BRIEFING

Requested by the ENVI Committee



The 76th World Health Assembly

"WHO at 75: Saving lives, driving health for all"

KEY FINDINGS

The **76th World Health Assembly (WHA)** will take place in Geneva, Switzerland, from **21 to 30 May 2023**. The WHA is the highest decision-making body of the World Health Organization (WHO), gathering annually and composed of delegations from all 194 Member States (MS). The WHA discusses and votes on the decisions and resolutions prepared by either WHO's Executive Board (EB), Director-General or proposed by groups of MS. The Executive Board is composed of 34 individuals elected for three years, and its annual meeting takes place in January.

The theme for the 76th WHA is "**WHO at 75: Saving lives, driving health for all**". The decisions and resolutions will fall under four pillars, three of which contribute to the "triple billion targets" defined in the Thirteenth General Programme of Work (GPW13):

- One billion more people benefiting from universal health coverage (Pillar 1)
- One billion more people better protected from **health emergencies** (Pillar 2)
- One billion more people enjoying better **health and well-being** (Pillar 3)
- More effective and efficient WHO providing better support to countries (Pillar 4)

The Assembly meeting will consist of a plenary and two committees (A and B), as well as technical meetings. The documents to be discussed during the WHA are regularly uploaded and updated on the WHA's dedicated <u>webpage</u>, as well as the preliminary daily <u>timetable</u>.

The 76th WHA will take place from 21 to 30 May 2023, in Geneva, Switzerland. The theme of the 76th WHA is "WHO at 75: Saving lives, driving health for all". WHO started its activities on 7 April 1948, 75 years ago, an occasion to look back on public health milestones and achievements, remaining challenges and progress on public health targets. WHO's core messages for this anniversary are that the right to health is a basic human right and that strong health systems and universal health coverage are essential. However, WHO's Director-General notes this year that "the world is off track to reach most of the triple billion targets and the health-related Sustainable Development Goals" and that "urgent action is needed to accelerate progress, or the world may fall further off track". 2022 presents a contrasted picture of progress and setbacks on global health indicators.

A brief history of the WHA and EU and Member States' participation

1. History and functioning of the WHA

When diplomats from all over the world met to create the United Nations (UN) in 1945, one of their key topics of discussion was the establishment of a **global health organisation**: the World Health Organization (WHO), whose purpose is to attain the **highest possible level of health** for all peoples.



The WHO Constitution establishes the World Health Assembly (WHA) as its decision-making body¹, which meets at least yearly to adopt conventions, agreements, regulations and recommendations on any matter within the competence of WHO or relating to its operations². In addition, special sessions can be organised, as in 2006 and 2021 (regarding the instrument on pandemic preparedness and response). The WHA also has the power to alter or repeal existing conventions and agreements. It reviews and approves the programme budget and assesses the financial statements submitted by the Director-General (DG). The current DG is Tedros Adhanom Ghebreyesus, appointed on 1 July 2017 and re-appointed on 24 May 2022³.

The WHA meets annually in **Geneva**, Switzerland, to set **global health priorities**. The agenda is set by the Executive Board (EB), composed of 34 qualified experts in the field of health⁴. Once decisions are taken, the EB acts as the executive organ, while the WHO Secretariat and the six regional offices coordinate the tasks. The WHA is composed of representatives of **all WHO Member States** (MS)⁵. As of today, it includes **194 MS** (all UN members except for Liechtenstein, the Cook Islands and Niue⁶). All EU MS are WHO MS, and the **EU** can participate in the WHA as an **observer**. The European Commission (EC) participates in different committees and technical meetings⁷. Further observers include bodies of the UN, the World Bank and non-state actors, which have been granted the privilege of being in official relations with WHO.

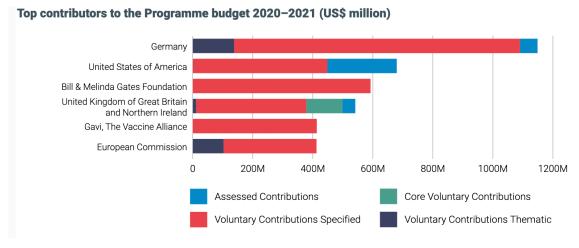
The 76th WHA will be presided by Malta's Deputy Prime Minister and Minister for Health, Chris Fearne⁸.

2. WHO/WHA and the EU

The **EC coordinates** the EU's approach on global health issues and aligns it with the EU's health policy objectives. As an important partner of WHO's regional office for Europe (WHO EURO), the EU represents 27 of the 53 countries in the WHO European Region. **Cooperation** between the EU and WHO in health-related areas benefits EU MS and associated countries⁹. **Collaboration at all levels** is essential given the complexity of current public and global health challenges. Therefore, WHO and the EU have established a <u>strategic partnership</u> both at technical and political levels, extending beyond the health sector.

