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International Regulatory Cooperation and International Organisations: the Case of the World Health Organization (WHO)

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Joining Forces on Global Standards for Better Lives
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Delegates are invited to submit their comments by 26 September 2016.

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The World Health Organization (WHO) is the leading intergovernmental organisation in the field of health. WHO fulfils a core public policy objective by providing its Member States an institution devoted to cooperation and coordination, including of a regulatory nature, in the field of health. It is particularly active in providing a platform for exchange of information among regulators, pursuing data collection and analysis, putting a strong accent on the importance of research, and having an extensive range of different normative activities. The WHO is also involved in crisis management in support of health emergencies faced by its Members States. WHO has undertaken extensive internal reforms to ensure its continued relevance as a global standard-setter, which provides a useful reference for other international organisations. This Case Study provides an overview of WHO's role in International Regulatory Co-operation (IRC) - its institutional context, its main characteristics, its impacts, successes and challenges.

INTRODUCTION: THE RELEVANCE OF WHO FOR INTERNATIONAL REGULATORY CO-OPERATION

1. International co-operation in the field of health started as back as in 1851 when the first international sanitary conference was convened in Paris to harmonise and reduce to a safe minimum the conflicting and costly maritime quarantine requirements of different European nations. This conference led to the adoption of an international sanitary convention, addressing cholera, and was followed by a number of other international and regional arrangements leading to the creation of the World Health Organization (WHO) in 1948.

2. This case study provides insights into the WHO, a traditional core intergovernmental organisation (IGO) and specialised agency of the United Nations. WHO, as an institution, reflects the classical approach to treaty-based, centre of government co-operation. WHO fulfils a core public policy objective by providing its Member States an institution devoted to cooperation and coordination, including of a regulatory nature, in the field of health. As such, it displays similar features to other IGOs, including a wide variety of different instruments of cooperation, both of a binding and soft law nature.

3. As a distinct constitutional entity, however, WHO shows a number of specific features that makes it an interesting case to consider:

- The area of public health includes the involvement of numerous actors, beyond State-actors, including non-governmental organisations, private actors, philanthropic foundations, academic institutions and hybrid institutions such public-private partnerships. Member States of the Organisation are committed to effective and extensive collaboration with all these various actors, and at the same time focused on safeguarding the independence and impartiality of the work of the Organisation.
- The scientific nature of the issues addressed by the WHO and the high stakes for human health call for extensive exchange of information, data collection, and scientific research, to ensure that health policies are grounded in the best scientific knowledge. This requires a secretariat with highly specialized technical skills.
- The threat to human health and safety that some epidemics may present calls for strong resources for emergency action. For this, appropriate means of crisis management are essential for WHO to

effectively fulfil its mandate. The WHO has therefore been improving its mechanisms to assist in emergency situations, with the most recent reform in this field introduced in 2016. This feature presents particularly interesting features within the world of IGOs as sampled in OECD (2016).

- The local and regional nature of certain public health threats calls for means adapted to local specificities and the possibility to act urgently. The six regional offices of WHO, as well as the numerous country offices are a key feature in strengthening the Organisation's ability to collaborate closely with domestic authorities, and through them, local actors and health professionals. This global, regional and national presence, both decentralises WHO activity and, at the same time, ensures alignment at the three levels of the Organisation, and constitutes a relatively unique feature of the Organisation.

4. Recently, WHO has undertaken extensive internal reforms to ensure its continued relevance as a global standard-setter. This effort is of relevance to other IGOs faced with similar challenges. As part of these efforts, the organisation is working to improve the alignment, flexibility, predictability and transparency of the organisation's financing, and to improve its risk management activities. In particular, improvements to internal governing practices and to the way the organisation engages with external stakeholders will help clarify and strengthen the position of the organisation and achieve greater coherence among the many players involved in global health.

5. This case study describes how the organisation supports international regulatory cooperation (IRC) by providing an overview of its institutional context, the main forms of regulatory cooperation it offers to its Member States, and how regulatory quality is safeguarded. It also offers some reflections on the impact and success of regulatory cooperation through WHO.

THE CONTEXT OF THE REGULATORY COOPERATION

Area of work and objectives

6. The objective of the WHO, as defined in Article 1 of its Constitution, is “the attainment by all peoples of the highest possible level of health”. Health is in turn defined positively in the Preamble of the Constitution as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. The Preamble further provides that “[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition” and “[t]he 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.”

7. Health is therefore considered as a positive state encompassing both the individual and the community, as well as a human right. The Health Assembly¹, has reaffirmed the right to health, in particular, along the lines of Article I of the Alma Ata Declaration adopted by the International Conference on Primary Health Care in 1978, and has reaffirmed its commitment to the principle enunciated in Article 1 of the Constitution.²

8. The scope of the activities of the organisation being ultimately dependent upon its objective - in this sense that the organisation has authority to take action in relation to any activity insofar as its effects on health are concerned³ - the positive and broad definition of “health” enshrined in the Preamble of the Constitution has enabled the organisation to adapt to the “globalization of public health” (Fidler, 2001). Thus, WHO continues to be able to effectively address new threats to health such as those related to the growing epidemic of noncommunicable diseases, and to interact with other regulatory initiatives in the fields of international security, international trade and intellectual property rights, and the law on access to biological resources.

9. As the directing and coordinating authority on international health work, WHO provides leadership on matters critical to health and engages in partnerships where joint action between countries is needed, helps shape the research agenda, sets norms and standards, articulates evidence-based policy options, provides technical support to countries and monitors health situation throughout the world. WHO’s work covers a wide range of areas, in particular health systems, noncommunicable and communicable diseases, preparedness, surveillance and response, and the promotion of health through the life course.

10. Cooperation with domestic authorities is vital to the organisation to ensure follow-up to decisions reached at the international level. WHO works with all Member States to support their national health development process, whether or not WHO has a physical presence in their territories, and cooperates with governments and other partners in supporting countries’ national health strategies and plans.

¹ World Health Organization (1970)(1977), Resolutions WHA23.41 and WHA30.43.

²World Health Organization (1998), World Health Declaration. World Health Organization, Geneva.

³As acknowledged by the International Court of Justice in its advisory opinion of 8 July 1996 on the *Legality of the Use by a State of Nuclear Weapons in Armed Conflict* (I.C.J Reports 1996, p. 14, para 21.

11. Six leadership priorities currently give focus and direction to the organisation's work under a planning tool known as the Twelfth General Programme of Work, 2014-2019. These priorities are: advancing universal health coverage; accelerating the achievement of the health-related Millennium Development Goals; addressing the challenge of noncommunicable diseases and mental health, violence and injuries and disabilities; implementing the provisions of the International Health Regulations (2005); increasing access to essential, high-quality and affordable medical products; and addressing the social, economic and environmental determinants of health.⁴ WHO's work is further driven by the United Nations Sustainable Development Goals (SDGs), which were adopted by the United Nations General Assembly in September 2015. Health has a central place in SDG 3: Ensure healthy lives and promoting well-being for all at all ages, as well as in the 13 targets relating thereto.

Institutional landscape and WHO's position in that landscape

12. Although WHO is the specialised agency for global health within the United Nations system, the institutional landscape in which international health cooperation takes place has become increasingly complex. Specific health-related matters also fall under the mandate of other international and regional IGOs, including the Food and Agriculture Organization (FAO), the World Trade Organization (WTO), the World Organization for Animal Health (OIE) and the World Intellectual Property Organization (WIPO). The WHO has a variety of collaboration practices with these organisations, and with other specialised UN agencies, as well as regional and intergovernmental organisations. Modes of interaction span a broad range of instruments, including co-sponsored programmes, MoUs, joint meetings and exchange of information (OECD, 2016). Furthermore, WHO interacts with a broad range of other bodies operating in the field of health, such as partnerships and non-State actors (NSAs).

United Nations and other intergovernmental organisations

13. Cooperation with the United Nations and other IGOs is explicitly foreseen in the Constitution and is conducted on the basis of multilateral and bilateral agreements and arrangements.⁵ In addition, WHO closely interacts with the United Nations system through various decision making organs including the Chief Executives Board, the United Nations Development Group, the High Level Committee on Management and the High Level Committee on Programmes. The Head of a WHO Country Office is a member of the United Nations Country Team coordinated by the United Nations Resident Coordinator, and WHO offices actively engage in the development and implementation of the United Nations Development Framework.

14. Cooperation with IGOs is also explicitly foreseen in the WHO International Health Regulations (2005) (IHR) and the WHO Framework Convention on Tobacco Control (WHO FCTC), which will be presented later in the chapter. Under the IHR, WHO is expected to cooperate and coordinate its activities with other competent IGOs or international bodies in the implementation of the Regulations, including through the conclusion of agreements or similar arrangements. Under the WHO FCTC, the Conference of the Parties may request the cooperation of competent international and regional IGOs, including financial and development institutions. Also, there are many instruments such as resolutions and decisions adopted by the Health Assembly that call on partners, including IGOs, to support and contribute to the accomplishment of the instrument concerned, and to work jointly with Member States and with the WHO Secretariat, as appropriate. In many cases, and in accordance with the mandate received by the governing bodies, UN agencies and other competent IGOs participate in the development process of such policies by

⁴ WHO, Twelfth General Programme of Work 2014-2019, contained in document A66/6 and approved in resolution WHA66.1.

⁵ See Article 70 of the WHO Constitution. The agreements concluded with the United Nations and eleven other IGOs can be found in World Health Organization (2014), *Basic Documents*, 48th ed.

providing, along with Member States and other interested stakeholders, comments on preparatory work towards such instruments.

15. Additionally, the WHO Secretariat arranges more informal working processes and participates jointly with other IGOs in activities, in furtherance of its mandates. Mention can be made, for instance, of WHO's participation in the Joint Emergency Management Plan of the International Organizations, effective as of 1 July 2013, which describes the framework for preparedness for and response to an actual, potential or perceived radiation incident or emergency and, specifically, the arrangements of the participating international organisations for responding to any such incident or emergency.⁶ Cooperation with regional IOs, such as the European Union and the African Union, has also become particularly important at all three levels of the organisation, i.e. at the global, regional and country level.

