Executive Summary

Why this study?

Public health is inherently a global challenge and thus assumes high priority for international cooperation. The World Health Organization (WHO) is the directing and coordinating authority for health, but the interaction between health issues and other policy domains – human rights, development policy, intellectual property (IP) and international trade – creates a strong rationale for cooperation and coordination between the WHO and other international organizations, in particular the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO). This study and its updated and reviewed second edition have emerged from an ongoing programme of trilateral cooperation among these agencies. It responds to an increasing demand, particularly in developing countries, for strengthened capacity for informed policy-making in areas of intersection between health, trade and IP, focusing on access to and innovation of medicines and other medical technologies. The need for cooperation and coherence at the international level has intensified over the past decades, as successive multilateral decisions have confirmed.

The study is set in an evolving health policy context. An integrated approach can reinforce a dynamic, positive interplay between the measures that promote innovation and those that ensure access to vital medical technologies. 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 needs for information in an accessible, systematic format to support ongoing collaborative efforts.

Navigating the study

The study has been prepared as a capacity-building resource for policy-makers. The study is structured so as to enable users to grasp the policy essentials, and then to look more deeply into areas of particular interest. After explaining the need for policy coherence and the role of each of the cooperating agencies to address the global disease burden and health risks (see Chapter I), the study lays out a general panorama of the policy landscape (see Chapter II), so that all interrelated elements can be seen in context. It then provides more detailed accounts of issues specifically connected with innovation (see Chapter III) and access (see Chapter IV). The contents reflect the multilateral policy debate over the past two decades, recognizing that innovation and access are inevitably intertwined – both are indispensable ingredients to meeting an evolving global disease burden.

- Chapter I presents the general background to health policy relating to medical technologies and to international cooperation in this field, sets out the distinct roles and mandates of the three cooperating agencies, and outlines the global disease burden that defines the essential challenge for health policy.
- Chapter II outlines the essential elements of the international framework – health policy, IP and trade policy, including regulatory issues, as well as technical barriers to trade, sanitary and phytosanitary measures, health services and procurement rules. It lays the basis for the following, more detailed analysis of the innovation and access dimensions in Chapters III and IV. It outlines the key insights of economics for medical technology innovation and access. A final section reviews the policy issues associated with traditional medical knowledge and access to genetic resources, in view of its significance for national health systems and as an input to medical research.
- Chapter III provides a more detailed overview of policy issues concerning the innovation dimension of medical technologies. The historical pattern of medical research and development (R&D) provides a backdrop for analysing the current R&D landscape. The chapter looks at challenges with overcoming market failures in medical product R&D in areas such as neglected diseases and antimicrobial resistance. It then outlines alternative and complementary instruments to incentivizing and financing R&D. It outlines the role of IP rights in the innovation cycle, including issues relating to IP management in health research and selected pre- and post-grant patent issues. A final section looks at influenza vaccines as a distinct example of innovation management and product development to address a specific global health need.
- Chapter IV deals with key aspects of the access dimension, describing the context for access to health technologies, with more detailed case studies on access in respect of HIV/AIDS, hepatitis C, tuberculosis (TB), non-communicable diseases (NCDs), and vaccines. It sets out the key determinants of access related to health systems, IP and trade, and it analyses access to health products in specific areas. It reviews in particular pricing policies, transparency across the value chain of medicines and health products, taxes and mark-ups, and procurement mechanisms, as well as regulatory aspects and initiatives to transfer technology and boost local production, patent quality and review procedures, compulsory and voluntary licences, free trade agreements and international investment agreements, tariffs and competition policy.

As access and innovation issues are increasingly considered across a broader range of policy areas, a

more diverse set of stakeholders, values, experience, expertise and empirical data now shapes and informs policy debates, through:

- greater diversity of policy voices, creating opportunities for cross-fertilization between traditionally distinct policy domains
- enhanced possibilities for harvesting the practical lessons of a far wider range of innovation and access initiatives
- improved global inclusiveness, quality and availability of empirical data on a range of interconnected factors, including the global health burden, access and pricing of medicines, regulatory and trade policy settings, and national IP systems.