At the 70th Session of the WHO Regional Committee for Europe in September 2020, the EC and WHO EURO issued a **joint statement** on the **reinforcement and tailoring of their partnerships** to emerging issues and new health priorities. The statement highlights five shared **priority areas**: (i) health security against health emergencies and other threats; (ii) effective, accessible, resilient and innovative health systems; (iii) a comprehensive response to NCDs with a focus on cancer; (iv) sustainable food systems and health; and (v) health cooperation with non-EU countries in the WHO European Region¹⁰.

This technical and political collaboration also resulted in increased **financial cooperation**, with the EU becoming a major **voluntary** financial contributor. The EC contributed USD 412 million to WHO activities in 2020-2021 (over 5% of WHO's budget), which made it the 6th largest donor¹¹. Together, the EU and its MS contributed USD 1.72 billion (over 1/5 of WHO's budget) on the same period.



Source: WHO, Executive Summary of Results Report, Programme budget 2020–2021.

Most recently, the EC announced investing EUR 125 million in the Universal Health Coverage (UHC) Partnership for 2023-2027¹². WHO and EU also recently agreed to reinforce the strategic cooperation on the

global health security and architecture, on the implementation of the EU's Global Health Strategy (2022-2026) and of the Cross-Border Health Threats Regulation (EU) 2022/2371¹³. The <u>EU's Global Health Strategy</u> is the external dimension of the European Health Union and aims to attain the 2030 SDG targets. The Strategy supports the leadership of a well-financed, accountable and efficient WHO and a mandate covering health data governance and health workforce. In addition, the Strategy's targets and priorities align with WHO's 'triple billion' targets.

The EC's **Health Emergency Preparedness and Response Authority** (HERA) and WHO's Hub for Pandemic and Epidemic Intelligence furthermore launched a 5-year administrative arrangement in December 2022 to increase multi-level preparedness for and response to health emergencies, with a EUR 15 million allocation under the EU4Health funding programme. It involves sharing data and analytics, joint action to develop new countermeasures against antimicrobial resistance (AMR), funding national capacities for SARS-CoV-2 and emerging pathogens' detection and genomic surveillance in Africa, and support to the COVID-19 Technology Access Pool (C-TAP)¹⁴.

Public health matters have gained political momentum in the EU. As per their <u>programme</u>, the **Swedish Presidency of the Council** will encourage efficient EU collaboration in the talks on the development of a global treaty on pandemic preparedness and response, on potential amendments to the International Health Regulations (IHR), and internally, will aim at renewing the EU Global Health Strategy.

Global context

The EU strongly condemns Russia's military aggression against **Ukraine** and its huge impact on the health and well-being of people. Regarding **COVID-19**, the EU calls for the integration of the lessons learnt from the pandemic and the establishment of an effective well-organised international infrastructure. In this sense, it supports the revision of the IHR 2005 and the conclusion of an international pandemic agreement under the aegis of WHO¹⁵. Due to the insistence of the People's Republic of China, **Taiwan** has not been able to participate in the WHA since 2017 and has not yet received an official invitation to this year's WHA (as of 26 April 2023), despite support from the G7 nations¹⁶ and several EU Member States. The agenda of the WHA76 includes a report on the 'Health conditions in the occupied **Palestinian territory**, including east Jerusalem, and in the occupied Syrian Golan' (A76/15).

76th World Health Assembly's tabled resolutions, decisions and reports

The work of the 76th WHA will be divided into four pillars corresponding to the specific objectives set out in the Thirteenth General Programme of Work (GPW13)'s '**triple billion targets**' by 2025¹⁷: one billion more people benefiting from **universal health coverage** (pillar 1), one billion more people better protected from **health emergencies** (pillar 2), and one billion more people enjoying **better health and well-being** (pillar 3). Pillar 4 focuses on the realisation a 'more effective and efficient WHO providing better support to countries'. These four objectives aim at attaining the health-related Sustainable Development Goals (SDGs).

1. **Pillar 1**: One billion more people benefiting from universal health coverage

The dossiers under this pillar deal in particular with health systems and services, health workforce, health information systems, medicines, vaccines and health products but also governance and financing. **Universal health coverage** (UHC) means that all people have access to the full range of quality health services they need, when and where they need them, without financial hardship. It covers the full continuum of essential health services, from health promotion to prevention, treatment, rehabilitation, and palliative care across the life course. ¹⁸

The documents to be discussed and/or proposed for adoption under Pillar 1 will include the following items:

Agenda item	Description	Comment and position	
Committee A			
13.1. Reorienting Health Systems to primary health care as a resilient foundation for UHC and	This report by the DG prepares the Sep. 2023 UN GA's high-level meeting on UHC, reviewing progress halfway through the timeline to achieve the SDGs	The decision on the preparation of the UN GA high-level meeting on UHC was proposed by 44 MS, including the 27 EU MS. The resolutions on integrated	

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preparation for a highlevel meeting of the UNGA on UHC (EB152/5) / (A76/6) To adopt: (EB152(3), EB152(4), EB152(5) and EB152(6))

(2015-2030). It follows the 2019 Political Declaration on UHC by the UN GA.