16. Cosponsored programmes also provide an interesting example of effective cooperation of WHO with other IGOs. Cosponsored programmes are integral to core WHO activities and part of its programmatic accountability framework, but are financially and/or programmatically cosponsored by a number of other agencies. Cosponsored programmes include the Special Programme on Research and Training in Tropical Diseases (TDR), the Special Programme of Research, Development Research and Training in Human Reproduction (HRP), the African Programme for Onchocerciasis Control (APOC), and the FAO/WHO Joint Food Standards Programme (Box 1 and Case study of the FAO). The United Nations Programme on HIV/AIDS (UNAIDS), established in 1995, is also co-sponsored by WHO and several other UN agencies, programmes and funds. UNAIDS is located in Geneva and has its own governance structure, which comprises the Programme Coordinating Board, the Committee of Cosponsoring Organizations and the Secretariat.

Box 6. The Joint FAO/WHO Food Standards Programme (Codex Alimentarius)

The Joint FAO/WHO Food Standards Programme (Codex Alimentarius) was established by the governing bodies of FAO and WHO in 1961 and 1963 respectively. Since its inception, the joint programme has produced a large amount of food standards, which are collected in the Codex Alimentarius.

The principal organ of the Codex Alimentarius is the Codex Alimentarius Commission, which adopts food standards and provides for their publication. The Commission is also empowered to establish subsidiary bodies such as General Subject Committees, which develop all-embracing concepts and principles applying to foods in general, specific foods or groups of foods; and Commodity Committees, which develop standards for specific foods or classes of food.

As a standard-setting programme, cooperation through Codex Alimentarius is organized around regional coordination committees in the six Codex geographical regions with biannual meetings and coordinators appointed by the Commission for each of the region. There is much interaction between the Member States through these committees, for the development and adoption of these standards and priority settings.

Development and adoption of food standards to be included in the Codex Alimentarius follows a very complex and long procedure that involves the preparation and discussion of a project proposal at committee level, the review of such proposal by the executive organ of the Commission, the preparation of a draft text and its circulation to Members and interested parties for comments, finalization of the draft and, eventually, its adoption by the Commission as a formal Codex text, which is then published by the Secretariat.

Codex standards may concern areas where other international organisations also exercise their regulatory competence, such as in the area of animal and plant health, fruit and vegetable quality, or food technology standards. This concurrence of competence is often addressed through mutual collaboration, for example by participating as observers in their respective governing bodies.

⁶ Joint Radiation Emergency Management Plan of the International Organizations EPR-JPLAN (2013), available at www-pub.iaea.org/MTCD/publications/PDF/EPRJplan2013_web.pdf (last accessed 13 July 2016).

Although such standards are not per se legally binding, they are widely observed. Most importantly, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) acknowledges the importance of harmonising standards internationally so as to minimize or eliminate the risk of sanitary, phytosanitary and other technical standards becoming barriers to trade, and specifically identifies Codex standards as the relevant standard-setting organisation for food safety.

Importantly, and of particular significance to work this case study aims to contribute to, reference to Codex standards in the WTO agreement results in such standards acquiring, albeit indirectly, legally binding force with respect to States parties to the SPS agreement.

Partnerships, non-State actors, collaborating centres and other international bodies

17. Issues pertaining to international health involve a wide range of other actors, beyond IGOs. The description of the institutional landscape in which WHO operates would not be complete without mentioning, first of all, public-private partnerships (PPPs), which pursue public health objectives convergent with and complementary to those of WHO. Some PPPs are legally incorporated entities external to WHO, whereas others are unincorporated alliances within WHO with their own governance.

18. WHO-hosted partnerships derive their legal personality from WHO and are subject to the Organisation's rules and regulations. They have a formal governance structure and programmatic accountability frameworks. WHO currently hosts four PPPs – the International Drug Purchase Facility (UNITAID), the Alliance for Health Policy and Systems Research, the European Observatory on Health Systems and Policies, and the Partnership for Maternal, Newborn and Child Health. As of the time of writing, WHO is represented on the Boards of UNITAID, the Alliance for Health Policy and Systems Research and the Partnership for Maternal, Newborn and Child Health, while the WHO Regional Office for Europe is one of the partners of the European Observatory on Health Systems and Policies.

19. The Health Assembly has adopted a policy on WHO's engagement with global health partnerships, which provides a framework to guide WHO's assessment of, and decisions concerning potential engagement in health partnerships, as well as specific parameters to be applied in cases where WHO agrees to host a formal partnership.

20. The recently adopted Framework of Engagement with non-State Actors (see below) also applies to the activities of hosted partnerships, as well as to WHO's engagement in partnerships, including PPPs. For WHO to engage, the partnership must demonstrate a clear added value for public health, have a clear goal that concerns a priority area of work of WHO, be guided by the technical norms and standards of WHO, support national development objectives, ensure appropriate and adequate participation of stakeholders, establish clear roles for partners, and pursue first and foremost public-health goal tasks. In addition, WHO must evaluate transaction costs along with potential benefits and risks, at all levels.

21. WHO's engagement with NSAs is also extensive due to the significant role they play in the advancement and promotion of public health. While relations with NGOs and commercial enterprises were governed by separate, dedicated policies until May 2016, all WHO's engagements with NSAs are now governed by a single "Framework of Engagement with non-State Actors" and its four Policies and Operational procedures related to, respectively, nongovernmental organisations, the private sector, philanthropic foundations and academic institutions.⁷

⁷ Sixty-ninth World Health Assembly (2016), Resolution WHA69.10.

22. The Framework, which is aimed at both promoting engagement and safeguarding the integrity of WHO's public health mandate⁸, identifies four types of interaction with NSAs (i.e. participation of NSAs in consultations, hearings, and other meetings of the organisation; provision of financial or in-kind contributions; provision of up-to-date information and knowledge on technical issues; advocacy activities; and technical collaboration, including through product development, capacity-building, operational collaboration in emergencies and contribution to the implementation of WHO's policies) and establishes mechanisms to manage conflicts of interest and other risks of engagement. The Framework will help shape cooperation for future engagements, especially in the normative arena.

23. In addition, the Organisation relies on the expertise provided by approximately 800 formal WHO Collaborating Centres, which carry out activities in support of the Organisation's programme. The regulatory framework surrounding this technical/scientific collaboration is provided by the Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms.⁹ Other collaborative efforts, differently named, are in place. For example, WHO provides technical leadership and secretariat support to the Global Alliance Against Chronic Respiratory Diseases, a voluntary alliance of national and international organisations, institutions, and agencies committed towards the common goal to reduce the global burden of respiratory diseases that was launched in 2008. These collaborative arrangements are fully within the scope of WHO policy and managerial control, and subject to WHO governing body oversight.

Reform of the World Health Organization

24. Since 2010, WHO's capability to handle the increasingly complex challenges in the field of health in the 21st century has been at the heart of a set of reforms discussed by Member States under the leadership of Director-General Dr Margaret Chan.

25. These reforms encompass three components: programs and priority setting, governance and management. Programmatic reform involves priority setting and a strengthened technical delivery model.¹⁰ On one hand, priorities must be defined and addressed in a systematic, transparent and focused manner; on the other hand, aligning resources – both technical and financial – is essential to the effective and efficient delivery of these priorities and to avoid an overcommitted and overstretched organisation. Steps were taken with the Programme Budget 2014-2015 and further developed in the Programme Budget 2016-2017 to have programmatic priorities with clear outputs and supported by adequate financing. The results chain for the Programme budget 2016-2017 has also been strengthened by developing indicators for organisational outputs, linked to measurable health outcomes.

⁸. Paragraph 4 of FENSA provides as follows: "WHO's engagement with non-State actors supports implementation of the Organization's policies and recommendations as decided by the governing bodies, as well as the application of WHO's technical norms and standards. Such an effective engagement with non-State actors at global, regional and country levels, also calls for due diligence and transparency measures applicable to non-State actors under this framework. In order to be able to strengthen its engagement with non-State actors for the benefit and interest of global public health, WHO needs simultaneously to strengthen its management of the associated potential risks. This requires a robust framework that enables engagement and serves also as an instrument to identify the risks, balancing them against the expected benefits, while protecting and preserving WHO's integrity, reputation and public health mandate. »

⁹. Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms See Basic Documents, 48th ed. Geneva: World Health Organization; 2014; pp. 131-138.

¹⁰. For more information on WHO reform see the dedicated webpage on the WHO website at www.who.int/about/who_reform/en/ (last accessed 18 August 2016).

26. Governance reform seeks to clarify and strengthen the positioning of the organisation in an effort to achieve greater coherence among the many players involved in global health. This can be achieved by improving governing practices internally and engaging more effectively with external stakeholders.

27. Managerial reform seeks to improve WHO's ability to achieve the best possible results, by attracting and retaining the best talent and using the resources entrusted to the organisation in a more effective and efficient manner. To this end, different human resources reforms, based on the human resources strategy, have been adopted to ensure that staffing is matched to needs at all three levels of the Organisation. Other steps have been taken to strengthen accountability, transparency and internal controls, as well as to achieve better evaluation, information management and communication.

28. Starting with the Special session of the Executive Board in January 2015 following the Ebola outbreak and continuing with the Sixty-ninth World Health Assembly in May 2016, WHO Member States furthermore agreed to a remarkable innovation in the Organisation's history, the establishment of the new Health Emergencies Programme. The new programme is designed to deliver rapid, predictable, and comprehensive support to countries and communities as they prepare for, face or recover from emergencies caused by any type of hazard to human health. More specifically, the new Programme will help Member States build their capacity to manage health emergency risks and, when national capacities are overwhelmed, to lead and coordinate the international health response to contain outbreaks and provide effective relief and recovery to affected people (WHO, 2016).

MAIN CHARACTERISTICS OF REGULATORY COOPERATION IN THE CONTEXT OF THE WHO

Governance arrangements and operational modalities

29. The following sections describe the governance structure of the organisation, its membership, decision-making process and budget. WHO's near universal membership makes it a global forum for IRC in the field of health. Indeed, normative activities are at the heart of WHO's functions. Full-financing of the biennial programme budget, which is today mainly achieved through voluntary contributions of Member States and other donors, remains one of the major challenges faced by the organisation.