The cross-cutting character of these policy domains means that some themes are introduced in Chapter II, in the course of sketching out the general policy framework, and are later elaborated in Chapter III and/or Chapter IV, which look in more detail at how these elements have bearing on innovation and access, respectively. For example, the general elements and principles of IP policy are set out in Chapter II, while Chapter III elaborates aspects of IP policy, law and practice that bear particularly on innovation of medical technologies, and Chapter IV considers how specific aspects of IP impact access to technologies. Similarly, the broad rationale for regulation of medical technologies is set out in Chapter II, and Chapters III and IV deal with the implications of product regulation, respectively, for the innovation process and for access to medical technologies. Regarding trade policy, Chapter II sets out the main elements, and Chapter IV considers the impact of trade and trade policy settings on access to medicines and other medical technologies.

The global burden of disease necessitates dynamic responses

The global burden of disease is in transition. Populations are ageing due to progress in preventing and treating infectious diseases. But the burden of NCDs in low- and middle-income countries (LMICs) is rising, leading to a double burden of disease (see Chapter I, section C). While preventive measures with respect to lifestyle, physical inactivity, tobacco use and harmful use of alcohol, nutrition and environmental factors are key, the innovation system has to adjust to these changes in the global disease burden. The focus on access to medicines – which, in the past, has been on communicable diseases such as HIV/AIDS, TB and malaria – has broadened. Access to treatments for NCDs, including expensive cancer treatments in middle-income countries, will be the challenge of the future and the focus of the access debate (see Chapter IV, section B.4).

Access to medicines and the right to health

Access to medicines and health services is an element of the fulfilment of the right of everyone to the enjoyment of the highest attainable standard of health. Furthering access to medicines is also part of the United Nations Sustainable Development Goals (SDGs) (see Chapter II, section A.1–3). Lack of access to health technologies is rarely due to a single factor. The "value chain" of medicines and health products (see Figure 4.3) includes R&D, regulation, selection, procurement and supply, distribution, prescribing of medicines and diagnostics, dispensing, and responsible use (see Chapter IV, section A.2). Selection of the medications requires a health system to identify which medicines are most important to address the national burden of disease. This selection can be guided by the WHO Model List of Essential Medicines. Political commitment to adequate and sustainable funding is a basic condition for effective and sustainable access. Universal health coverage (UHC) has crystallized as a key aim of the SDGs (see Chapter IV, section A.1). Affordable prices are a critical determinant of access to medicines, especially in countries where the public health sector is weak and a large part of the population pays for medicines out of pocket. Generic medicine policies are key interventions to control health budgets and make medicines and other health products and services more affordable. Yet even generic medicines can still be unaffordable to health systems. A substantial part of the global population cannot access even the most basic medicines (see Chapter IV, section A.3). The overarching condition for providing access to needed medical technologies and health services is a functioning national health-care system (see Chapter IV, section A.4–12.).

Efforts to scale up treatment coverage for HIV/AIDS have become a major focus for policy-makers since the turn of the millennium. Low prices for generic antiretroviral treatments have helped governments and donor agencies strive to end the AIDS epidemic by 2030, as set out in target 3.3 of the SDGs (see Chapter IV, section B.1). In the area of antimicrobial resistance (AMR), there is a need to simultaneously secure wide availability of core antimicrobials, while also ensuring good stewardship (appropriate antimicrobial use to improve patient outcomes and minimize the development and spread of resistance) and the research in, and development of, new antimicrobials (see Chapter II, section A.5, Chapter III, section C.2 and Chapter IV, section B.2).

While most cases of TB can be successfully treated with medicines that have been available for many decades and are low cost, there has been growing concern about drug-resistant TB. Three new medicines were approved between 2012 and 2019 to treat drug-resistant TB, but access to them has been limited for reasons including

limited clinical data, lack of national registration, high prices and a lag in implementing new treatment guidelines (see Chapter IV, section B.3).

NCDs put an enormous and continuous financial strain on household budgets, and major gaps in access to both originator and generic medicines for NCDs persist. Shortcomings in access have been highlighted, for example, for newer cancer treatments and insulin for diabetes. For all countries, the cost of inaction far outweighs the cost of taking action on NCDs (see Chapter IV, section B.4). Health systems, including in high-income countries, face rising launch prices, in particular for cancer and "orphan" medicines.