The WHA is invited to adopt resolutions on integrated emergency, critical and operative care for UHC and protection from health emergencies (EB152(3)); increasing access to medical oxygen (EB152(4)); preparation of the high-level meeting of the UNGA on UHC (EB152(5)); and strengthening diagnostics capacity (EB152(6)).

emergency, critical and operative care for UHC and protection from health emergencies, and on access to medical oxygen, were proposed by several WHO MS including the 27 EU MS. The resolution on strengthening diagnostics capacity was proposed by African MS and Indonesia. The EU calls for achievements in terms of UHC, fight against tuberculosis, and pandemic preparedness and response (PPR). 19

13.2. Political declaration of the third high-level meeting of the GA on the prevention and control of non-communicable diseases, and mental health (EB152/6), (A76/7 Add.1)

This report has been requested by the WHA in 2019 and presents the progress achieved and proposed updates to the **menu of policy options** and cost-effective interventions to prevent and control NCDs. These concern tobacco use, harmful use of alcohol, unhealthy diet, physical inactivity, fighting cardiovascular diseases, diabetes, chronic respiratory diseases, and cancer.

This is a central item on the agenda and covers many items high on the political agenda of the EU (NCDs, mental health). The updated menu has received the support of the World Heart Federation²⁰. The EU supports the update and defends stronger efforts on mental health²¹. The Healthier Together EU Non-Communicable Diseases Initiative sought alignment with WHO.

To adopt: (EB152(11))

The WHA is invited to endorse the menu of policy options and cost-effective interventions.

13.3. Substandard and falsified medical products (EB152/7)

This report of the mechanism on substandard and falsified medical products (collaboration mechanism between WHO MS) notes the recommendation to independently evaluate the mechanism.

coordinated and shared system (web-based tools and platforms) at EB152; as well as a resource optimisation, thus supporting the evaluation²².

The EU advocated for a stronger,

To adopt: (<u>EB152(9)</u>)

Context: Creation of the African Medicines Agency. The WHA is invited to adopt a decision to launch the independent evaluation.

The 12th meeting of the mechanism should take place in November 2023.

13.5. Draft global strategy for infection prevention and control (EB152/9),

To adopt: (EB152(7))

This report presents the draft global strategy for infection prevention and control prepared by the DG. An action plan will be developed in 2023-2024 to complete the high-level strategy.

The WHA76 will be invited to adopt the Global Strategy on infection prevention and control.

This draft global strategy (DGSIPC) will support MS' preparedness against infectious diseases (e.g. MERS-CoV, SARS-CoV-2, Ebola) via multi-level actions, as well as against multidrug-resistant antimicrobial resistance (MDR-AMR) and healthcare associated infections (HAI).

13.7. Standardisation of medical devices nomenclature (EB52/11)

This report on international classification, coding and nomenclature of medical devices presents progress towards integrating available information related to medical devices (terms, codes, definition, into the MeDevIS database), linking it with other WHO platforms and ICD-11.

The EU supports the initiative, urging the DG to allocate sufficient resources to this task, and defends the use of the European Medical Devices Nomenclature (EMDN) used by the European database on medical devices ²³. Support for international standards is highlighted in the EU's Global Health Strategy.

Committee B

27.1. Progress reports (A76/37)

Progress reports on:

A. Strengthening **local production of medicines** and other health technologies to improve access B. Health in the 2030 Agenda for Sustainable

B. Health in the 2030 Agenda for Sustainable Development

C. Global action on patient safety D. **Antimicrobial resistance**

E. Eradication of dracunculiasis

Reports A and D are key files. Report A aims at reducing dependence of LMICs on HICs and increasing resilience of the production and supply chains. This is supported in many ways. A key working area is IP rights (patents) via the COVID-19 technology access pool (C-TAP) and the Medicines Patent Pool²⁴.

Other files include the:

- Global Strategy for Women's, Children's and Adolescents' Health (2016–2030) (A76/5);
- Strengthening rehabilitation in health systems (EB152/8);
- Global road map on defeating meningitis (EB152/10), (EB152(8)).

2. Pillar 2: One billion more people better protected from health emergencies

The dossiers under this pillar deal with health emergencies (epidemics/pandemics and conflicts), access to life-saving health services, disease prevention, emergency preparedness and response, risk prevention, detection (early warning), assessment and management.