Membership

30. WHO is an IGO whose membership is "open to all States" pursuant to Article 3 of its Constitution. States already members of the United Nations may become Members of the WHO by signing or otherwise accepting its Constitution in accordance with their constitutional processes. Other countries may become Members when their application has been approved by a simple majority vote of the Health Assembly. The admission procedure is regulated in more detail in the Rules of Procedure of the Health Assembly. As of 2015, the WHO is composed of 194 Member States.

31. The Constitution provides for an additional category of membership by allowing territories or groups of territories, which are not responsible for the conduct of their international relations, to be admitted as Associate Members upon application made on their behalf by the Member or other authority responsible for their international relations. The rationale behind this provision was the need to ensure participation of such territories in the new organisation. The nature and extent of the rights and obligations of Associate Members have been determined by the Health Assembly. They fully participate in the activities of the organisation, but do not enjoy the right to vote. There are currently only two Associate Members, i.e. Puerto Rico and Tokelau.

32. Territories or groups of territories, which are not responsible for the conduct of their international relations and which are not Associate Members, have nevertheless the right to be represented and to participate in regional committees, without the right to vote, upon consultations between the members in the region concerned and the authority having responsibility for their international relations.

Governance structure

33. At the global level the organisation is composed of three organs: the Health Assembly, the Executive Board, and the Secretariat.

The Health Assembly

34. The Health Assembly is the decision-making body of the organisation.¹¹ It is attended by no more than three delegates per Member, chosen from among the persons most qualified in the field of health, and by as many alternates and advisers as they wish, as well as by representatives of Associate Members and the Executive Board. The Health Assembly meets at least once a year in regular session, and in such special sessions as may be necessary. So far, a special session of the Health Assembly has been convened

¹¹ Its composition, functioning and functions are addressed in Chapter V of the WHO Constitution and the Rules of Procedure adopted by the Health Assembly itself.

only once, in 2006, to accelerate the procedure to elect the next Director-General following the death of the former Director-General, Dr Lee Jong wook.

35. The functions of the Health Assembly are, *inter alia*, to determine the policies of the organisation, appoint the Director-General, supervise the financial policies of the organisation, review and approve the budget.¹² The main committees of the Health Assembly are Committee A, which deals predominantly with program and budget matters, and Committee B, which deals predominantly with administrative, financial and legal matters.

The Executive Board

36. The Executive Board consists of thirty-four persons, technically qualified in the field of health, designated by as many Members for a three-year term. Member States entitled to designate persons to serve on the Executive Board are elected by the Health Assembly, one third of the Executive Board being renewed each year. The Executive Board meets at least twice a year, normally in January and in May right after the Health Assembly's session, and in such special sessions as may be necessary. So far, three special sessions have been convened, in 2006, 2011 and 2015 respectively, to address: the consequences of the sudden death of the former Director-General, Dr Lee Jong-wook, WHO reform, and the Ebola emergency.

37. The main function of the Executive Board is to give effect to the decisions and policies of the Health Assembly and to act as the executive organ of the Health Assembly.¹³ Among its other functions, the Executive Board submits a general program of work to the Health Assembly for consideration and approval, establishes such committees as the Health Assembly directs and may, on its own initiative or on the proposal of the Director-General, set up any other committees that will facilitate its work. At present, the Executive Board has established the Programme Budget and Administration Committee (PBAC), which, according to its terms of reference, either makes recommendations to the Executive Board or acts on its behalf; the Independent Expert Oversight Advisory Committee (IEOAC), which reports to the PBAC; and the Standing Committee on Nongovernmental Organisations, which has however been recently abolished further to the adoption of the Framework of Engagement with non-State actors mentioned above.

38. Representatives of the United Nations and of other participating IGOs, as well as nongovernmental organisations, international business associations and philanthropic foundations which have been granted official relations by the Executive Board in accordance with the Framework of Engagement with non-State actors are invited to participate in sessions of the WHO's governing bodies.

39. Furthermore, although the concept of "observers" is not mentioned as such in the WHO Constitution, five "quasi-permanent observers (the Holy See, the Order of Malta, the International Committee of the Red Cross, the International Federation of Red Cross and Red Crescent Societies, and Palestine) are regularly invited to attend sessions of the Health Assembly, in addition to other entities participating based on an *ad hoc* invitation by the Director-General. Observers may attend, without the right to vote and make a statement on the subject under discussion, upon the invitation of the President or Chairmen of these bodies.

The Secretariat

40. The Secretariat comprises the Director-General as well as all technical and administrative staff. The Director-General, subject to the authority of the Executive Board, is the chief technical and administrative officer of the organisation and is appointed by the Health Assembly on the nomination of

¹². Article 18 of the WHO Constitution.

¹³. Article 28 of the WHO Constitution.

the Executive Board.¹⁴ Staff members are appointed by the Director-General in accordance with the Staff Regulations established by the Health Assembly. As of December 2015, the organisation counted more than 7000 health and other experts, and support staff, working at all three levels of the organisation.¹⁵

41. WHO's headquarters are located in Geneva, Switzerland, pursuant to a decision by the First World Health Assembly in 1948. However, the WHO is, as noted above, characterized by a decentralized nature, key for enabling a tailored assistance to their Members and fostering exchanges directly between country authorities. Further to a decision of the First World Health Assembly, six geographical areas - Africa, the Americas, South-east Asia, Europe, Eastern Mediterranean and Western Pacific – were defined and six regional organisations set up to meet the special needs of such areas.¹⁶

42. Each regional organisation consists of a regional committee and a regional office led by a regional director. Regional committees are composed of representatives of Member States, Associate Members and other territories, if applicable, in the region concerned. They usually meet once a year. Each regional committee has adopted its own set of procedural rules. Under Article 50 of the Constitution, regional committees are mandated, *inter alia*, to formulate policies on matters of an exclusively regional character and supervise the activities of the regional office. Regional offices serve as the administrative organs of regional committees and carry out within the region the decisions of the Health Assembly and the Executive Board. They are headed by a Regional Director, appointed by the Executive Board after nomination by the regional committee.

43. A particular status is enjoyed by the Pan American Health Organization (PAHO) in as much as, under the WHO Constitution, PAHO “shall in due course be integrated with the Organization”. Accordingly, the Directing Council and the Pan American Sanitary Bureau serve respectively as the Regional Committee and the Regional Office of the WHO Region for the Americas based on an agreement between WHO and PAHO.

44. In addition to regional offices, WHO has also established offices in more than 150 countries, territories and areas, although some WHO country offices provide support to more than one country, territory or area. A WHO office works with the host Ministry of Health, other ministries and government institutions as appropriate. In general, an agreement is concluded between WHO and the government concerned to set out the administrative and legal framework for the technical cooperation between the parties. Each office has a unique profile of staff, programmatic priorities, and finances, which define its modalities of cooperation with a respective Member State and with the wider range of partners active in that country.

45. WHO's country offices play a key role in ensuring appropriate technical cooperation with countries and leadership in the health sector. WHO staff located in country offices provide advice on technical issues and provide assistance throughout the health sector. Country office staff help plan, implement and monitor programmes in cooperation with other actors in the region, and support advocacy and resource mobilisation efforts. Finally, the local offices contribute greatly to improve the cooperation between WHO Members. They facilitate exchanges among countries and help build capacities, enabling exchanges to be driven primarily by countries themselves.¹⁷ As a specialized agency of the United Nations,

¹⁴. Article 31 of the WHO Constitution.

¹⁵. Workforce data as of December 2015 available at: www.who.int/about/finances-accountability/budget/WHA69_HR_2015.pdf?ua=1

¹⁶. In accordance with article 44(a) of the WHO Constitution.

¹⁷. WHO (n.d.), “WHO's work with countries”, <http://who.int/country-cooperation/what-who-does/en/> (accessed 27 June 2016).

led by technical considerations, WHO's impartiality is a critical factor that greatly contributes to the achievement of health-related objectives.

46. A number of offices, other than country offices, have been set up to serve as liaison offices (such as the WHO Office at the European Union based in Brussels, Belgium), to provide administrative support (such as the Global Service Centre based in Kuala Lumpur, Malaysia) or to provide technical support on specific health areas (such as the WHO Centre for Health Development based in Kobe, Japan). In addition, geographically dispersed offices have been established within the WHO European Region, which are fully integrated into the work of the Regional Office and provide technical capacity in specific health areas.

Decision-making process

47. Decision-making is formally governed by the principle of "one state, one vote". The Rules of Procedure of the Health Assembly and the Executive Board provide for decision-making by simple majority except for decision on important questions, such as the adoption of conventions or agreements, amendments to the Constitution, and suspension of the voting privileges and services of Members, for which a two thirds majority of the Members present and voting is required. However, virtually all negotiations are conducted, and almost all decisions are adopted by consensus, which in WHO's practice is understood as the adoption of decisions without a formal vote but not necessarily as unanimity.

Programme and budget

48. While WHO's core functions that guide the work of the Secretariat are established in the General Programme of Work, the programme budget identifies the scope of activities and specifies achievements expected during each two-year period.¹⁸ The regular budget is subject to monitoring and oversight by the governing bodies. The Director-General prepares and submits to the Executive Board the financial statements and budget estimates.¹⁹ The Executive Board has the task of considering the budget estimates and submitting them to the Health Assembly with recommendations it may deem advisable.²⁰ Then, the Health Assembly reviews and approves the programme budget.²¹

49. The latest programme budget approved as of the time of writing was USD 4385 million for the biennium 2016-2017, which represented an increase of 8% in "base" budget over the biennium 2014-2015²². WHO's financing has undergone a major transformation over the past decades. WHO is supposed to be financed through a regular budget funded from contributions assessed on Member States based on the latest available United Nations scale of assessment with a maximum assessment rate of 22% and a minimum assessment rate of 0.001%, taking into account differences in membership between WHO and the United Nations.²³

¹⁸. The current Programme Budget can be accessed at: www.who.int/about/finances-accountability/budget/PB201617_en.pdf (last accessed 7 June 2016).

¹⁹. Articles 34 and 55 of the WHO Constitution.

²⁰. Article 55 of the WHO Constitution.