Hepatitis C has seen treatment breakthroughs, but these new treatments entered the market at very high prices, leading to treatment being unavailable, rationed or delayed in numerous countries. Thanks to the conclusion of licensing agreements for some of the treatments, generics are available at relatively low prices in most LMICs (see Chapter IV, section B.5). National immunization programmes are a highly effective public health tool for the prevention of illness and the spread of infectious diseases. Distinct market conditions and know-how requirements create a different landscape for the development and dissemination of vaccines (see Chapter III, section B.4(e) and Chapter IV, section B.7; see also Chapter III, section E). Other areas addressed by the study are access to paediatric formulations and medical devices (see Chapter IV, sections B.6 and B.8).

Measures to contain costs and increase access

Governments employ many different means to contain costs for medical technologies. Policies aimed at increasing access concern areas such as procurement, pricing and IP (see Chapter IV, sections A and C), and they increasingly use health technology assessments to control costs (see Chapter IV, section A.4). Import tariffs (see Chapter IV, section D.1), various taxes (see Chapter IV, section A.5) and mark-ups along the supply chain (see Chapter IV, section A.6) can increase consumer prices and constrain access, and can also be targeted by cost-containment policies, which must, however, ensure sustainable margins for commercial suppliers in order to be economically viable.

Differential pricing applied by companies can be a complementary tool to increase access. Price differentials may exist across different geographical areas or according to differences in purchasing power and socio-economic segments (see Chapter IV, section A.4(g)). Another strategy for enhanced access to medicines is to promote the development of local production capacity and leverage technology transfer. Policy coherence associated with local production is crucial to achieving sustainable public health and industrial development benefits (see Chapter IV, section A.10).

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) makes available to WTO members flexibilities in implementing access policies, such as patentability criteria and patent review procedures, and regulatory review exceptions (see *inter alia* Chapter II, section B.1 and Chapter IV, section C.3). With regard to access to patented products, these flexibilities include the use of compulsory or government-use licensing, wherein generic versions of the patented product can be locally manufactured or imported without the authorization of the patent holder.

Regulation of health technologies

Regulation of health technologies addresses essential health policy objectives: products must be safe, efficacious and of adequate quality. It also shapes the landscape for access and innovation. Regulatory review processes affect the time and cost it takes to bring new products to market and may delay market entry of new products (see Chapter II, section A.6).

Clinical trials are research studies in which groups of human participants are enrolled to evaluate the safety and/or effectiveness of new health technologies. The registration and publication of clinical trials are important for public health. The WHO considers registration of clinical trials a scientific and ethical responsibility and maintains the International Clinical Trials Registry Platform. From the perspective of public health policy, clinical trial results should be publicly available, so that researchers and other interested groups can assess the efficacy and potential side effects of new products (see Chapter III, section B.7). The emergence of biotherapeutic medicines has raised challenges for regulatory systems, notably with regard to regulating similar biotherapeutic (also termed biosimilar) products (see Chapter II, section A.6).

Another challenge for regulatory systems is posed by substandard and falsified (SF) medical products, which are found in all parts of the world but are typically a much greater problem in regions where the regulatory and enforcement systems are weak. To effectively combat SF medical products, regulatory intervention may be required, whereas the approach to falsified or counterfeit medical products may involve criminal investigation (see Chapter II, section B.1(f) and Chapter IV, sections A.12 and C.3(h)). WHO prequalification has contributed substantially

to improving access to quality medical products in developing countries through ensuring compliance with quality standards (see Chapter IV, section A.11(a)).

