INFORMAL DISCUSSION OF THE ZERO DRAFT ROADMAP REPORT ON ACCESS TO MEDICINES AND VACCINES 2019-2023

10 SEPTEMBER 2018

Contributions received from the United Nations and other International Organizations

- United Nations Development Programme

Contributions received from the Intergovernmental organization

- South Center

Contributions received from non-State actors in official relations with WHO

- Caritas Internationalis
- Drugs for Neglected Diseases initiative (DNDi)
- European Society for Medical Oncology (ESMO)
- International Association for Hospice and Palliative Care, Inc. (IAHPC)
- International Council of Nurses (ICN)
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
- International Society of Nephrology (ISN)
- International Pharmaceutical Federation (FIP)
- Knowledge Ecology International (KEI)
- Medicines for Europe
- Medicines Patent Pool
- MSF International
- Oxfam GB
- Save the Children
- Stitching Health Action International (HAI)
- Union for International Cancer Control (UICC)
- World Heart Federation (WHF)
- World Psychiatric Association (WPA)
- World Stroke Organization (WSO)
- Written submission of Knowledge Ecology International (KEI) and 15 groups: Comments on the WHO Roadmap on Access to Medicines and Vaccines 2019-2023
UNDP intervention at WHO discussion on Roadmap on Access to Medicines and Vaccines 2019-2023

Geneva, September 10th 2018

• The Memorandum of Understanding concluded between WHO and UNDP in this past May has reinvigorated an already strong partnership. We are pleased to continue to support the work of WHO on Access to Medicines and Vaccines as set out in the draft Roadmap and other key documents such as GPW 13.

• The discovery, development and delivery of health technologies is critical for the attainment of universal health coverage, and other health-related targets found in the Agenda 2030. Health technology innovation and access are also key to the attainment of UNDP’s Strategic Plan of 2018-2021 and our HIV, Health and Development Strategy.

• In the course of our work in support of countries striving to meet health related targets in Agenda 2030, we are constantly reminded that millions are being left behind in accessing vaccines, medicines and diagnostics.

• In that vein, we would like to make the following comments on the draft Roadmap:

  o The development challenges associated with lack of access to medicines and other health technologies are not new. That said, we welcome the timely attention being paid to all diseases, all technologies and all countries without which, universal health coverage would remain a pipe dream.

  o The consultation around the draft Roadmap also presents an opportunity to consolidate the important work WHO has done and
continues to do in this area. We congratulate WHO on the multi-pronged approach found in the draft Roadmap including attention to:

i. Fair pricing,
ii. addressing registration barriers, and
iii. improving procurement and supply chain management among other elements

• These elements are central to the Access and Delivery Partnership which brings together UNDP, WHO, TDR and others to strengthen the health systems of low and middle income countries. The Roadmap also channels some of the recommendations of the United Nations Secretary General High-Level Panel on Access to Medicines, including the need to strengthen work on the application and management of intellectual property from a public health perspective.

• Agenda 2030 needs a strong and well-resourced WHO to respond to new challenges and opportunities as and when they emerge. As central as WHO’s role is to public health, targets within agenda 2030 such as universal health coverage will require the elevation of health priorities across the UN system. They will also require the strengthening of multi-sectoral national responses and partnerships. Active involvement from all parts of the UN and from other stakeholders will be a key element of success. And on that note, I’ll end by registering on behalf of UNDP our readiness to support the delivery of a roadmap that places patients at its centre –regardless of where they live or what diseases they may be living with or affected by.

Thank you
South Centre Statement for the Informal Consultation on the Roadmap on Access to Medicines

September 2018

The draft roadmap is an important work in progress that needs to be further detailed with clear deliverables and timelines. The roadmap will need to ensure complementarity of its work and the implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA).

In 2006, the report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) recognized “the need for an international mechanism to increase global coordination and financing of R&D medications”, and recommended that work toward the adoption of an R&D agreement should continue. Following the adoption of the GSPOA, by the World Health Assembly (WHA) in 2008, in 2010 the WHA established the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) which recommended WHO member States to start negotiations on a binding international instrument on health R&D, as the best way to create an appropriate framework to ensure priority setting, coordination, and sustainable financing of affordable medicines for developing countries. However, this recommendation has not been considered by the WHO member States. In 2016 the United Nations Secretary-General established a High-Level Panel on Access to Medicines that recommended initiating a process for governments to negotiate global agreements on the coordination, financing and development of health technologies, including negotiations for a binding R&D convention that delinks costs of R&D from end prices to promote access to good health for all.

