per cent) and unsafe water, sanitation and handwashing (3 per cent).[45]

Health risks are in transition: populations are ageing due to successes against infectious diseases. At the same time, patterns of physical activity, as well as food, alcohol and tobacco consumption, are changing. Low- and middle-income countries (LMICs) now face a double burden of increasing chronic, non-communicable conditions, as well as the communicable diseases which traditionally affect the poor. Understanding the role of these risk factors is important for developing clear and effective strategies for improving global health (WHO, 2009; Jamison et al., 2013).

Figure 1.3: Global burden of disease ranking, 1990 and 2017



Source: Institute for Health Metrics and Evaluation. Global Burden of Disease study, available at: http://ihmeuw.org/4sdh. Data are given as Level 2 risk groups.

D. Factors shaping public health policy

Key points

- Achieving sustainable and more equitable public health outcomes depends on the dynamic interplay of national public health policy, including effective health systems and adequate financing of health systems, a sound regulatory environment, trade and competition settings, procurement policies, innovation strategies and the IP system.
- Innovation cannot take place in isolation from concerns about access, and access has to be seen in the broader context of the need for innovation and effective regulation.
- There is a continuing need for new, adapted and more effective health technologies to meet the challenges presented by the evolving global burden of disease.
- An increasing number of national, regional and international policy processes, including the framing of trade agreements, involving a multiplicity of agencies, are tackling issues that impact access to, and innovation in, medical technologies.

1. Seeking effective outcomes within a complex policy environment

Building a sustainable global response to the demand for both innovations in medical technology and effective and equitable access to needed technologies is a complex and constantly evolving challenge. While it is often expressed in abstract or political terms, the effort fundamentally concerns how to deliver improved health outcomes. Creating new medical technologies, assessing these technologies, providing for their effective distribution and ensuring that they are used rationally are, ultimately, practical processes. These processes range from the work of laboratory research scientists to the care provided by community health workers in a rural clinic.

The policy, economic and legal environment influences and can determine the actions, choices, priorities and allocation of resources that are applied at a practical level. This policy environment is complex: it comprises laws, regulations and policy instruments, at national, regional and international levels, which address diverse fields, including public health, international trade and the IP system. Effective progress and sustained impact on public health cannot be attained by working within the confines of one discrete set of policy measures or legal instruments. Lack of coherence, or the prospect of conflict, between law and policy in different fields can thwart progress and impede practical benefits. It follows that understanding the intersections between these different policy measures is key to ensuring that they work harmoniously for overall public health benefit.