Innovation in medical technologies: the evolving policy landscape

Innovation in medical technologies requires a complex mix of private- and public-sector inputs. It differs from innovation more generally due to the ethical dimension of health research, a rigorous regulatory framework, liability questions and the high cost and high risk of failure. Economic, commercial, technological and regulatory factors have precipitated rapid change in the current landscape for R&D, involving more diverse innovation models and a wider range of active players. Providing adequate incentives to absorb the high cost and associated risks and liabilities is a central policy challenge; this has been the historic role of the patent system, in particular as applied to pharmaceuticals. While estimates vary of the actual cost of medical research and product development, innovation is undoubtedly costly and time consuming. The risk and uncertainty of innovation increases R&D costs in this sector, which include the development costs of the vast majority of inventions that fail before reaching the market (see Chapter III, section B.3). Rising expenditure for medical research has not been matched by a proportionate increase in new products entering the market, sparking a debate about research productivity and a quest for new models of innovation and for financing R&D. Many initiatives are exploring new strategies for product development, thus informing a rich debate about how to improve and diversify innovation structures to address unmet health needs. Current policy discussions have identified possibilities for open innovation structures, and a range of "push and pull" incentives, including schemes such as prize funds that would delink the price of products from the cost of R&D (see Chapter III, section C.5). The WHO Consultative Expert Working Group on Research and Development: Financing and Coordination recommended some of these options, including beginning negotiations on a globally binding convention or treaty on R&D (see Chapter III, sections C.4 and C.5(i)).

New thinking on industry's role and structure and the public/ private divide

The evolving innovation landscape is driving change in the pharmaceutical industry. Driving factors include rising global spending on prescription drugs, increasing payer scrutiny of prescription drug prices in high-income markets, the progress of non-profit initiatives engaged in medical research and product development, new research tools and platform technologies, increased industry focus on personalized medicines, and the greater share of global demand from large middle-income-country markets. The historic industry model of vertically integrated in-house R&D is opening up to more diverse and collaborative structures, with major industry players developing products by integrating technologies that are licensed in or acquired through mergers and integration of smaller firms. Originator firms have also invested in generic production capacity. An increasing proportion of new medicines are for orphan indications. At the same time, most large pharmaceutical companies have withdrawn from antimicrobial research in light of the poor potential for investment returns.

The role of public research and academic institutions, increasingly, also in developing countries, has come under the spotlight as those institutions seek to reconcile public-interest responsibilities with the capital and product development capacity offered by private-sector partnerships (see Chapter II, section C; Chapter III, sections A and B; and Chapter IV, section D.5(d)).

Research and innovation gaps in neglected diseases and other areas: a policy challenge generating practical initiatives

For diseases that predominantly affect people living in poorer countries, the innovation cycle is not self-sustaining and fails to address their health needs, due to low potential for revenue, underfunded health services and generally weak upstream research capacity. A similar situation arises where sales are likely to be low, for example, in antibiotics and treatments or vaccines for emerging pathogens. In this type of environment, market-based incentives, such as patent protection, cannot by themselves address the health needs of developing countries.

The landscape of health research for these diseases has evolved. Product development partnerships (PDPs) have been a significant development over the past decade, drawing together not-for-profit entities and industry players, with major philanthropic funding, significantly increasing the number of products in development for neglected diseases, and identifying pathways regarding existing research gaps (see Chapter III, section C.6). Originator pharmaceutical companies also engage increasingly in philanthropic research. Several companies have established dedicated research institutes to research diseases disproportionately affecting developing countries or participated in cooperative projects to share assets and knowledge, such as WIPO Re:Search, which has been developed to make better use of IP-protected assets

and improve access (see Chapter III, section C.6–8). However, much more needs to be done by the international community in this area.

AMR has been recognized as a global threat, and is addressed by many countries in national action plans and by a WHO Global Action Plan on Antimicrobial Resistance. Private investments are insufficient to fill current R&D gaps. New non-profit initiatives have been established by a range of actors to reinvigorate the pipeline of drug candidates.

The IP system at the centre of debate on innovation and access

Apart from the patent system and test data protection, other relevant IP rights include trademarks, for example, the relationship with international non-proprietary names (INNs), and copyright, for example, covering the package insert of medicines (see Chapter II, section B.1(d)–(e)). The patent system has been widely used for health technologies, especially by the pharmaceutical sector. Indeed, the pharmaceutical sector stands out in terms of its dependence on patents to capture returns to R&D, but its role in innovation and how to enhance its effectiveness are matters of continuing debate (see Chapter III, section B). The rationale for having patents is to make investment in innovation attractive and to offer a mechanism that ensures that the knowledge contained in the patent documents is accessible. Patents can function to structure, define and build innovation partnerships. The role of intellectual property rights (IPRs) in the innovation cycle is addressed in Chapter III, section D. The impact of patents on access is complex and an area of particular focus. IP policy, the laws that embody the policy, and the administration and enforcement of those laws each aim to balance and accommodate a range of legitimate interests in a way that promotes overall public welfare (see Chapter II, section B.1).