²¹. Article 18(f) and 56 of the WHO Constitution.

²². This term refers to the "base" programmes of categories 1 to 6 of the programme budget (i.e. communicable diseases, noncommunicable diseases, promoting health through the life course, health systems, preparedness, surveillance and response, and corporate services/enabling functions), plus polio, special programmes and the event-driven component of Outbreaks and crisis response. More information can be found at : <http://who.int/about/finances-accountability/budget/en/> (last accessed 29 August 2016).

²³. Fifty-sixth World Health Assembly (2003), Resolution WHA56.33.

50. However, the proportion of voluntary contributions has increased significantly to almost three quarters of the Organisation's financing in the last years. Besides Member States, a wide range of donors contributes to WHO activities, for example public agencies or NGOs. In-kind or in-service contributions are accepted after assessment on a case-by-case basis. Starting from 2013, the Health Assembly has approved the budget for biennial financial periods under all sources of funds, namely, assessed and voluntary contributions, instead of assessed contributions only. To ensure that full funding of the Programme Budget can be achieved, a Financing Dialogue has been arranged with Member States and key non-State contributors to ensure that WHO is well-equipped to address the increasingly complex challenges of the health of populations in the 21st century. The financing dialogue process consists of an integrated series of events and activities that includes a strategic planning and preparation phase, two milestone financing dialogue meetings, bilateral meetings, mission briefings and Regional Committee discussions. It aims at improving alignment, transparency, predictability and flexibility of WHO's financing and broadening WHO's contributor base.²⁴

Forms of regulatory cooperation provided by the WHO to its Member States

51. IRC takes place within WHO in various forms. Very much like other IGOs, the Organisation is particularly active in the upstream phases of the policy cycle, providing a platform for exchange of information among regulators, pursuing data collection and analysis, putting a strong accent on the importance of research, and having an extensive range of different standard-setting activities (OECD, 2016). While it is less active in the downstream phase of the policy cycle, the WHO still performs crisis management in support of health emergencies faced by its Members States.

Data collection

52. Data collection as well as the production and dissemination of health statistics are a core activity of the Organisation. WHO programmes compile and disseminate a broad range of statistics that play a key role in advocacy for health issues, monitoring and evaluation of health programmes and provision of technical assistance to countries.

53. Data collection takes place in various ways. At the global level, the organisation provides data and analysis on global health priorities through the Global Health Observatory data repository²⁵, which provides access to over 1000 indicators on priority health topics. The repository contains an extensive list of indicators that can be selected by theme, indicator and country. It issues analytical reports on the current situation and trends for health priority issues.

54. Publications include the "World Health Statistics", which compiles statistics for key health indicators on an annual basis, and the "WHO Global Health Estimates" which provides a comprehensive and comparable assessment of mortality and loss of health due to diseases and injuries for all regions of the world. The WHO Indicator and Measurement Registry (IMR)²⁶ is a central source of metadata of health-related indicators used by WHO and other organisations, which facilitates complete and well-structured indicator metadata, harmonization and management of indicator definitions and code lists, internet access to indicator definitions, and consistency with other statistical domains.

²⁴Details of the Funding of the 2016-2017 Programme Budget – Details can be found at <http://extranet.who.int/programmebudget/Biennium2016/Financing>.

²⁵ Accessible at <http://www.who.int/gho/database/en/> (last accessed 12 August 2016).

²⁶ Accessible at: www.who.int/gho/indicator_registry/en/ (last accessed 12 August 2016).

Research

55. The fundamental importance of research in the field of health as the foundation for sound health policies is recognized in Article 2 of the WHO Constitution. Since its inception, the Organisation has opted not to engage directly in primary research, and has instead provided support in the areas of capacity-building, research priorities-setting, and standard development for good research practice and affordable health technologies and evidence-informed policy.

56. The 2010 WHO Strategy on Research for Health is based on the premise that policies and practices in support of health worldwide should be grounded in the best scientific knowledge. A Research Ethics Review Committee (ERC) composed of experts nominated and appointed by the Director-General has been tasked to ensure that research involving human subjects, supported by WHO, meets the highest ethical standards. ERC, which is guided in its work by the World Medical Association Declaration of Helsinki as well as the International Ethical Guidelines for Biomedical Research Involving Human Subjects, is mandated to review all research projects that involve human participants and are supported, either financially or technically, by WHO.

57. The organisation has several particularly important research-focused initiatives. Special mention should be made of the WHO Centre for Health Development (Kobe Centre), whose focus is on the consequences of social, economic and environmental change and its implications for health policies. The co-sponsored Special Programme for Research and Training in Tropical Diseases supports innovative research on neglected priority needs for disease control whereas the cosponsored Special Programme of Research, Development and Research Training in Human Reproduction is the main instrument within the United Nations system for research in human reproduction. A separate institution for research in cancer – the International Agency on Research in Cancer – was established by the Health Assembly in 1965 (Box 2).

Box 7. The International Agency for Research on Cancer (IARC)

The IARC was created in 1965, through a resolution of the World Health Assembly, as the specialized cancer agency of the World Health Organization. Its objective is to promote international collaboration in cancer research by bringing together a wide range of inter-disciplinary skills. By pursuing its mission, the IARC plays an important role in terms of normative regulatory cooperation through the issuance of many quasi-normative texts. Since 1971, more than 900 environmental factors that can increase the risk of human cancer have been evaluated through the IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Interdisciplinary Working Groups of expert scientists review the published studies and evaluate the weight of the evidence. The Monographs series are complemented by the IARC Handbooks of Cancer Prevention, which provide evaluations of the cancer-preventive potential of agents and interventions and are also produced by an international Working Group of experts. Mention should also be made of the WHO/IARC Classification of Tumours series - authoritative and concise reference books for the histological and molecular classification of tumours prepared by a group of internally recognized experts – as well as of the Scientific and Technical Publications that disseminate the results of IARC-coordinated scientific research and focus on particular topics of a technical nature.

58. WHO significantly avails itself of the expertise and research made available by countries or other partners with WHO playing an important coordinating role and validating the outcome of such research (Burci and Vignes, 2004). As mentioned in the first section, several Collaborating Centres, i.e institutions such as research institutes at national level, parts of universities or academies, have been designated by the Director-General to carry out activities in support of the organisation's programmes. At the time of writing there are over 700 WHO collaborating centres in over 80 Member States working with WHO on areas such as nursing, occupational health, communicable diseases, nutrition, mental health, chronic diseases and health technologies. Networks of collaborating centres have been created in many technical areas, such as the Global Network of WHO Collaborating Centres working on Communicable Diseases, the network of WHO Collaborating Centres for Injury and Violence Prevention and the network of WHO Collaborating Centres for Traditional Medicine.

Normative functions

59. Under Article 2 of the Constitution, the organisation can propose conventions, agreements and regulations, and make recommendations with respect to international health matters. Although an analysis of the WHO Constitution and its preparatory work shows that conventions and agreements were considered as central instruments in the handling of global health issues, “soft law” in the form of non-binding recommendations has so far played a much more prominent role (Burci and Vignes, 2004).

Conventions and agreements

60. The most powerful tool for norm-setting for the WHO are conventions and agreements that the Health Assembly has the authority to adopt with respect to any matter within the competence of the organisation.²⁷ The Health Assembly has adopted only one international convention so far, i.e. the WHO Framework Convention on Tobacco Control (WHO FCTC). Furthermore, in 2012, the Conference of the Parties to the WHO FCTC adopted the Protocol to Eliminate Illicit Trade in Tobacco Products, which is open for ratification and accession by Parties to the Convention²⁸. Article 19 of the Constitution requires the majority of two-thirds of the vote of the Health Assembly to adopt a convention or agreement, which shall come into force for each Member State when accepted by it in accordance with its constitutional processes. Article 20 of the Constitution further prescribes that each Member State has to take action regarding the acceptance of such convention or agreement within eighteen months after the adoption by the Health Assembly by notifying the Director-General of the action taken, and if it does not accept such convention or agreement within the time limit, and has to furnish a statement of the reasons for non-acceptance. In case of acceptance, each Member agrees to make an annual report to the Director-General on the action taken with respect to such convention or agreement. It should be noted, however, that this provision has not been rigorously implemented with regard to the WHO FCTC.

Regulations

61. Regulations constitute a legally binding yet separate instrument at the disposal of WHO Member States. Article 21 of the WHO Constitution gives the Health Assembly the authority to adopt regulations in five articulated areas, namely (i) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease; (ii) nomenclatures with respect to diseases, causes of death and public health practices; (iii) standards with respect to diagnostic procedures for international use; (iv) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce; and (v) advertising and labelling of biological, pharmaceutical and similar products moving in international commerce.

62. This provision is especially innovative because it allows the organisation to provide a particularly efficient process of entry into force – binding all Member States at the same time except for those that may choose to “opt-out”. So far, the Health Assembly has adopted two sets of international regulations under Article 21 of the Constitution.

²⁷ Article 19 of the WHO Constitution.

²⁸ More information on the Protocol can be found at: <http://www.who.int/fctc/protocol/en/> (last accessed 8 September 2016).

63. First, a set of regulations regarding nomenclature with respect to diseases and causes of death were adopted in 1948 and then completely revised in 1967.²⁹ The 1967 Nomenclature Regulations require Member States to compile mortality and morbidity statistics using the revision in force at any given time of the International Classification of Diseases (ICD).³⁰

64. Secondly, the Health Assembly has adopted international regulations in the area of sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease.³¹ The first set of International Sanitary Regulations were adopted in 1951 and then replaced by and renamed the International Health Regulations in 1969, which were in turn revised in 1973 and 1981. These regulations were intended to monitor and control six specific infectious diseases (cholera, plague, yellow fever, smallpox, relapsing fever and typhus).

65. To address the growing number of public health risks resulting from increased travel and trade in the last quarter of the 20th century, the Health Assembly at its Fifty-eighth session in 2005 dispensed with a disease-specific model and adopted the revised International Health Regulations (2005)³², aimed at disease, regardless of source, which entered into force on 15 June 2007 (Box 3).