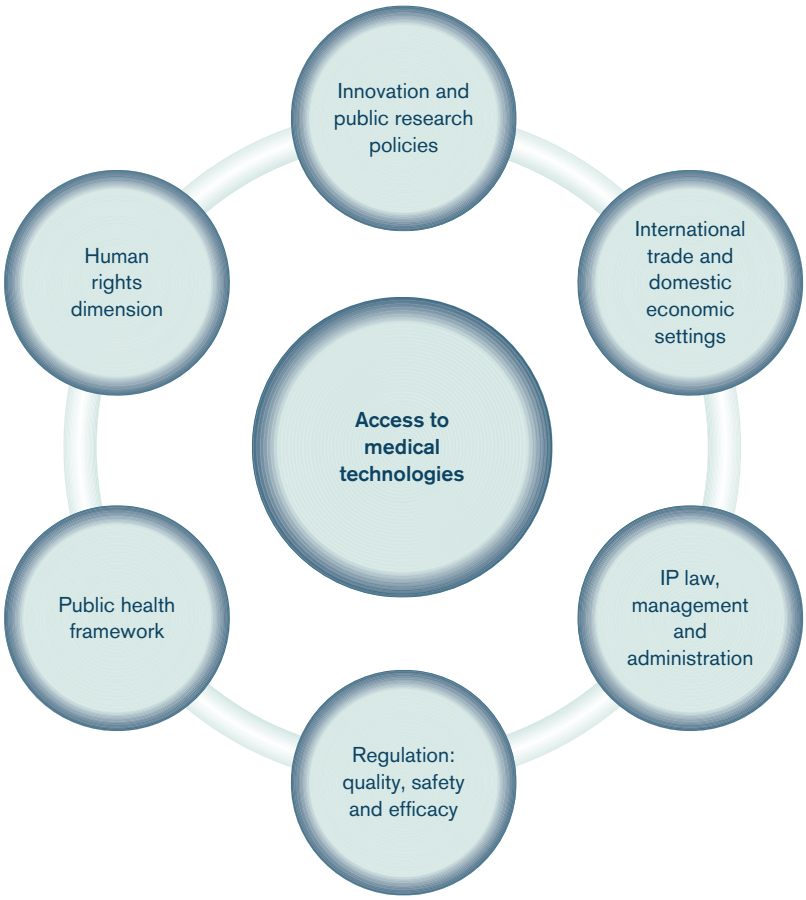
2. Transforming policy intersections

The emphasis on "intersections" – understanding the linkages and interplay between distinct areas of law and policy (see Figure 1.4) – is a consistent theme in recent debate on public health policy. This study identifies two levels of intersection:

- Points of interaction between the legal and policy principles in different domains, so that law and policy instruments can be interpreted and applied in practice to promote public health
- The integration of sets of data drawn from diverse fields, so that policy-makers can work from an improved, integral base of information, combining data on public health, determinants of access to medical technologies, coverage of relevant IP rights and trade settings.

Trade and commercial perspectives are sometimes regarded as being essentially at odds with promoting public health. Yet the commercial environment, the promotion of competition and of private-sector innovation, and the regulation of trade are crucial determinants for access to medicines. International trade is vital for access to medical technologies, and no country is entirely self-sufficient, even those that have strong local production. Economies of scale for industry and a competitive market can improve affordability of medical technologies. Openness to international trade generally promotes competition, improving affordability and access. By enabling a wider range of suppliers to serve the population, it can also enhance security of supply. Trade policy settings, such as tariffs, quotas and other

Figure 1.4: The distinct policy domains of public health



regulations, have a direct effect on prices and availability. Many governments have taken national legal and policy measures to enable or promote generic competition in the supply of medicines in order to reduce prices. WTO rules have been interpreted in dispute settlement to provide for public health objectives, such as enhanced entry of generic medicines, and the Doha Declaration has affirmed that the TRIPS Agreement can and should be interpreted from a public health perspective.

Trade policy and the economics of global production systems are also key factors in strategic plans to build domestic production capacity that aim for better access to medical products. Procurement policies favouring open and competitive tendering, coupled with the rational use of medicines, become all the more important in ensuring continued access in a fiscal climate in which national budgets are under pressure and philanthropic programmes face funding constraints. Programmes for access to medicines also stand to benefit from better, more integrated use of data, including on current and projected disease burdens, efficacy of medicines, the costs of R&D, price and IP coverage of medicines, and trade and regulatory measures.

Policy discussions have increasingly covered the innovation dimension. Indeed, the intersection between innovation and access is fundamental, and forms the fulcrum of the present study. Policy measures aimed at promoting access or innovation need to recognize that these two concepts are intrinsically intertwined. Merely leveraging enhanced access to the stock of existing, proven medicines is insufficient. The current pharmacopeia needs constant expansion to keep pace with the evolving disease burden. The disease burden continues to evolve, with, for example, the growing burden of NCDs in LMICs becoming a priority area of concern. New strains of viruses and AMR challenge the efficacy of existing treatments. And medical innovation has historically failed to address major diseases that are endemic in the LMICs.

3. Building stronger links between local, national and global levels

Countries develop national health policies and strategies for guiding health development, taking into account the international legal and policy framework. Conceptually,

Figure 1.5: Policy intersections between distinct levels

Policy intersections: from international instruments to individual projects

An overview of the policy framework of medical technologies, highlighting the interplay and feedback loops between individual R&D programmes and international law and policy instruments

International and national legal and policy settings ultimately guide choices and outcomes at the practical level, creating or otherwise contributing to the necessary incentives, legal underpinning and resources …

… but, in turn, the policy framework is ideally shaped by a broad base of expertise and empirical data gleaned from practical experience with innovation.

these policies and strategies are based on, and draw their strength from, a national vision for social development and relevant policies. National health policy is aimed at organizing and strengthening the national health systems in such a way that they effectively help in achieving the objectives of the policy. Health policy refers to decisions, plans and actions that are undertaken to achieve specific health-care goals within a society. It may be in the form of a formal document backed up by institutionalized processes and reviewed periodically, or it may be dispersed among a number of different documents, including notices, plans, strategies, decisions and directives. Health laws, rules and technical guidelines are also considered to be components of health policy.