The documents to be discussed and/or proposed for adoption under Pillar 2 will include the following items:

Agenda item	Description	Comment and position	
Committee A			
14.1. Independent Oversight and Advisory Committee (IOAC) for the WHO Health Emergencies Programme (A76/8)	The IOAC was established in 2016 by the Director-General, and reinforced in 2023, to oversee and guide the WHO Health Emergencies Programme. It reports findings to the WHA upon request.	Document A76/8 has not yet been published.	
14.2. Implementation of the International Health Regulations (2005) (A76/9)	This is an annual report by the Director-General on progress in implementing the IHR (2005). The WHA is invited to consider how the implementation of the IHR (2005) can be strengthened, in the time prior to its revision in 2024.	This file is independent of the discussion on the revision. The Council had supported the technical revisions of the amendment rules of the IHR (2005), adopted at the WHA75, as they showed their limitations during the Ebola and SARS-CoV-2 outbreaks.	
15.1. Strengthening the global architecture for health emergency preparedness, response and resilience (EB152/12) (A76/10)	This report outlines a draft framework consisting of 10 proposals: 1/ Global Health Emergency Council and WHA main committee on emergencies; 2/ Targeted amendments to IHR (2005); 3/ Scale up Universal Health and Preparedness Reviews; 4/ Strengthen health emergency workforce; 5/ Strengthen health emergency coordination; 6/ Partnerships and networks for collaborative surveillance; 7/ Coordination between finance and health decision-makers; 8/ Strengthen and finance the FIF PPR; 9/ Expand funds for emergency response; 10/ Strengthen WHO. The WHA will likely be invited to adopt the WHO framework on emergency preparedness, response and resilience.	The EU supports the initiative and welcomes WHO's leadership. However, the EU calls for further dialogue on the 10 proposals and their implementation. It welcomes the negotiations on the Pandemic agreement, the revision of IHR (2005), the establishment of the FIF PPR, and on preparedness reviews and monitoring ²⁵ .	
15.1. Strengthening clinical trials to provide high-quality evidence on health intervention and improve research quality and coordination (EB152/13)	On the basis of requests from the Assembly in Resolution WHA75.8 of 2022, WHO conducted consultations to "strengthen clinical trials" and this report presents the best practices and other measures identified to strengthen the global clinical trial ecosystem, in particular harmonisation. A self-assessment tool will be developed by WHO to evaluate clinical trial ecosystems.	The EU supports the centrality of regulatory capacity and supervision and harmonisation of ethics review and regulatory procedures. The EU is active <i>inter alia</i> though the European and Developing Countries Clinical Trials Partnership (EDCTP). The EU proposed a questionnaire on clinical trials' capacities ²⁶ .	
15.2. Implementation of resolution WHA75.11 (2022) (EB152/16) (A76/12)	This report follows up on the request by the WHA in 2022 to explore avenues in which WHO could support Ukraine regarding diverse health aspects. The EB was asked to provide guidance on action in response to the health emergency in Ukraine and in refugee-receiving and -hosting countries.	Central point: health situation in Ukraine as a consequence of Russian aggression. At EB152, the EU supported the report's conclusions and asked for further efforts to address sexual exploitation, abuse and harassment; and reporting on sexual and reproductive health, and maternal and child health.	
Committee B			
27.1. Progress reports (A76/37) (A76/37 Add.1)	nandamic prevention, preparedness and response		

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Other files include the:

- Global Health for Peace Initiative (EB152/17);
- Poliomyelitis eradication (<u>EB152/18</u>), (<u>A76/13</u>);
- Polio transition planning and polio-post-certification (EB152/19), (A76/14).

3. Pillar 3: One billion more people enjoying better health and well-being

The dossiers under this pillar deal with nutrition, reproductive health, mental health, communicable and non-communicable diseases, care for the ageing population, antimicrobial resistance, health effects of climate change. This pillar also has a focus on specific populations (women, children, adolescents).

The documents to be discussed and/or proposed for adoption under Pillar 3 will include the following items:

Agenda item	Description	Comment and position		
Committee A				
16.1. Well-being and health promotion (EB152/20) To consider: Decision (A76/7 Add. 2)	A <u>draft version</u> of a WHO Framework for Integrating well-being into public health has been submitted to the MS. The EB supported a greater emphasis on mental health and environmental determinants.	The WHA is invited to adopt the global framework for integrating well-being into public health utilizing a health promotion approach. ²⁷		
16.2. Ending violence against children through health systems strengthening and multisectoral approaches (EB152/21)	This report presents the implementation of Resolution WHA74.17 (2021) requiring actions to prevent violence against children, incl. the establishment of an inter-ministerial coordination process.	The EB underlined the importance of integrating violence prevention into health service provision and highlighted the need for training of health workers, multisectoral collaboration and improved data.		
16.3. Social determinants of health (EB152/22) To adopt: (EB152(12))	This report by the Director-General presents the implementation of Resolution WHA74.16 (2021) on social determinants of health. This point of the agenda also includes the proposal to adopt a resolution on accelerating action on global drowning prevention .	The draft resolution on accelerating action on global drowning prevention was proposed by 61 WHO MS, including the 27 EU MS.		
16.4. The highest attainable standard of health for persons with disabilities (EB152/23)	This report presents the implementation of Resolution WHA74.8 (2021) requiring action to improve disability inclusion in the health sector, with a focus on access to effective health services, protection during health emergencies and access to cross-sectoral public health interventions.	As a party to the UN Convention on the Rights of Persons with Disabilities, the EU fully supports the conclusions of the report ²⁸ .		
Committee B				
Progress reports on: H. The role of the health sector in the Strategic Approach to International Chemicals Management towards the 2020 goal and beyond I. WHO global strategy on health, environment and climate change: the transformation needed to improve lives and well-being sustainably through healthy environments J. Decade of Healthy Ageing 2020–2030 K. Water, sanitation and hygiene in health care facilities L. Prevention of deafness and hearing loss M. Plan of action on climate change and health in small island developing States N. Global action plan on the public health response to dementia				

Other files include:

- United Nations Decade of Action on Nutrition (2016-2025) (EB152/24), to adopt: (EB152(13));
- Behavioural sciences for better health (<u>EB152/25</u>), to adopt: (<u>EB152(23)</u>).