Box 8. The International Health Regulations (2005) (IHR)

The International Health Regulations (IHR) are an international legal instrument that is binding on 196 countries across the globe, including all the Member States of WHO. Their aim is to prevent, protect against, control and respond to the international spread of disease while avoiding unnecessary interference with international traffic and trade. They are also designed to reduce the risk of disease spread at international airports, ports and ground crossings.

The IHR set an extensive legal framework to ensure exchange of information between countries on public health emergencies, with the WHO centralizing the information and thus facilitating access to it. They indeed require countries to notify WHO of all events that may constitute a “public health emergency of international concern” (PHEIC), and to respond to requests for verification of information regarding such events. Countries also have the obligation to report to WHO evidence of a public health risk identified outside of their territory which may cause international disease spread

States parties to the IHR have delegated to the Director-General the authority to determine whether an event constitutes a PHEIC in accordance with the criteria and procedure set out in the Regulations. In arriving at this determination, the Director-General takes into account several elements, including the advice of an Emergency Committee composed of experts.

WHO’s response to a PHEIC includes temporary recommendations concerning appropriate public health responses for application by the countries affected by such an emergency, as well as by other States and by operators of international transport. Standing recommendations indicating the appropriate measures for routine application for specific ongoing public health risks may also be issued.

²⁹ Twentieth World Health Assembly (1967), Resolution WHA20.18.

³⁰ A spin-off from the ICD has been elaborated by the WHO of a supplementary classification of impairments, disabilities and handicaps in 1980; and a second edition of this classification has been endorsed by the World Health Assembly under the title “International Classification of Functioning, Disability and Health”, even though the new classification is not an integral part of the ICD.

³¹ Under article 21 (a) of the WHO Constitution.

³² Fifty-eighth World Health Assembly (2005), Resolution WHA58.3.

Soft law instruments

66. So far, the Organisation has mainly exercised its normative function through the adoption of recommendations by the Health Assembly, styled as “resolutions” or sometimes as “decisions”, as well the development of a diverse range of technical standards by the Secretariat. Article 23 of the Constitution indeed gives power to the Health Assembly to make recommendations with respect to any matter within the competence of the organisation. Irrespective of the many names that can be assigned to them (e.g. codes, strategies, global plans of action, road maps or frameworks), such recommendations are not legally binding upon States. However, they represent the agreed outcome of extensive governing body consideration, and consultation processes with Member States and often other stakeholders involving face-to-face meetings. They therefore carry a strong political force towards implementation at both the international and country level.

67. Since 1948 the Health Assembly has adopted a large number of these recommendations on a wide range of topics. Mention can be made, for example, of the recently adopted “Global Strategy and Action Plan on Ageing and Health 2016-2020”³³ and the “WHO global plan of action to strengthen the role of the health system within a national multisectoral response to address interpersonal violence, in particular against women and girls, and against children”³⁴, as well as of the Pandemic Influenza Preparedness Framework (Box 4).

68. Only two “codes” have been adopted so far: the “International Code of Marketing of Breast milk Substitutes”, which was adopted by the Health Assembly in 1981 to ensure protection and promotion of the safe and adequate nutrition for infants and the proper use of breast-milk substitute³⁵; and the “WHO Global Code of Practice on the International Recruitment of Health Personnel”, a comprehensive, multilateral framework for strengthening the health workforce, which places emphasis on the international mobility of health professionals and encourages information exchange on issues related to health personnel and health systems in the context of migration.³⁶

Box 9. The Pandemic Influenza Preparedness Framework (PIP Framework)

The PIP Framework is an innovative public health instrument, adopted by the Health Assembly in 2011 in accordance with Article 23 of the Constitution³⁷ that seeks to better prepare the world to respond to pandemic influenza. It aims at improving pandemic influenza preparedness and response, and strengthening the protection against the pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system (“WHO GISRS”), with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing, the sharing of H5N1 and other influenza viruses with human pandemic potential, and access to vaccines and sharing of other benefits.

Under the PIP Framework, the sharing of PIP biological materials within the WHO GISRS network of laboratories is governed by Standard Material Transfer Agreement 1 (SMTA1), which establishes the rights and obligations of GISRS laboratories with respect to many matters. In addition, the Framework establishes two mechanisms to facilitate access to the benefits that result from the sharing of viruses with human pandemic potential: the Partnership Contribution, which is an annual contribution to WHO from influenza vaccine, pharmaceutical and diagnostic manufacturers that use the WHO GISRS; and a Standard Material Transfer Agreement 2 (SMTA 2), which is a legally

³³ Sixty-ninth World Health Assembly (2016), Resolution WHA69.3.

³⁴ Sixty-ninth World Health Assembly (2016), Resolution WHA69.5.

³⁵ Thirty-fourth World Health Assembly (1981), Resolution WHA34.22.

³⁶ Sixty-third World Health Assembly (2010), Resolution WHA63.16.

³⁷ Sixty-fourth World Health Assembly (2011), Resolution WHA64.5.

binding agreement between WHO and non-GISRS entities (including manufacturers, biotechnology firms, and academic and research institutions) that receive PIP biological materials from WHO GISRS³⁸.

By providing access and benefit-sharing, the Framework may constitute a specialized international instrument under the terms of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol). Should that be the case, access to biological specimens covered by the Framework and benefit-sharing resulting therefrom would not be subject to the obligations arising out of the Nagoya Protocol. A study will be presented to the Executive Board, in January 2016, on whether and the extent to which the implementation of the Nagoya Protocol may affect the sharing of pathogens and, consequently, entail any public health implications.

Of note is also the coordination role played by WHO with regard to the sharing of influenza viruses through WHO GISRS. This network has been collecting and monitoring influenza viruses for more than 60 years. WHO GISRS monitors the evolution of influenza viruses and provides recommendations in areas including laboratory diagnostics, vaccines, antiviral susceptibility and risk assessment. Finally, and of great importance, WHO GISRS also serves as a global alert mechanism for the emergence of influenza viruses with pandemic potential.

69. In addition, the Secretariat elaborates technical recommendations which are not approved by the Health Assembly, but rather take the form of technical documents elaborated by groups of experts or external collaborators. The organisation has established mechanisms to seek expert advice on the diverse range of health issues that it is called to handle. “Expert Committees” advise the Director-General who then reports back to the Executive Board on their meetings and recommendations and about his/her observations and recommendations.³⁹ Study groups, scientific groups and collaborating centres also play a substantive role in the development of recommendations and standards.⁴⁰

70. Technical standards and recommendations may also be developed by the Secretariat based on a grant of authority by a governing body, but not endorsed or approved as such by the latter (Burci and Vignes, 2004). An example of this type is the WHO’s Model List of Essential Drugs, first prepared by a WHO Expert Committee in 1977 at the request of the Health Assembly. The Model List, which has been updated by the WHO Expert Committee on the Use of Essential Drugs every two years since 1977, serves as a guide for the development of national and institutional essential medicine lists.⁴¹ Another example in the area of pharmaceutical products is the International Nonproprietary Names (INNs) Programme, which aims at facilitating the identification of pharmaceutical substances or active pharmaceutical ingredients (Box 5). The list of INNs is not adopted by the governing bodies, who have however taken decisions concerning the procedure for selection of INNs and General Principles for Guidance in devising INNs.⁴²

³⁸ Signed SMTA2 Agreements can be accessed at www.who.int/influenza/pip/benefit_sharing/smta2_signed/en/.

³⁹ They are guided by the “Regulations for Expert Advisory Panels and Committees” contained in World Health Organization (2014), Basic Documents, pp. 121-130.

⁴⁰ They are guided by the “Regulations for Study and Scientific Groups, Collaborating Institutions and Other Mechanisms of Collaboration” contained in World Health Organization (2014), Basic Documents, pp. 121-130.

⁴¹ The current WHO Model List of Essential Medicines as well as the revised procedure for its update are available at www.who.int/selection_medicines/list/en/ (last accessed 11 July 2016).

⁴² World Health Organization (2004), Document EB115/11, Annex 1 and Annex 2.

Box 10. International Non-proprietary Names Programme (INN Programme)

The INN Programme was initiated in 1950 and began operational in 1953 when the first list of INN for pharmaceutical substances was published. The INN Programme offers a managed, coordinated network between WHO, INN experts and national nomenclatures committees. These three groups collaborate closely to select a single name of worldwide acceptability for each active substance that is to be marketed as a pharmaceutical. Nonproprietary names are intended for use in pharmacopoeias, labelling, product information, advertising and other promotional material, drug regulation and scientific literature, and as a basis for product names. Each INN is a unique name that is globally recognized and is public property. The names, which are given the status of an INN, are selected by WHO on the advice of members of the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations serving the INN Expert Group at the end of a very complex procedure involving the applicant, WHO Secretariat and the INN experts.

Although they have only recommendatory nature, their use is often required by national law. Since inception of the Programme, more than 8500 INN have been established, which are used globally by National Drug Regulatory Authorities and developed in collaboration with several national drug nomenclatures bodies, such as the British Approved Names (BAN), Dénominations Communes Françaises (DCF), Japanese Adopted Names (JAN) and United States Adopted Names (USAN).

71. Further, the WHO Secretariat develops a wide range of guidelines intended to assist national programme managers, providers, and other stakeholders make informed decisions with respect to health care delivery. The development of such guidelines follows specific internal procedures and criteria which aim at ensuring that guidelines are free from conflict of interest, meet a public health need and are consistent with the principles of a comprehensive and objective assessment of the available evidence and of transparency. WHO also produces “rapid advice guidelines” in response to a public health emergency (for example influenza), where WHO is required to provide global leadership and guidance, while “standard guidelines” are developed in response to a request for guidance arising from uncertainty or controversy in a single clinical or policy area.

72. A rigorous process ensures that WHO guidelines are developed using best practices and making appropriate use of evidence. The guideline process is managed by a WHO steering group, while the formulation of recommendations is done by the WHO Guideline Development Group (GDG) comprised of external experts and stakeholders. Guideline development plans and final products are reviewed and cleared by the WHO Guideline Review Committee to ensure that, before final clearance and publication of the guidelines, evidence is gathered, and its quality is properly assessed and synthesized. GDG membership is balanced, representative. A critical focus at all stages is to ensure that conflicts of interest are fully addressed and appropriately managed.