Promoting medical innovation policy is a challenge, as it operates at the intersection of several policy domains. The essential challenge for innovation in medical technologies can be expressed in simple terms:

- First, to secure the requisite resources (including know-how, research and product development capacity, clinical trial expertise, regulatory infrastructure, background and platform technologies and research tools, and financing)
- Second, to apply these innovation resources most effectively towards addressing unmet public health needs.

Yet meeting this challenge entails working on complex intersections between different policy areas, applying a mix of incentives and market interventions, providing funding and other support for R&D, developing infrastructure, and building a public research base and a skilled research workforce. Equally, promoting innovation can entail making better use of existing resources, leveraging access to existing technologies, drawing on drug development skills and R&D infrastructure, and drawing more effectively on indigenous research and innovation capacity, to expand the medical technology development pipeline. A host of international, regional and national legal and policy instruments influence innovative activity.

International legal instruments need to be understood through the prism of national experience with their implementation. A systematic understanding of the intersection between these different layers of policy and practice (see Figure 1.5) is required to assess how international, national and institutional policies determine actual innovation outcomes, and how, in turn, practical experience influences the policy framework.

4. The empirical challenge: an accessible base for policy

Policy-makers dealing with the challenges of medical technology access and innovation are more numerous and more diverse than at any time previously, and contend with a host of policy, legal and administrative structures at national, regional and international levels. For example, national regulatory authorities who seek to safeguard the public against unsafe or ineffective medicines deal with clinical trial data that may be protected by IP laws, and work within a legal and policy framework shaped by multiple international and regional instruments. Patent offices, which face unprecedented workloads, must use the best possible sources of technological data when searching and examining prior art[46] to decide whether

Box 1.3: Health and medical technologies: fundamental concepts

While the terms “health technologies” and “medical technologies” are sometimes used interchangeably, “health technologies” is the broader term, encompassing medical technologies. There are no watertight definitions of either term. The WHO defines a health technology as application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives.[47]

Medical technologies are associated with the concept of medical intervention. These interventions can be preventive (e.g. vaccine), diagnostic (e.g. in vitro diagnostic kit, stethoscope, thermometer), therapeutic (e.g. medicine, surgical instrument, surgical procedure, implant) or rehabilitative (e.g. physiotherapy equipment, assistive device such as a crutch). Medical devices are a subgroup of medical technologies, including any article, instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article that does not achieve its primary intended action in or on the human body solely by pharmacological, immunological or metabolic means. Examples include syringes, defibrillators, in vitro tests and hip prostheses. Health technologies include, in addition to medical technologies as outlined above, for example, assistive technologies, such as a white stick which may be used by a person who is blind, or a treadmill and exercise equipment which may be used as a health-promoting device.[48]

As technology evolves, more combination products materialize – such as medicines in medical devices delivery sets. There are also more and more examples of combined medical technologies. Metered-dose inhalers for the treatment of asthma are an example of important essential medicines commonly delivered through proprietary devices.

to grant patents on claimed inventions. Procurement programmes must contend with a host of rapidly evolving factors while assessing evolving disease burdens, clinical needs, the selection of essential medical technologies, efficacy, prices and availability, and regulatory and IP aspects. Common to all these diverse challenges is the requirement for a stronger empirical base so that policy choices are more likely to address practical needs. While there have been significant improvements in the quality and inclusiveness of data, as well as access to the necessary information technology (IT) tools required to convert raw data into accessible knowledge services for stakeholders, more needs to be done to further improve the empirical basis for solid decision-making.

Development of health technologies (see Box 1.3) is, in many cases, a complex, risky and uncertain process, drawing on diverse inputs originating from both the public and private sectors, and often requiring scrupulous testing and regulatory oversight. Innovation in medicines and vaccines is among the most uncertain and expensive forms of technology development, creating the need for distinct innovation structures, close regulatory and ethical attention, appropriately high standards of safety and efficacy, and specific or targeted incentives.