The global IP framework is defined in particular by the treaties administered by WIPO and the TRIPS Agreement, which forms part of the WTO legal system and in turn incorporates the substantive provisions of several WIPO treaties, including the Paris Convention. The TRIPS Agreement sets minimum standards for IP protection and enforcement. For example, patents must be available for any innovation in all fields of technology, provided they are new, involve an inventive step (or are non-obvious) and are capable of industrial application (or are useful). Substantive patent examination leads to a higher degree of legal certainty regarding the validity of granted patents. Where search and examination are of low quality, this can have an adverse effect because it may raise false expectations in respect of the patent's validity. Review procedures allow courts and other review bodies to correct erroneous grant of patents and give relief where necessary, in order to ensure that the patent system, as a whole, functions as a public-interest policy tool. Strict patentability criteria and strict patent examination supported by patenting examination guidelines contribute to preventing strategies employed to delay the entry of generic competition, such as "evergreening" (see Chapter III, section D.4(b) and Chapter IV, section C.1).

Integral to the patent system is the requirement to disclose the innovation described in patent documents, thus creating an extensive knowledge base. The resultant patent information serves as a tool for charting freedom to operate, potential technology partnerships, and procurement options, as well as giving policy-makers insights into patterns of innovation (see Chapter II, section B.1(b)(viii)–(xi)). While patent information has become more accessible, coverage of data for many LMICs remains a challenge. Recent trends show a growth in patent applications on health technologies from key upper-middle-income economies (see Chapter III, section A.5).

The protection of clinical trial data also illustrates the complex relationship between the IP system and innovation and access. Protecting these data against unfair commercial use is important given the considerable efforts made to generate these data, which are needed to bring new medicines to the market. For this purpose, in some jurisdictions, newly approved medicines are protected by periods of regulatory exclusivity, such as data exclusivity and market exclusivity, during which the medicines regulatory authority may not accept a submission for approval of a generic and/or may not approve a generic for marketing. The TRIPS Agreement requires protection of test data but does not specify the exact form it should take, and national authorities have taken diverse approaches (see Chapter II, section B.1(c)).

How IP is managed can determine its impact on public health

Appropriate licensing of patents can help build partnerships and enable innovation through cooperation to bring new health technologies to fruition. Private-sector licensing strategies typically aim at commercial objectives, but public-sector entities can use patents to leverage public health outcomes. New models of socially responsible licensing protect IP while ensuring that new health technologies are available and affordable. Public–private partnerships have resulted in creative licensing agreements that forgo profit maximization in favour of providing essential technologies to poorer countries at affordable prices. Voluntary licences also form part of corporate social responsibility programmes, especially for HIV/AIDS treatments. The Medicines Patent Pool

has reinforced the trend towards voluntary licensing programmes that increase access to medicines by enabling new formulations and enhancing provision of cheaper generic medicines for developing countries (see Chapter IV, section C.3(b)).

Policy options and IP flexibilities also impact on public health

A wide range of policy options and flexibilities are built into the international IP regime and can be used to pursue public health objectives. Action is needed at the regional and domestic levels to determine how best to implement such flexibilities, so that the IP regime responds to each country's individual needs and policy objectives. Key options include transition periods for least-developed countries (LDCs) (see Chapter II, section B.1), differing IP exhaustion regimes, refining the criteria for grant of a patent, making available pre-grant and post-grant review procedures, exclusions from patentability and exceptions and limitations to patent rights once granted, including regulatory review exception ("Bolar" exception) to facilitate market entry of generics, as well as compulsory licences and government-use licences. Countries have used one or more of these instruments to improve access to medicines for both communicable and noncommunicable diseases (see Chapter IV, section C.1–3). WTO members amended the TRIPS Agreement to permit wider use of compulsory licensing. The additional flexibility enables members that need to import medicines because of insufficient or no local manufacturing capacity to seek supply from generic manufacturers in other countries where the medicines are patent protected. For this purpose, potential exporting members can grant special compulsory licences exclusively for export under what is termed the "Special Compulsory Licensing System" (see Chapter IV, section C.3 and Annex III). While the legal scope for flexibilities is now clearer, thanks also to the Doha Declaration, and some flexibilities are widely implemented (such as "Bolar" exceptions), policy debate continues on the use of measures such as compulsory licensing.