Regulatory support activities

73. WHO provides support to countries in the fulfilment of their responsibility to establish strong national medicines regulatory authorities. Assessment of national medicines regulatory systems, dissemination of guidance, provision of training opportunities to implement global guidelines adapted to the national context, facilitation of the exchange of regulatory information and enhancement of international regulatory collaboration among regulators, through global and regional networking, are some of the many ways through which support is provided to countries. A few examples are provided below to illustrate WHO’s supporting activities to national regulators.

74. The International Conference of Drug Regulatory Authorities (ICDRAs) has provided drug regulatory authorities of WHO Member States with a forum to meet and discuss ways to strengthen collaboration since 1980. As a platform established to develop international consensus, ICDRAs continues to be an important tool for WHO and drug regulatory authorities in their efforts to harmonize regulation and improve the safety, efficacy and quality of medicines. ICDRAs’ recommendations are proposed for action among agencies, WHO and related institutions.

75. The Paediatric Medicines Regulatory Network (PmRN), is instead composed of representatives from National Medicines Regulatory Authorities, and aims to support availability of quality medicines for children through facilitation of communication, collaboration and regulatory harmonization across manufacturing, licensing and research.

76. In the area of food safety, WHO and FAO manage jointly the International Food Safety Authorities Network (INFOSAN), a global network of national food safety authorities with the secretariat in WHO. INFOSAN aims to promote the rapid exchange of information during food safety related events, share information on important food safety related issues of global interest, promote partnerships and collaboration between countries, and between networks, and help countries strengthen their capacity to manage food safety emergencies.

77. There are two additional areas where WHO plays a central role to support national regulatory authorities. First, WHO has the Prequalification of Medicines Programme, which aims at ensuring that medical products meet acceptable standards. While the focus was originally on medicines for treating HIV/AIDS, tuberculosis and malaria, the programme's scope has been extended over time. Assessment of the quality, safety and efficacy of medical products is conducted by experts from WHO and national regulatory authorities worldwide based on international pharmaceutical standards. The WHO List of Prequalified Medicinal Products is used by international procurement agencies and increasingly by countries to guide the purchase of medicines. Secondly, a WHO Emergency Use Assessment and Listing (EUAL) procedure was set up to provide guidance to interested UN procurement agencies and national regulatory authorities on the quality, safety and performance of certain In Vitro Diagnostics (IVDs). An EUAL procedure may be opened with respect to any disease that has been declared a Public Health Emergency of International Concern under the IHR.

Crisis management

78. Countries face a broad range of emergencies caused by a variety of hazards, which differ in scale, complexity and international consequences. It is one of WHO's functions to furnish necessary aid, in emergencies, upon the request or acceptance of Governments. The Organisation's role in the area of crisis management has become more operational in nature as shown, in particular, by specific surveillance and response obligations arising out of the IHR. Also, the WHO intervenes on international health crisis by coordinating with other agencies in the context of a humanitarian crisis. WHO has the responsibility of empowering humanitarian country teams to better address the health aspects of the crisis. Indeed, it is the leading agency of the health cluster established by the Inter-Agency Standing Committee of the United Nations, which ensures inter-agency coordination of humanitarian assistance.⁴³

79. Outside the UN framework, WHO co-operates with a wide network of humanitarian partners worldwide, the Red Cross and Red Crescent movement, Collaborating Centres, universities and other academic institutions, NGOs and senior public health experts. Other key partners are intergovernmental institutions such as the African Union, the Council of Europe and the International Organization of Civil Protection.

80. The Organisation's work in emergencies is guided by the Emergency Response Framework⁴⁴. Foreign Medical Teams made up of groups of health professionals from governments, charities, militaries and international organisations have been set up to ensure the availability of health professionals to treat patients affected by emergency or disasters. They work under the guidelines of the WHO Classification and Minimum Standards for Foreign Medical Teams that address the principles and core standards of how

⁴³ Inter-Agency Standing Committee (n.d), <https://interagencystandingcommittee.org/> (last accessed 28 June 2016).

⁴⁴ Available at www.who.int/hac/about/erf/en/ (last accessed 11 July 2016).

registered teams must function and declare their operational capabilities. The Secretariat has also developed a global registration system where emergency medical teams can be verified and classified ready to be deployed to health emergencies.

81. As mentioned in the first section, WHO is undergoing a substantial reform to ensure that the organisation's emergency capacities are fit for purpose. In May 2016, the Health Assembly welcomed the progress made in the development of a new Health Emergencies Programme, the elaboration of an implementation plan and timeline for the new Programme, and the establishment of the Emergencies Oversight and Advisory Committee.⁴⁵

82. The new Programme is designed to deliver rapid, predictable and comprehensive support to countries and communities as they prepare for, face or recover from emergencies caused by any type of hazard to human health. The new Programme will consist of a single workforce using common standards and processes to provide a fast, effective and predictable response to health emergencies, addressing the full risk management cycle of prevention, preparedness, response and early recovery. WHO will provide leadership within the context of the IHR and health, in relation to the broader humanitarian and disaster-management system (WHO, 2016).

Ensuring regulatory quality

83. Expert advice made available to WHO at different stages of the policy-making process, significantly contributes to ensure regulatory quality of WHO's policies, programmes and strategies. In addition, WHO has increased efforts in assessing the implementation and impact of its policies. While *ex ante* impact assessment is only occasionally conducted, internal evaluation and monitoring of implementation by countries as well as review of normative instruments are more frequent.

Consultation processes

84. WHO engages with a wide range of stakeholder groups by systematically providing them with an opportunity to comment on its proposed actions and, from time to time, by inviting them to participate in standard-setting activities, to sit on expert advisory groups or *ad hoc* working groups. The general public may also, on occasion, be invited to comment on proposed actions of the Organisation through the WHO web site.

85. As mentioned in the first part of this study, expert consultation is one of the essential features of WHO.⁴⁶ Due to the manifold nature of the disciplines involved and rapid advancements affecting technical fields, the technical expertise of WHO staff is often complemented by the input of Expert Committees, as well as Study Groups, Scientific Groups and Collaborating Centres.

86. A good example of WHO's interaction with a broad range of stakeholders is provided by the INN Programme. Designated members of the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations form the so called "INN Expert Group", to which the Secretariat transmits proposals for recommended INNs and proposals for substitution of such names. The INN Expert Group

⁴⁵. Sixty-ninth World Health Assembly (2016), Decision WHA69(9).

⁴⁶. While the Framework of Engagement with non-State Actors replaces previous policies on interaction with nongovernmental organisations and commercial enterprises, separate policies continue to apply regarding WHO's relations with individual experts (Regulations for Expert Advisory Panels and Committees, see Basic Documents, 48th ed. Geneva: World Health ; 2014; pp. 121-130), and scientific collaborations (Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms See Basic Documents, 48th ed. Geneva: World Health Organization; 2014; pp. 131-138).

takes decisions on the selection of new INNs as a result of consultations that take place at least twice a year, and ensuing correspondence. Decisions are taken by consensus, in the lack of which the matter will continue to be discussed by correspondence or at the next consultation, if necessary.⁴⁷ Furthermore, throughout the process that leads to the adoption or substitution of INNs, the Secretariat engages with Member States as well as national and regional pharmacopoeia commissions or other bodies designated by Member States, with the original applicant and with any interested person who may wish to file a formal objection to a proposed name within the set deadline.⁴⁸

87. Another significant example of expert consultation is provided by the Emergency Committee in the context of the IHR. The Emergency Committee provides technical advice to the Director-General in the context of a PHEIC. In addition, the IHR Review Committee makes technical recommendations to the Director-General regarding, *inter alia*, amendments to the IHR and provides technical advice to the Director-General with respect to standing recommendations and any other matter referred to it by the Director-General. The IHR also provide for a “consultation” process between a State Party and WHO by giving States Parties the opportunity to keep WHO informed to ensure appropriate investigative and health response measures.

88. As far as guidelines are concerned, a Handbook for Guidelines Development has been developed that provides detailed instructions for guideline developers on application of high quality methodology for guideline development, appropriate collection and management of experts’ declared conflict of interest, expert group composition, instructions for the management of group process, developing plans for implementing and adapting guidelines, and minimum standards for reporting.⁴⁹ Different groups serve as platforms to allow experts, end-users, affected individuals, or other persons interested in the subject of the guidelines to participate in the guidelines development process. In addition, a separate body – the Guidelines Review Committee – has been established to ensure specifically that WHO guidelines are of the highest quality (Box 6).

Box 11. The Guidelines Review Committee

The Guidelines Review Committee (GRC) is an advisory body composed of experts, which was established by the Director-General in 2007 to ensure that WHO guidelines are of the highest quality, and are developed through a transparent, evidence-based decision making process. The GRC meets on a monthly basis to review initial proposals for guideline development and final versions of guidelines prior to their publication.

The review of initial proposal includes an assessment of whether the guideline development process will be able to meet the WHO requirements that are described in the WHO handbook for guideline development. The review of final submissions is conducted to ensure the process and form of the recommendations has followed the WHO requirements guidelines.

The GRC also offers suggestions and advice on how to improve the quality of the guidelines. GRC is supported by a Secretariat, which *inter alia* coordinates and provides technical support on guidelines development to WHO Secretariat, organises trainings, implements the Handbook and maintains a database of GRC approved guidelines.

⁴⁷. See “Working Process for the INN Expert Group”, contained as an Appendix to document EB115/11, adopted by the Executive Board in resolution EB115.R4.

⁴⁸. See “Procedure for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances” contained in Annex 1 to document EB115/11, adopted by the Executive Board in resolution EB115.R4.

⁴⁹. World Health Organization, WHO Handbook for Guideline Development. 2nd edition (2014), available at www.who.int/kms/handbook_2nd_ed.pdf.

Evaluation and implementation monitoring

89. The Organisation’s activities have been subject, starting from 2012, to a formal Evaluation Policy, which provides a framework for the evaluation function and evaluation processes to ensure the systematic application of a set of key principles – impartiality, independence, utility, quality and transparency.⁵⁰ This policy applies to any assessment of an activity, project, programme, strategy, policy, theme, sector and operational area institutional performance.