It should also be stressed that one of the critical aims of this roadmap should be to support R&D of vaccines and medicines for diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the fullest the provisions in the Agreement regarding flexibilities to protect public health, and, in particular, provide access to medicines for all. The HLP on access to medicines has also made a recommendation for the WHO to establish and maintaining an accessible international database on prices of patented and generic medicines and biosimilars in the private and public sectors of all countries where they are registered. This key recommendation should be taken up in this roadmap. Moreover, it will be important that clear milestones and timelines for deliverables of the activities are clearly established. In the discussions on fair pricing, affordability of medicines should be at the centre of any understanding of fair pricing.

On intellectual property (IP), the roadmap focuses on management of IP for supporting innovation for public health. IP management is not the role of WHO. On the contrary, the focus should be on use of flexibilities in the IP system to support realization of public health goals, providing training and capacity building to countries for the same and undertaking health impact assessment of work of WIPO and WTO.
WHO should also help build capacity of countries for proper implementation of IP laws in line with the TRIPS Agreement and make full use of its flexibilities. The South Centre offers to work in partnership with WHO to provide developing countries with training programmes on the use of IP flexibilities for public health.
WHO Zero Draft Road Map for Access 2019-2023

Contribution by Caritas Internationalis

14 September 2018
Caritas Internationalis, a Catholic Church-related Confederation of 165 national members spread in 200 States and territories of the world, is pleased to submit the following contribution as input for the process led to the adoption of the Road Map on Access 2019-2023.

The points raised in this document reflect concerns of national member organizations of 6 regions of the Confederation, notably: North America; Latin America and the Caribbean; Africa; Asia; Middle East and North Africa; Oceania.

For further information, please do not hesitate to contact the Focal Point of Caritas Internationalis for Health and HIV, Mr. Stefano Nobile (snobile@caritas-internationalis.com or +41 76 219 54 90).

Activity Area 1 – Research and Development for Medicines and Vaccines that Meet Public Health Needs

- Caritas Internationalis supports the three Specific Actions proposed for Activity Area 1, most especially the Specific Action 3 (support improved capacity for R&D and clinical trials countries)
- Caritas Internationalis suggests including a new Specific Actions aimed at promoting transparency and understanding of costs related to R&D; negotiation of a WHO binding treaty on R&D in which Member States commit to dedicate at least 0.01% of GDP to basic and applied research relevant to health needs of developing countries is also suggested
- Caritas Internationalis encourages WHO to include in the Road Map references to support for R&D in and of traditional medicines

Activity Area 2 – Fair Pricing and Financing Policies

- Caritas Internationalis encourages to link the outcome of health technology assessment with a pricing policy that ensures that society will not pay more for new products that do not bring a significant improvement in their clinical outcomes
- Caritas Internationalis suggests the inclusion of the promotion of transparency in understanding of all costs associated with the health-product chain, from the R&D until its use and disposal, so that society can make informed-decision about their price
- Caritas Internationalis encourages WHO to focus on ensuring “affordability of essential health products” by the poorest and most vulnerable in particular; specifically, by disaggregating affordability indicators at the country level by wealth quintile and one or more globally recognized vulnerability indices

Activity Area 3 – Application and management of Intellectual Property to Contribute to Innovation and Promote Public Health

- People living under vulnerable conditions are the most negatively affected by the protection of intellectual property rights over medicines. Therefore, Caritas Internationalis encourages to change the whole approach of Activity Area 3 in order to orient it to achieve the exemption from IP protections of medicines on national lists or on the WHO Model List for Essential Medicines as well as give countries the capacity to fully use the public health safeguards contained in the TRIPS agreement, including compulsory licenses as well as pro-health patentability criteria

Activity Area 4 – Procurement and Supply Chain Management

- Caritas Internationalis strongly encourages to include the promotion of policies and measures to combat the illicit trafficking of medicines and vaccines
Activity Area 5 – Appropriate Prescribing, Dispensing and Use of Medicines

• Caritas Internationalis strongly encourages to include actions on combating resistance to medical product through prescription of correct dosages and products of good qualities

Activity Area 6 – Regulatory Systems to Ensure Quality, Safety and Efficacy of Medicines and Vaccines

• Caritas Internationalis strongly encourages the adoption of an approach aimed at looking at “essential regulation” rather than “smart regulation”; in fact, Caritas Internationalis’ opinion is that populations, especially those living in low- and middle-income countries, will benefit more from a “essential regulation” rather than from a “smart regulation”.
• Due to the high price of biological products, Caritas Internationalis strongly encourages WHO to fulfil the spirit and content of WHA67.21, in particular “update the 2009 guidelines, taking into account the technological advances for the characterization of bio-therapeutic products and considering national regulatory needs and capacities”
• Caritas Internationalis suggests including supportive policies to effectively combat counterfeit, substandard and falsified medicines and vaccines including through the promotion of certificate of quality for medical products

Activity Area 7 – Preparedness for Emergencies

• Caritas Internationalis suggests addressing deficiencies of lifesaving medical products in vulnerable areas
• Caritas Internationalis suggests including the provision of vaccines to populations living in emergency settings, in particular to children
• Caritas Internationalis suggests including references on the need to train at-risk populations on ways of transmission of highly transmittable diseases such as Hepatitis B, Hepatitis C and HIV