International trade is an essential avenue to access

International trade is vital for access to medicines and other medical technologies, markedly so for smaller and less-resourced countries. Trade stimulates competition, which, in turn, reduces prices and offers a wider range of suppliers, improving security and predictability of supply. Trade policy settings – such as tariffs on medicines, pharmaceutical ingredients and medical technologies – therefore directly affect the accessibility of such products (see Chapter II, section B.3–5 and Chapter IV, section D). Trade policy and the economics of global production systems are also key factors in strategic plans to build domestic production capacity in medical products. Non-discriminatory domestic regulations founded on sound health policy principles are also important for a stable supply of quality health products. Access to foreign trade opportunities can create economies of scale to support the costs and uncertainties of medical research and product development processes.

Developed countries have dominated trade in health-related products, but India and China have emerged as leading global exporters of pharmaceutical and chemical inputs and, in the case of China, of medical devices, and some other developing countries have shown strong export growth recently. Countries' imports of health-related products differ considerably according to their level of development, illustrating substantial and widening gaps in access: in 2016, a small number of countries (China, European Union member states, Japan and the United States) accounted for the majority of imports. Some new players are emerging from developing countries, while LDC imports have grown least, starting from a low base.

Import tariffs on health-related products can affect access: since they increase cost early in the value chain, their impact on price may be magnified. Developed countries have largely eliminated such tariffs, in line with the WTO Pharmaceutical Agreement of 1994. Other countries have reduced tariffs significantly, but the picture is still mixed: some developing countries structure tariffs to promote local production, while LDCs apply lower tariffs (see Chapter IV, section D.1).