90. The WHO Secretariat commissions three types of evaluations: thematic evaluations focussing on selected topics; programmatic evaluations focusing on a specific programme; and office-specific evaluations focusing on the work of WHO in a country, region or at headquarters in respect of WHO’s objectives and commitments. In addition, WHO develops a biennial, organisation-wide evaluation plan as part of the organisation’s planning and budgeting cycle. The Evaluation Policy, as complemented by the WHO Evaluation Practice Handbook⁵¹, guides the work of the Evaluation Office, which manages, commissions or conducts corporate/centralized evaluations. Thirteen evaluations were recently conducted at all levels of the Organisation, and the implementation of their findings and recommendations analysed.

91. The Evaluation Office also continues to monitor progress in implementation of previous evaluations whose recommendations had not been fully responded to at the time of the annual evaluation report to the Executive Board.⁵² That being said, different solutions regarding implementation monitoring and evaluation, tailored to the specific instrument or programme concerned, have been adopted, some of which are described below.

92. As far as implementation by countries is concerned, it is worth recalling that, under Chapter XIV of the WHO Constitution, Member States are required to report annually to the organisation on the action taken and progress achieved in improving the health of its people, and on the action taken with respect to recommendations made to them by the organisation and with respect to conventions, agreements and regulations. This requirement has not been systematically implemented and it is difficult to identify a general trend with regard to monitoring the implementation of WHO’s recommendations. There are, however, many areas where implementation and reporting are quite robust, including the WHO FCTC, the IHR, the PIP Framework, and the WHO Global Code of Practice on the International Recruitment of Health Personnel.

WHO Framework Convention on Tobacco Control (WHO FCTC)

93. One of the most stringent mechanisms for monitoring implementation is provided by the WHO FCTC, which requires each Party to submit to the Conference of the Parties (COP), through the Convention Secretariat, periodic reports on the implementation of the Convention⁵³. The objective of reporting is to enable Parties to learn from each other’s experience in implementing the WHO FCTC and the reporting forms the basis for reviews by the COP of progress in implementation of the Convention internationally.

⁵⁰. The Evaluation Policy as contained in document EB131/3 was approved by the Executive Board in decision EB131(1).

⁵¹. WHO (2013), *WHO Evaluation Practice Handbook*, available at http://apps.who.int/iris/bitstream/10665/96311/1/9789241548687_eng.pdf?ua=1 (last accessed 12 August 2016).

⁵². More information of both categories of reports can be found in document EB139/9.

⁵³. Article 21.1 of the WHO FCTC.

94. In November 2010, at its fourth session, the COP decided to adopt a single biennial reporting instrument consisting of a core questionnaire mandatory for all Parties.⁵⁴ All data reported by Parties are available in an Implementation Database.⁵⁵

95. At its fifth session, the COP acknowledged the need to conduct an overall assessment on the impact of the WHO FCTC, which will be performed by a group of seven independent experts.⁵⁶ The purpose of the assessment is to evaluate the impact of WHO FCTC on the implementation of tobacco-control measures and its effectiveness as a tool to reduce tobacco consumption and prevalence during its first decade of operation.

International Health Regulations (2005) (IHR)

96. Reporting requirements have also been laid down in the IHR. States Parties and the Director-General report annually to the Health Assembly on the implementation of the Regulations.⁵⁷ The annual report submitted by the Director-General to the Health Assembly, through the Executive Board, gives an account of actions taken by the Secretariat within the framework of the Regulations regarding the international response in the previous year to public health events and emergencies, and any other relevant information regarding implementation of the IHR.

97. The Review Committee on the Role of International Health Regulations (2005) in the Ebola Outbreak and Response has concluded that it is imperative to prioritise the implementation of the Regulations in all countries and to strengthen the Secretariat's capacity and partnerships to support States Parties.⁵⁸ The Committee made 12 recommendations to ensure implementation of the Regulations based on new proposals and to improve compliance with the Regulations.⁵⁹ With specific regard to the requirement that countries develop, strengthen and maintain core capacities for surveillance and response, WHO has developed the new IHR Monitoring and Evaluation Framework for Core Capacities.⁶⁰ In addition to the annual reporting, the Framework includes after-action reviews, simulation exercises and addresses independent (external) evaluation.⁶¹ While the Secretariat's initial focus has been on the development of

⁵⁴. All implementation reports and the annexes to those reports are available on the WHO FCTC web site, on country pages dedicated to each Party that has submitted at least one implementation report (see : www.who.int/fctc/reporting/party_reports.)

⁵⁵. The database can be accessed at:<http://apps.who.int/fctc/reporting/database>.

⁵⁶. Decisions FCTC/COP5(12) and FCTC/COP6(13).

⁵⁷. In accordance with paragraph 1 of article 54 of the IHR and resolution WHA61.2 (2008).

⁵⁸. World Health Assembly (2016), Document A69/21.

⁵⁹. The Sixty-ninth World Health Assembly, in May 2016, decided to request the Director-General to develop for the consideration of the Regional Committees in 2016 a draft global implementation plan for the recommendations of the Review Committee that includes immediate planning to improve delivery of the International Health Regulations (2005) by reinforcing existing approaches, and that indicates a way forward for dealing with new proposals that require further Member State technical discussions. The Director-General will submit a final version of the global implementation plan for the consideration of the 140th session of the Executive Board.

⁶⁰. The IHR core capacity monitoring framework used a self-assessment questionnaire by States Parties since 2010 to report to the Health Assembly on the status and development of the minimum core public health capacities required by the International Health Regulations (2005). See IHR Capacity Scores for all reporting States Parties for 2015 available at www.who.int/gho/ihr (accessed 30 May 2016).

⁶¹. The International Health Regulation (2005) Monitoring and Evaluation Framework is contained in the Annex to document A69/20.

the independent evaluation component, the three other components of the new tool are being finalised, together with all relevant guides and tools. Reporting to the Health Assembly using the new format is planned for 2017.⁶²

PIP Framework

98. In the context of the PIP Framework, implementation is subject to the oversight of the Health Assembly, and monitoring by an Advisory Group composed of eighteen independent experts in health policy, public health, or influenza from all six WHO regions, which also provides recommendations to the Director-General on its evaluation of implementation. In formulating advice to the Director-General, the Advisory Group interacts with industry and other stakeholders.

99. The PIP Advisory Group met in a special session in October 2015 to seek views from Member States, industry and other stakeholders on the 2016 PIP Framework Review and recommended that a small independent group of experts be established to review implementation of the PIP Framework using a transparent and inclusive approach. The Review will focus on what the achievements have been since the PIP Framework was adopted, whether implementation of the PIP Framework improved global pandemic influenza preparedness, including interpandemic surveillance, and capacity to respond; and what the challenges and possible ways of addressing them are. It is expected that the Review Group will provide its final Report to the Director-General by October 2016, for consideration by the governing bodies of the Organisation in 2017.

100. Tools to monitor implementation are also in place with regard to the WHO Global Code of Practice on the International Recruitment of Health Personnel, mentioned above.⁶³ The reporting process is indeed an integral component of the effective implementation of the voluntary principles and practices recommended by the Code. To monitor the progress made in implementing the Code, and in accordance with the request of the Health Assembly, a national self-assessment tool was created for Member States.

101. At the time the Secretariat presented the Sixty-sixth World Health Assembly with the first report on progress made in implementing the Code, 85 Member States had designated national authorities and 56 had submitted reports using the national reporting instrument. In 2015, the Sixty-eighth World Health Assembly reviewed the report of the Expert Advisory Group on the Relevance and Effectiveness of the Code and concluded that the Code remains relevant and that evidence of its effectiveness is emerging but work to develop, strengthen and maintain the implementation of the instrument should be viewed as a continuing process.

102. An updated national reporting instrument (NRI) for the second round reporting was launched in March 2015 for a period extending until February 2016. The NRI comprises three modules facilitating a comparative assessment of implementation relative to the 10 main articles of the Code, reporting on the current stock and inflow of foreign-trained doctors and nurses, and contributions by independent stakeholders to the national reporting process describing their experiences. The quantity and the quality of reporting by Member States on the implementation of the Code have improved considerably in the second round. By 4 March 2016, 74 of the 117 designated national authorities (63%) had completed and submitted a report using the NRI for the second round of national reporting. The vast majority of countries that have submitted reports in the second round are those that are the known source and destination countries for the international migration of health personnel. There has been an increase of 37% in the number of designated

⁶². In February 2016, the IHR (2005) Joint External Evaluation Tool was finalized and, together with partners and experts, voluntary joint external evaluation missions to countries have begun.

⁶³. The Code of Practice was adopted by the Health Assembly in resolution WHA63.16.

national authorities, which will have a significant impact on the implementation of the Code in those Member States.

Guidelines

103. Monitoring and evaluation systems are also used to collect and analyse data to assess the effectiveness and impact of the guideline. The WHO Handbook for Guidelines Development requires the guidelines to include outcome or performance measures that can be monitored for the main recommendations. Performance measures may be related to guideline dissemination, adaptation and endorsement in the national context, policy changes, changes in end-user knowledge and understanding, in practice performance or in health outcomes and inequities and economic or other social consequences. Ideally, there should be baseline measures against which to assess performance in relation to the potential change induced by the guideline. Operational and implementation research can be performed to assess service providers' and end-users' perceptions, and the values and preferences related to guideline implementation. The guideline should propose a specific set of indicators to be monitored and evaluated, including relevant disaggregation of data.

104. Although there has been no assessment to date of the extent to which WHO recommendations have been followed in the context of national guidelines, nor of the factors that may influence this, a recent study has concluded that uptake of WHO recommendations in national guidelines is high and associated with strength of recommendations and evidence of quality, in particular a higher level of evidence quality was associated with greater uptake at the national level irrespective of the recommendation's strength (Nasser S.M.U. and al, 2015).

105. As far as implementation measures in WHO guidelines are concerned, though, an analysis of the implementation sections of WHO guidelines approved by the WHO GRC between December 2007 and May 2015 has shown that most mentioned implementation techniques were very brief, with general policy strategies occurring most often, and underscore the fact that stronger guidance for implementation would be welcomed, for example through structured and increased detail on implementation considerations, information on what is needed by countries to adapt the guideline to the local context and specific options from implementation strategies (Wang et al. 2016).