4. **Pillar 4**: More effective and efficient WHO providing better support to countries.

The dossiers under this pillar relate to financing, staffing, and administrative matters.

The dossiers of Pillar 4 for WHA76 focus on financial matters and sustainable financing, audit and oversight, staffing matters, management, legal and governance. Some key files are the proposed programme budget 2024-2025, which suggests a 20% increase of assessed contributions (MS membership contributions) compared to 2022-2023 (A76/4 and A76/4 Add.1; A76/4 Add.2), **Sustainable financing**: feasibility of a **replenishment mechanism**, including options for consideration (A76/32), **Global strategy on digital health** (Decision WHA73(28) 2020) on which the WHO and EU agreed to closely cooperate, and the **Eleventh revision of the International Classification of Diseases** (Resolution WHA72.15(2019)).

The EU welcomes the increased **transparency** in the preparation of the draft budget 2024-2025, the strong country focus, and the focus on the **sustainability and predictability of the financing**; and the actions towards reforming WHO financing and enabling functions. However, it urged the secretariat to include a description of the outcomes, i.e. what the secretariat will deliver in practice, to increase accountability²⁹. The Thirteenth General Programme of Work has been prolonged due to financial and time constraints and given new priorities³⁰. It also encourages reforms of WHO's HR management³¹.

WHO Convention on crisis preparedness and response

Overview

In December 2021, WHO's MS decided to establish an <u>intergovernmental negotiating body</u> (INB) to draft and negotiate a convention, agreement or other international instrument under the Constitution of WHO in a government-led process (WHO CA+, hereinafter 'Pandemic Accord'). The main objective is to strengthen pandemic prevention, preparedness and response (PPR). In fact, Article 19 of the <u>WHO Constitution</u> gives the 194 MS forming the WHA the authority to adopt conventions or agreements on any matter within WHO's competence. The <u>INB's work</u> is based on the principles of inclusiveness, transparency, efficiency, MS leadership and consensus. The INB <u>met for the first time</u> in February 2022 focusing on the working modalities. At EU level, in March 2022 the <u>Council adopted</u> a decision authorising the opening of negotiations. At the <u>second meeting of the INB</u> in July 2022, it was agreed that the Pandemic Accord should contain **both legally binding and non-legally binding elements**. Along with the INB process, MS and relevant stakeholders, as well as experts and the wider public participated in a global consultation.

In December 2022, at its third meeting open to all MS and relevant stakeholders, the INB considered the Conceptual Zero Draft (CZD) of the Pandemic Accord, including its structure, and discussed the future of the negotiation process. The participants agreed that the INB Bureau – with support from the WHO Secretariat – would prepare the Zero Daft, based on the CZD and inputs received during the third meeting, with legal provisions, for consideration by the INB at its fourth meeting. The Zero Draft is structured with a preamble, vision, 8 chapters, and 38 articles. Topics covered include equity, strengthening and sustaining capacities, coordination, collaboration and cooperation, financing for PPR and recovery of health systems, in addition to institutional arrangements.

In February-March 2023, the <u>INB considered the Zero Draft of the Pandemic Accord</u> at its <u>fourth meeting</u> and confirmed the Draft as the basis for commencing negotiations. Subsequently, the INB launched a drafting group (textual discussion, proposed edits). The discussion of the Zero Draft started at the fourth meeting and continued at the <u>fifth meeting of the INB</u> at the beginning of April 2023.

Summary of the key points of the working draft of the Pandemic Accord

The Zero Draft published in February 2023 aims to improve the global PPR. The key points of the draft include provisions to achieve global, equitable access to medical products by supporting the global supply chain and logistics network³², promoting sustainable and equitably distributed production and transfer of technology and know-how, regulatory strengthening and support relevant research. Furthermore, the Zero Draft focuses on the need to strengthen and sustain capacities for PPR and recovery of health systems through the support of health systems' resilience, the reinforcement of the

health and care workforce, the promotion of relevant preparedness monitoring, simulation exercises and universal peer review, as well as the protection of human rights with a particular emphasis on persons in vulnerable situations. The **global coordination, collaboration and cooperation** is considered among the key elements of the Zero Draft. Lastly, the **need for adequate financing** is also addressed³³.