Providing access to medicines, vaccines and other medical technologies – the key focus of this study – is an essential ingredient for an effective response, but it is far from being sufficient in and of itself to achieve broad public health objectives. At the national level, the political commitment of the government is required so that it allocates the requisite financial resources to the health sector to develop strong health systems. Effective access to medical technologies is dependent on access to appropriate clinical infrastructure and medical services. Prevention is another key aspect. For example, the major proportion of the burden of NCDs can be prevented by reducing the exposure of populations to tobacco use, unhealthy diets, physical inactivity and harmful use of alcohol. To this end, effective health prevention and promotion programmes are required to address the main risk factors.

As the disease burden shifts and evolves, there is a continuing need for new, adapted and more effective medicines. Access to necessary medical technologies is not, therefore, a static equation – an integral feature of appropriate access strategies must be recognition of the value of targeted and appropriate innovation, both for major new breakthroughs and for adaptations to, and improvements in, existing technologies.

Innovation does not take place in isolation from concerns about equitable access to medicines and other medical technologies. The social value of medical innovation must be measured in part by the extent to which it is effectively and sustainably available to the people who need it. The widespread and equitable health impact of new technologies cannot be achieved without ensuring appropriate means of access to finished products. Thus, an overall policy on medical innovation needs to consider the access dimension as well – how, in practice, a new technology will be made available to those who need it, so that it does not remain an abstract theory and is not reserved only for a narrow segment of society. Building access considerations into innovation policy has numerous dimensions, ranging from the core aim of research and product development activities, to work on "appropriate" or adaptive forms of existing technologies suitable for resource-poor clinical environments, and to consideration of freedom-to-operate (FTO) strategies and mechanisms for integrating technologies into a finished product so that it can be distributed widely and in the most effective form.

Access also has to be understood in a wider context. For example, regulation of medical products is an integral part of the access equation. "Access" is not simply the capacity to purchase – or to be supplied with – a basic commodity or consumer product. The availability of a technology generally must be backed by sound regulation that is both monitored and enforced, so as to provide reasonable guarantees that the technology is safe and effective. Equally, many medicines and technologies require a certain degree of clinical support and backup, including diagnosis, prescription and dispensation, and appropriate follow-up.

Endnotes

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3 WHA, Resolution WHA61.21: Global strategy and plan of action on public health, innovation and intellectual property; WHA, Resolution WHA62.16: Global strategy and plan of action on public health, innovation and intellectual property.

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16 See https://www.who.int/topics/essential_medicines/en/.

17 See https://extranet.who.int/prequal/.

18 See https://www.wipo.int/ip-development/en/agenda/.

19 See WIPO document A/59/8, available at: https://www.wipo.int/edocs/mdocs/govbody/en/a_59/a_59_8.pdf.

20 Agreement Between the World Intellectual Property Organization and the World Trade Organization of 22 December 1995, available at: https://www.wipo.int/treaties/en/text.jsp?file_id=305582.

21 See https://www.wipo.int/policy/en/scp/.

22 See https://www.wipo.int/patents/en/topics/public_health.html.

23 See https://www.wipo.int/about-wipo/en/activities_by_unit/index.jsp?id=122.

24 For example, see Article 8 of the TRIPS Agreement; the Doha Declaration on the TRIPS Agreement and Public Health; Article 2.1 of the Agreement on the Application of Sanitary and Phytosanitary Measures; Article 2.2 of the Agreement on Technical Barriers to Trade; and Article XIV(b) of the General Agreement on Trade in Services.

25 Doha Ministerial Declaration, adopted on 14 November 2001, WTO document WT/MIN(01)/DEC/1, para. 6.

26 For more information on the WTO activities, see WTO document IP/C/W/634.

27 See https://www.wipo.int/ip-development/en/agenda/recommendations.html.

28 WHA, Resolution WHA61.21: Global strategy and plan of action on public health, innovation and intellectual property, para. 4(5).

29 See https://www.who.int/phi/implementation/trilateral_cooperation/en/; https://www.wipo.int/policy/en/global_health/trilateral_cooperation.html; and https://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm.

30 For more details regarding each symposium see https://www.who.int/phi/implementation/trilateral_cooperation/en/; https://www.wipo.int/policy/en/global_health/events.html; and https://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm.

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35 See https://www.wto.org/english/tratop_e/trips_e/trilat_symp14_e/trilat_symp14_e.htm.

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46 For more information on prior art, see Chapter II, section B.1(b)(iv) and WIPO document SCP/12/3 Rev.2, para. 210.

47 WHA, Resolution WHA60.29: Health technologies.

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