Codex Alimentarius

106. Formal tools to ensure implementation, monitoring and evaluation have not been established in the context of Codex Alimentarius. As to evaluation, in 2002 FAO and WHO decided to undertake a formal evaluation of the Codex programme. An independent evaluation team conducted more than 20 country visits and sought information from an open call for public comment on the Codex website. The results, which found that Codex food standards were accorded very high importance by members, were mostly positive.⁶⁴ The final report indicated that while Codex standards were perceived as most useful for low and middle-income countries whose domestic regulations were not yet as developed, countries at all stages of development claimed to have adopted domestically 60% of Codex standards. Further to this report, the Fifty-sixth World Health Assembly urged Member States "to make full use of Codex standards for the protection of human health throughout the food chain".⁶⁵

107. An evaluation of the functioning and results of the Codex Trust Fund after 10.5 years of its 12-years lifespan was also commissioned by the FAO/WHO Consultative Group for the Trust Fund, which concluded that the Codex Trust Fund had been successful at fulfilling its primary mandate of widening

⁶⁴. The report is available at www.fao.org/docrep/meeting/005/y7871e/y7871e00.htm#E10E2.

⁶⁵. Resolution WHA56.23 Joint FAO/WHO evaluation of the work of the Codex Alimentarius Commission.

participation of developing and transition-economy countries in the Codex Alimentarius Commission. Its results helped to inform discussions in FAO and WHO and among Codex Member States on possible future measures to enhance further effective participation in the Codex by developing and transition-economy countries. It should be further added that the Codex Alimentarius Commission has adopted an approach for continuous monitoring of Codex work management. The Codex Commission at its Thirty-ninth session in 2016, requested the Secretariat to regularly review Codex work management as part of the monitoring of the Codex Strategic Plan and regularly inform both the Commission and the Executive Committee on the findings and recommended actions.

ASSESSMENT OF THE IMPACT AND SUCCESS OF REGULATORY CO-OPERATION THROUGH WHO

Benefits, costs and challenges of regulatory co-operation

108. WHO programmes, policies and strategies have global impacts. The fight against infectious diseases has significantly reduced the burden of such diseases, resulting in their complete eradication as in the case of smallpox, for example. WHO has also contributed since its inception to improved health outcomes through the provision of technical support to countries, the development of guidelines, norms and standards, and by facilitating the development and dissemination of drugs, vaccines and diagnostics.

109. WHO's role in health governance and its convening and facilitating power, in defining shared problems and bringing together stakeholders to negotiate both binding and soft law instruments is of central importance. WHO also tracks health trends nationally, regionally and globally, thereby alerting the world and individual countries to emerging health threats, tracking resources and results in the interest of accountability, and demonstrating progress in reaching internationally agreed goals.

110. Challenges to successful regulatory cooperation within WHO may arise from the lack of human and financial resources to implement the programme of work of the Organisation, difficulties in reaching agreement on specific areas of work due to differences of view among countries on underlying political and economic issues, and the lack of ratifications of legally binding agreement, which impedes the entry into force of the instrument concerned. For example, while the WHO FCTC provides an example of successful IRC through the WHO, its Protocol on Illicit Trade in Tobacco Products, adopted in November 2012, has not yet entered into force due to lack of sufficient ratifications.

Assessment of success

111. WHO's history is marked by numerous examples of successful regulatory cooperation activities, which makes it challenging to give due account to all of them. Suffice it to recall, that the IHR is the only international legally binding instrument which helps the international community monitor and respond to acute public health risks that have the potential to cross borders and threaten people worldwide. WHO's sole international convention so far, the WHO FCTC, is an evidence-based treaty that reaffirms the right of all people to the highest standard of health and represents a milestone for the promotion of public health and provides new legal dimensions for international health cooperation. Non-legally binding instruments, such as the WHO Model List of Essential Medicines and the International Nonproprietary Names, are now used globally by almost all national health regulators.

112. There are at least three factors which appear necessary to ensure successful regulatory cooperation within the WHO. First, the willingness among Member States to overcome diverse political interests with regard to certain specific issues surely contributes to the timely and efficient consideration of those interests by the organisation. Measures related to certain non-controversial health issues can be easily and rapidly adopted, as exemplified recently by the rapid consensus reached among countries at the Health Assembly to the need to address the global burden of mycetoma. And with political will, measures related to more complex or controversial health matters have also commanded consensus, albeit usually after extensive negotiations.

113. Secondly, existence of solid scientific and evidence basis is vital to build Member States' confidence and willingness to take action. Thirdly, transparency in the development process of normative and technical guidance is key to engagement and effective implementation. Credible, transparent and

inclusive elaboration processes of WHO policies surely contribute to successful regulatory cooperation in the field concerned.

114. The comprehensiveness of the Organisation's membership as well as the high rate of participation in its normative and technical instruments and activities is another factor contributes to the success of IRC within WHO. As already mentioned, WHO currently counts 194 Member States and two Associate Members, and cooperates closely with a wide range of stakeholders. Participation in WHO legally binding instruments is also very broad. The WHO FCTC currently counts 180 Parties, and the IHR are an international legal instrument that is binding on 196 countries, including two non-WHO Member States. Codex Alimentarius also helps illustrate the capability of WHO, in this case in collaboration with another UN agency, to attract participation by a high number of countries. With 188 Members, as well as 234 observers, the Codex Alimentarius has become the single most important international reference point for developments in food standards.

115. Furthermore, the WHO has shown great capacity to adapt to new developments and challenges in issues of public health. Thanks to its extensive exchange of information, data collection, research and policy analysis activities, combined with the possibility of acting upon its findings through various forms of normative instruments and tools, the Organisation has been able to address the increase and diversification of threats to health which have appeared since its inception. Identification of new threats is illustrated, for instance, by the recently adopted Global Plan of Action on Antimicrobial Resistance with specific work streams designed to address resistance to antimicrobial medicines that threatens human and animal health.

116. Finally, the capacity of the Organisation to recognise in a timely manner and address the need for structural change is a critically important strength. The best recent example in this regard is the establishment of the new Emergencies Programmes in the aftermath of the Ebola Virus crisis in 2014 and 2015. The new Programme constitutes a milestone towards a more operational WHO, in addition to the technical and normative role that the organisation has traditionally played.

CONCLUSION

117. International regulatory cooperation is at the heart of WHO's mandate. The organisation benefits from a Constitutional structure that enshrines a noble objective, empowers a global membership and provides both flexibility and accountability. As a result, it has been well placed to develop a wide range of normative, technical and, increasingly, operational mechanisms and tools to facilitate exchange of information and data among national health regulators, foster research in the field of health, and develop norms and standards through a variety of legally-binding and policy instruments. Its role in the management of health crisis faced by WHO Members is also of paramount importance, and the variety of local offices of the WHO Secretariat ensures its responsiveness to domestic conditions, both chronic and acute.

118. The Organisation also provides several mechanisms to ensure regulatory quality of its activities, in particular through regular and extensive expert consultations and engagement with a wide range of stakeholders. Different tools, tailored to the specific instrument or programme concerned, have been adopted to monitor their implementation and evaluate their effectiveness. The Organisation is also equipped with a general Evaluation Policy, which provides a framework for the evaluation function and processes to ensure the systematic application of a set of key principles.

119. Persisting problems, particularly related to the social determinants of health, as well as new and emerging public health threats make it imperative for WHO to be better equipped to address increasingly complex challenges of health in the 21st century. Since the launch of a set of reforms, in 2011, significant progress has been made towards meeting the objectives of being a more effective, efficient, transparent and accountable organisation that leverages its relative strengths and comparative advantages to improve health outcomes for all peoples. Thanks, *inter alia*, to the development of enhanced monitoring mechanisms, it is now possible to evaluate the impact of the various streams of reform against a set of performance indicators.⁶⁶ While implementation of the programmatic reform is almost completed, more works remains to be done to lead the governance and managerial reforms to completion. Furthermore, the outbreak of Ebola virus disease in West Africa drew some criticism towards the Organization's capacity to effectively act as "the directing and co-ordinating authority on international health work" in accordance with its constitutional mandate and showed the need to reform WHO's response in severe, large-scale emergencies. In this respect, financing the new Health Emergencies Programme is crucial to its full operationalization. As of 22 June 2016, a significant portion of the Programme's core budget was still not available.⁶⁷ It is hoped that the next financing meeting planned for October-November 2016 will contribute to the mobilization of additional voluntary contributions with a view to filling this gap. The Organization's ability to improve implementation of the IHR by countries, as recommended by the Review Committee on the Role of the IHR in the Ebola Outbreak and Response, will be of increasing importance to respond to any future health emergency. A draft global implementation plan will be submitted to the Board, next January, to follow-up on the recommendations of the Review Committee.⁶⁸ Finally, the Organization faces

⁶⁶. Document A69/4, Annex.

⁶⁷. Report by the Secretariat on "Reform of WHO's work in health emergency management". The report was prepared for consideration by the Regional Committees at their sessions in 2016 and is available at http://www.who.int/about/who_reform/emergency-capacities/RC_Reform-who-work-health-emergency-management-en.pdf?ua=1 (last accessed 9 September 2016).

⁶⁸. The Draft global implementation plan of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response is available at http://www.who.int/about/who_reform/emergency-capacities/RC_Draft-global-implementation-plan-IHR.pdf?ua=1 (last accessed 9 September 2016).

continuous challenges in navigating areas where there may be tensions between public health considerations and political and/or economic interests. This has been evidenced, in addition to those areas mentioned above, in areas such as the Organization's efforts to address the health impact of high sugar consumption, where guidelines developed by the Organization became subject to challenges that were seen by some to be driven by economic considerations. Addressing such challenges requires the careful marshalling of both technical processes and political will.⁶⁹ These, as well as other efforts, will be crucial to WHO's continued effectiveness in fulfilling its constitutional objectives and purpose.

⁶⁹ WHO (2015) Guideline: Sugars intake for adults and children, available at: http://apps.who.int/iris/bitstream/10665/149782/1/9789241549028_eng.pdf?ua=1 (last accessed 13 September 2016).

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