Timeline of the following phases of the procedure

The INB is planning to submit a **progress report to the WHA76** in 2023. Both the INB and WGIHR are to submit their final outcome/work to the WHA77 in May 2024³⁴. A lot of discussions remain ahead to clarify the scope of application of the CA+ (including in relation to the IHR) and to restructure the text by 2024. Moreover, during the WHA77 in 2024, the INB is expected to submit a draft version of the Pandemic Accord, on which the WHO Members will be able to agree or not. After being adopted, it will need to be ratified by the WHO MS³⁵.

International Health Regulations (IHR)

Overview

In 1951, the first set of <u>International Sanitary Regulations</u> were adopted by the MS of WHO, including mostly **notification and quarantine provisions for outbreaks** of six diseases: cholera, plague, relapsing fever, smallpox, typhus, and yellow fever. These Regulations were revised in <u>1969</u> and adopted as the <u>International Health Regulations (IHR)</u> to ensure the highest level of protection against the international spread of diseases with the least disruption to global traffic. With the increase in global trade and travel, and the unpredictable disease outbreaks and other public health threats, the WHA called for a substantial revision of IHR in 1995. The revision led to the extension of the scope of diseases and related health events taking into account almost all public health risks.

The <u>revised IHR</u> were adopted in 2005 at the WHA58 through <u>Resolution WHA58.3</u> and entered into force in 2007. The <u>Regulations</u> are an instrument of international law, **legally-binding on 196 countries**, including the 194 WHO MS. According to the provisions of the IHR, all signatories shall ensure the operation of surveillance systems and laboratories able to detect potential threats; the cooperation with other countries in the decision-making processes regarding public health emergencies; the reporting of specific diseases and any potential international public health emergencies, through participation in a network of National Focal Points; and the appropriate response to public health events³⁶.

Proposed amendments to the IHR (2005)

In light of recent disease outbreaks, including the outbreak of the <u>COVID-19 pandemic</u>, in January 2022, the WHO MS agreed to consider <u>potential amendments to the IHR (2005)</u>. In May 2022, the WHA decided to continue this work through the Working group on amendments to the IHR (WGIHR), and <u>invited MS to propose amendments to the IHR</u>. In October 2022, a <u>Review Committee regarding amendments to the IHR (2005)</u> was established with the aim of providing technical recommendations to the DG on amendments proposed by State Parties to the IHR (2005). The <u>first meeting of the WGIHR</u> took place in November 2022.

More than 300 amendments proposed by 16 States (some on behalf of regional groups and organisations) were compiled by WHO in an Article-by-Article Compilation of Proposed Amendments to the IHR (2005) following the first meeting of the WGIHR. The proposed amendments cover 33 of the 66 articles of the IHR, and five of its nine annexes. Additionally, six new articles and two new annexes have been proposed. The proposed amendments have been reviewed by the Review Committee, which issued technical recommendations in a report published in February 2023 for consideration by the WGIHR³⁷.

The <u>second meeting of the WGIHR</u> took place in February 2023 and it was followed by a respective <u>report</u>. During this meeting, the proposed amendments were discussed for the first time. The WGIHR heard the reasoning behind the <u>307 proposed amendments</u> and discussed them³⁸. In general, the proposed amendments submitted in accordance with <u>Decision WHA 75(9) (2022)</u>, cover the purpose and scope of the IHR (2005), the principles, the responsible authorities, the notification, the verification, information sharing, risk assessment, the determination of a Public Health Emergency of International Concern and intermediate level of alert, including temporary recommendations and the convening and functioning of the Emergency Committee, the public health response along with collaboration and assistance, health measures,

conveyances (means of transport in an international voyage), digitalisation of health documents, and compliance and implementation of the IHR (2005)³⁹.

As to the proposed amendments submitted on behalf of the EU MS, these include the following:

IHR (2005)	Summary of proposed amendment
Article 3	Reference to the precautionary principle. In particular, Parties and WHO should exercise caution, in particular when dealing with unknown pathogens.
Article 6	Along with the existing provisions, the State Parties shall communicate to WHO epidemiological and clinical data, as well as microbial and genomic data in case of an event caused by an infectious agent; the health measures implemented and other related information as requested by WHO. Additionally, with the aim of fostering event-related research and assessment, WHO shall make the information received available to all Parties.
Article 7	Following a notification of an event caused by an infectious agent, a State Party shall make available to WHO the microbial and genetic material and samples related to the notified event, as appropriate, not later than a certain number of hours after such material and samples become available.
Article 11	Change of the title to 'Exchange of information'. WHO shall facilitate the exchange of information between States Parties and ensure that the Event Information Site For National IHR Focal Points offers a secure and reliable platform for information exchange among the WHO and State Parties and allows for interoperability with relevant data information systems.
Article 12	Along with the existing provisions on determination of a public health emergency of international concern, regional or intermediate public health emergency of international concern shall be included.
Article 15	Regarding temporary recommendations, these should be as evidence-based, concise and operational as possible, and refer to existing guidance and international technical standards, when appropriate.
Article 23	In addition to the existing provisions, documents containing information concerning traveller's destination should preferably be produced in digital form, with paper form as a residual option. The WHA may adopt the requirements that documents in digital or paper form shall fulfil, in cooperation with the International Civil Aviation Organization (ICAO) and other relevant organisations. Documents meeting such requirements shall be recognised and accepted by all Parties.
Article 35	In addition to the existing provisions, health documents may be produced in digital or paper form, subject to the approval by the Health Assembly of the requirements that documents in digital form have to fulfil. Documents meeting such requirements shall be recognised and accepted by all Parties.
Article 36	Other types of proofs and certificates may be used by Parties to attest the holder's status as having a decreased risk of being the disease carrier, such proofs may include test certificates and recovery certificates.
Article 43	Along with the existing provisions, additional health measures shall be based on regular risk assessments, provide a proportionate response to the specific public health risks and be reviewed on a regular basis. Parties taking relevant measures shall ensure that such measures are compatible with measures taken by other Parties in order to avoid unnecessary interference with international traffic and trade while ensuring the highest achievable level of health protection.
Article 44	In addition to the existing provisions, WHO shall collaborate with State Parties, upon request, in strengthening regional planning, preparedness and response, in close cooperation with WHO Regional Offices and relevant international and regional organisations.
Article 48	Gender balance should be among the principles taken into consideration for the selection of members of the Emergency Committee by the Director-General.
Article 49	Additional information regarding the procedure, including a detailed agenda to be provided to the Emergency Committee and the Committee's responsibility to present its recommendations to relevant WHO bodies after the declaration of a public health emergency of international concern.
New Article 54 bis	Detailed rules regarding the promotion of the effective implementation of the IHR. Establishment of an expert committee, (the Special Committee on the IHR) with the aim of ensuring equitable regional representation and gender balance, and assist the Health Assembly.
Annex 1(4)	In addition to the existing provisions, microbial, epidemiological, clinical and genomic data shall be reported at the local community level and/or primary public health response level.

9

Annex 6

Promotion of the digitalisation of international certificates, as well as signatures and stamps in accordance with the IHR and specifications and requirements approved and reviewed periodically by the Health Assembly.

Lastly, in April 2023, the <u>third meeting of the WGIHR</u> took place. The report of the last meeting has not yet been published.

As to the relation between the Pandemic Accord and the IHR, the two instruments are very similar but with slight differences. For instance, the IHR working group only looks at how to respond to an emergency of international concern, whereas the Pandemic Accord also looks for ways to prevent a pandemic along with the reaction of national governments. Moreover, the IHR has already been ratified in many countries, therefore its amendments are automatically applicable⁴⁰. In general, the implementation and operationalisation of the IHR should be <u>promoted and supported, inter alia, through the Pandemic Accord</u>. Considering the extensive overlap, the IHR and INB working groups will likely collaborate further⁴¹.

Points of tension. A central point of discussion regarding pandemic preparedness and response is the status given to intellectual property rights (patents) in the development of pandemic-related medicinal products and vaccines. The pharmaceutical industry prefers committing to ensuring early access by reserving an allocation of real-time production of vaccines, treatments, and diagnostics for priority populations in lower-income countries (Berlin Declaration). In this context, stakeholders argue over the respective roles of the WHO, the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO). The evolving role of WHO in the context of the CA+ and revision of the IHR (2005) questions the scope given by MS to its competence (e.g. oversight over the supply chain of medical countermeasures, price transparency). Finally, the Organization's budget and its financing structure appear unsuitable for the conduct of WHO's current and future assignments.

WHO targets on communicable and non-communicable diseases

Communicable diseases. The UN and WHO's target for communicable diseases is the end of major epidemics by 2030 (AIDS, tuberculosis, malaria, neglected tropical diseases) and combatting hepatitis, water-borne diseases and other communicable diseases (SDG 3.3.). With regard to **HIV**, although significant progress has been made globally, no country achieved the goal of reducing new infections by 75 % by 2020 and increases have been observed in countries of the WHO European Region. The EU/EEA MS have seen far fewer diagnosed new infections compared to the rest of the region. **Tuberculosis** has also clearly declined since 2000. However, the world is currenlty not on track to reach global targets (90 % reduction in the number of deaths and an 80 % reduction in the incidence rate by 2030 compared with levels in 2015). The WHO European Region became the region with the lowest incidence of tuberculosis in 2017. The incidence of **malaria** in Europe is very low and almost all cases are 'imported'⁴². In European regions, the prevalence of **Hepatitis B** is relatively low compared to other regions, with 1.5 % of the adult population having acquired the virus, as a result of vaccination campaigns. **Poliomyelitis** appears to have been almost eradicated worldwide, except in Afghanistan, Malawi and Pakistan.