Competition policy promotes effective innovation and supports access

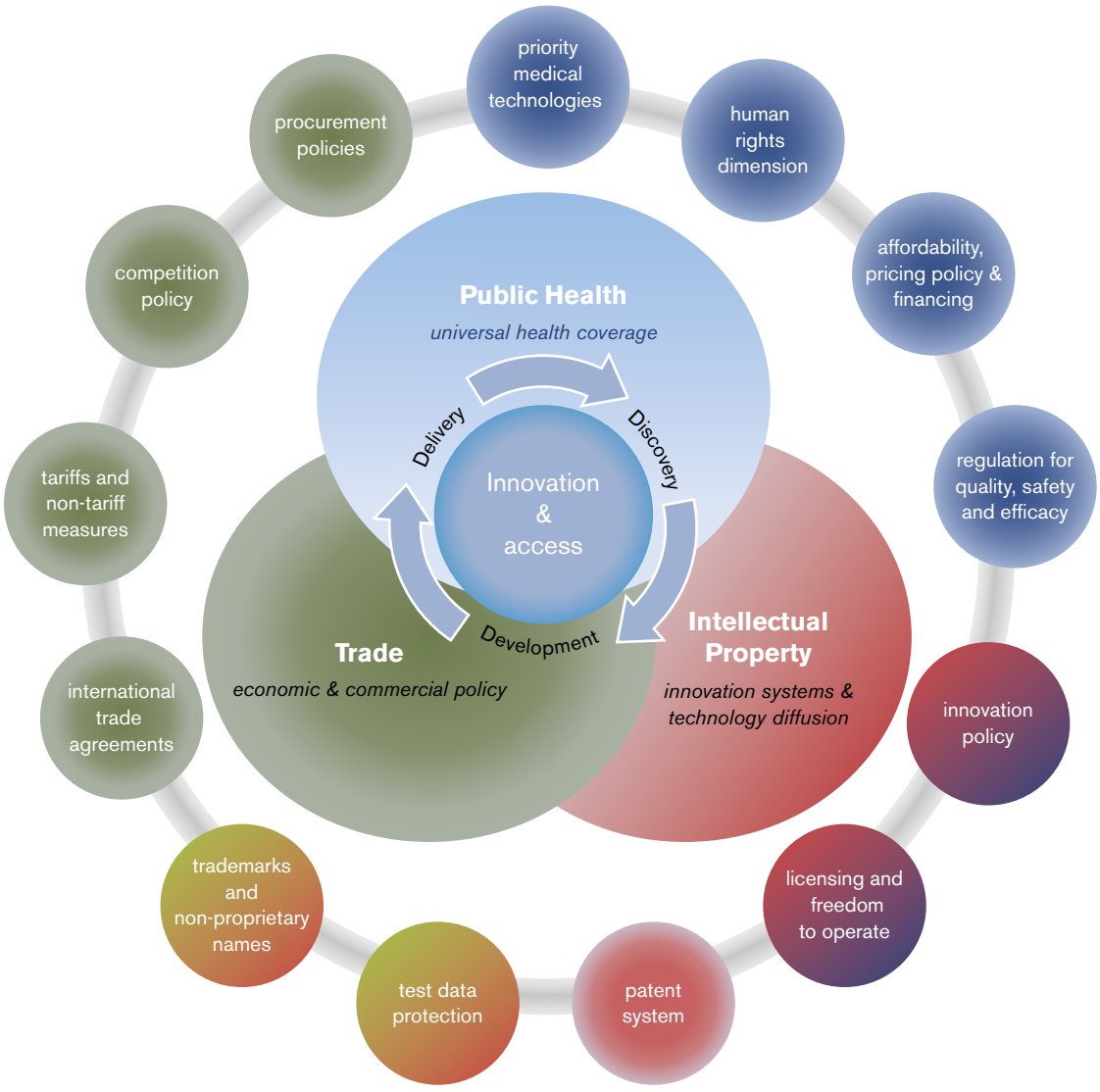
Competition policy is relevant to all stages in the process of supplying health technologies to patients, from their development to their sale and delivery. The creation of sound, competitive market structures through competition law and enforcement thus has an important role to play in both enhancing access to health technologies and fostering innovation in the pharmaceutical sector. It can serve as a corrective tool if IP rights hinder competition and thus constitute a potential barrier to innovation and access. Competition authorities in several jurisdictions have taken action to address anti-competitive practices in the pharmaceutical sector, including some patent settlements, certain licensing practices and pricing policies. Competition policy also has an important role to play in preventing collusion among suppliers of medical technology participating in procurement processes (see Chapter II, section B.2 and Chapter IV, section D.2).

Access to medical technologies through more effective government procurement

In many countries, access to medical technologies largely results from government procurement, with pharmaceuticals made available through public funds or subsidies. Procurement systems aim to obtain medicines and other medical products of good quality, at the right time, in the required quantities and at favourable costs. These principles are particularly important in the health sector, given the large expenditures, health impact of value for money and quality issues, with some programmes reportedly paying considerably more than necessary for medicines (see Chapter IV, section A.8).

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. Good governance in procurement is consistent with increasing access to medical technologies through lower prices and uninterrupted supply. The WTO's plurilateral Agreement on Government Procurement provides an international framework of rules to promote efficiency and good governance in public procurement, with particular application to procurement of medicines, promoting transparency, fair competition and improved value for public expenditure (see Chapter II, section B.4).

Mapping the policy intersections: key areas of law and policy for innovation and access



Free trade agreements have increasing relevance to access

The international policy and legal framework has been made more complex by the growth of free trade agreements (FTAs) and international investment agreements, outside the established multilateral fora (see Chapter II, section B.5 and Chapter IV, section C.5). Policy debate in this context has focused on IP, such as patent term extensions, regulatory exclusivities and other measures, such as patent linkage, as well as pharmaceutical regulation provisions in these agreements, and their impact on access to medicines. The later generation of FTAs often includes side letters or provisions confirming the Doha Declaration and, in particular, the right of WTO members to take measures to protect public health. These agreements also set standards in other policy areas with implications for access, notably, standards established on government procurement and competition policy, as well as preferential tariffs on pharmaceuticals, inputs and other health products. FTAs usually require implementation in domestic laws, which, in turn, can directly affect access to, and innovation in, medicines and medical technologies.