Non-communicable diseases. According to WHO, 74 % of deaths worldwide (41 million persons annually) are caused by NCDs, and 89.6 % in the European Region in 2019⁴³, although the impact is stronger in lowand middle-income countries. NCDs include heart diseases, strokes, cancer, diabetes and chronic lung diseases. The four major risk factors are tobacco use, physical inactivity, harmful use of alcohol and unhealthy diets⁴⁴. The sustainable development agenda targets a **reduction of premature deaths from NCDs by one-third by 2030** through prevention and treatment (objective 3.4.). In parallel, the prevention and treatment of substance abuse and harmful use of alcohol correspond to objective 3.5. Actions of WHO and its MS are framed by the Global action plan for the prevention and control of NCDs 2013–2030 and its Implementation roadmap 2023–2030.

According to the progress report of the Director-General, no country is on track to achieve all nine voluntary targets for 2025 (with a baseline in 2010) although there is still a margin to achieve the targets⁴⁵. The European Region **performed the best at reducing premature NCD mortality** (31 % between 2000 and 2019), particularly in the reduction of cardiovascular mortality⁴⁶. Looking at a central indicator, i.e. the probability of dying between 30 and 70 from any of cardiovascular disease, cancer, diabetes, or chronic

respiratory disease, the projected evolution for the European region **nevertheless remains below the target** set out in SDG 3.4. Looking at WHO MS' level data (indicators supporting the analysis of SDG 3.4.), disparities are observed between EU MS with higher rates of mortality from NCDs in Bulgaria, Hungary, Latvia, Lithuania, Romania and several EU candidate countries.

Overview of European Parliament's work and existing EU legislation

Below is a non-exhaustive summary of the European Parliament's work on the matters of the 76th WHA and, where relevant, existing EU legislation. In February 2023, the European Parliament set up a permanent subcommittee on public health, highlighting the growing prominence of public health matters for the Parliament and for the EU.

Prevention and control of NCDs and mental health. In the EU, the "Healthier Together" Initiative on **NCDs** aims to address cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders. Several resolutions were adopted by the EP on the importance of preserving mental health for various populations, in particular in <u>work-related policies</u> and in the context of the COVID-19 pandemic, <u>calling for an EU Action Plan on mental health</u>. Regarding NCDs, the EP <u>defended</u> an extension of the ECDC's role to cover major NCDs. **Tobacco use** is regulated at EU level, including regulation of tobacco products, restrictions on advertising, creation of smoke-free environments and specific taxation regime. EU legislation implements the WHO Framework Convention for Tobacco Control (FCTC). Furthermore, the Special Committee on **Beating Cancer** (BECA) operated between September 2020 and December 2021, leading up to the adoption of the EP <u>Resolution</u> of 16 February 2022 on strengthening Europe in the fight against cancer, defending a comprehensive and coordinated approach which takes full account of WHO's recommendations and the adoption of <u>Europe's Beating Cancer Plan</u>. The Plan contains ten flagship initiatives and supporting actions to prevent and combat cancer in the EU.

Infection prevention and control. The EP has developed expertise in several fields of infection prevention and control, e.g. via the work and resolutions around the European One Health Action Plan Against AMR and the constitution of the MEP Interest Group on Antimicrobial Resistance. Substandard and falsified medical products. The EU has a strong legal framework for the production of medicines including a Directive on falsified medicines for human use since 2011, containing rules to prevent falsified medicines from entering the legal supply chain and reaching patients. The recently proposed revision of the general pharmaceutical legislation may see reinforcements to these rules. **Medical devices nomenclature.** The Medical Devices Regulation (EU) 2017/745 aligns the medical devices nomenclature for the European database on medical devices (EUDAMED) with internationally recognised nomenclatures, taking into account the principles and orientations of the International Medical Device Regulators Forum (IMDRF) and WHO. Public health emergencies: preparedness and response. As a result of the COVID-19 pandemic, the EU reinforced the legal framework to combat cross-border health threats and extended the role of the European Centre for Disease Prevention and Control and the European Medicines Agency in 2022, as steps towards a European Health Union. The new rules will support the prevention and control of infectious diseases and improve preparedness and response. Recognising and addressing the social determinants of health and reducing health inequalities is reflected in the EP's resolution on the EU's Public Health Strategy post-COVID-19, and the right to affordable, good-quality healthcare is an integral part of the European Pillar of Social Rights⁴⁷. Most recently, the EP <u>called</u> on the Commission and MS to "take swift action to ensure that persons with disabilities, including psychosocial disabilities, are provided with the same range, quality and standards of free or affordable healthcare and programmes that are provided to other persons, including access to sexual and reproductive health services and initiatives under the EU Beating Cancer Plan".

Many of the files discussed also have connections with current legislative proposals, in particular the proposed revision of the EU general <u>pharmaceutical legislation</u>, or the proposed Regulation on <u>standard</u> essential patents.

Special acknowledgment is made to <u>WEMOS</u>, <u>Health Action International</u>, and the <u>International Federation</u> <u>of Pharmaceutical Manufacturers and Associations</u> for providing insights for this Briefing (May 2023).

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