Activity Area 8 – Good Governance

• In order to complement the Specific Action “Support Policy Dialogue and Improved Policy Coherence”, Caritas Internationalis suggests WHO to initiate discussions for the drafting and adoption of a binding instrument that requests Member States to adopt national laws addressing the blockade of generic drugs through civil, administrative and criminal sanctions
Monday, 10 September 2018

Intervention of Bernard Pècoul, MD, MPH, Executive Director, Drugs for Neglected Diseases initiative

Chair, distinguished colleagues,

DNDi welcomes the development of a roadmap to tackle access to and shortages of medicines. Today the consequences of lack of access to existing and new health tools are felt in all countries, at all levels of income, and across diseases areas, from insufficient R&D for neglected and emerging infectious diseases, AMR, and high prices of medicines, such as for Hepatitis C or oncology.

If this access crisis is to be resolved, the roadmap must include concrete deliverables in the short-, medium-, and long-term, that provide practical guidance and support to all the stakeholders involved.

Our experience over the last 15 years has shown that it is possible to work openly and collaboratively with a variety of partners to develop affordable and easy-to-use drugs provided there is a shared vision, clear definition of needs, target product profiles, careful coordination of partners, and policies to ensure sustainable, equitable access.

We would like to make the following proposals for some tangible deliverables:

1. Prioritization of R&D: priority setting based on public health needs, not commercial gain is crucial, The WHO has a key role in providing guidance through:
   - The reconvening of the Expert Committee on Health Research and Development to identify health R&D priorities. The WHO could then produce a list of missing essential medicines.
   - The formulation of a methodology for the prioritization of R&D needs, including through the use of TPPs.

2. Open and collaborative approaches to innovation can significantly speed up drug discovery, increase efficiency and reduce costs. The Roadmap should include:
   - A review and evaluation of existing models, and of best practices.
   - The development of a Code of Principles for Biomedical R&D, based on the practical implementation of the CEWG principles of affordability, effectiveness, efficiency and equity to provide guidance to all R&D actors.
   - The development of a pro-access legal terms repository, that promotes access to knowledge throughout the R&D process, and reflects the flexibilities provided for in the TRIPS Agreement.
   - Support to Member States to implement existing schemes which delink R&D costs from product prices and volume.
   - A specific commitment to help mobilize financial resources to ensure that plans can be turned into action.
3. Regulatory infrastructure
   • A review and identification of continued gaps in regulatory capacity, and harmonization of regional regulatory authorities, to continue to build capacity where needed.

4. Finally, there are two gaps in the implementation plan:
   • first, no mention is made of the importance of diagnostics, which are critical in facilitating access, and rational use, which is key to sustainable access;
   • second, the roadmap should include recognition of the specific needs of children, who are among the most neglected.

For our part, we will continue to contribute to the WHO efforts to achieve access for all people, everywhere.
Distinguished Chair, Esteemed Participants,

On behalf of the European Society for Medical Oncology (ESMO), I thank you for this opportunity to provide comments to the WHO Roadmap on Access to Medicines and Vaccines 2019-2023.

ESMO is the leading European professional organisation for medical oncology, with over 18,000 members from 150 countries. As medical oncologists, besides coordinating patient care, we administer cancer medicines, and perform clinical trials. With cancer as the second leading cause of death worldwide, we are key stakeholders in the discussion on access to medicines.

We welcome the Access Roadmap because cancer is both a communicable and a non-communicable disease that requires:

- Vaccines to prevent cancer-causing infections
- Access to anti-cancer medicines to provide effective treatment
- Access to opioids for cancer pain management

We would like to provide the following 5 comments to the Roadmap, focusing on inexpensive essential medicines:

1. In Activity 2 on fair pricing and financing policies, one deliverable is to encourage transparency and ensure fairer pricing. We propose that incentives for suppliers to enter and remain in nation markets should be considered, as recommended in the 2017 ESMO-Economist Intelligence Unit report on preventing and managing shortages of essential cancer medicines.

2. In Activity 4 on procurement and supply chain management, we propose inclusion of a recommendation that countries should use the WHO Model List of Essential Medicines to develop national essential medicines lists as recommended in the joint ESMO-Economist Intelligence Unit report. The medicines on the list should be prioritized for procurement and adequate reimbursement.

3. In Activity 5 on appropriate prescribing, dispensing and use of medicines, we would like to facilitate the deliverable to provide support for countries to regularly develop and revise treatment guidelines, by inviting WHO members states to consider that they can adopt or adapt the 75 ESMO Clinical Practice Guidelines that set the standard for quality cancer care and are used in countries around the world.
In the Results Framework Table on page 26, we propose that Target 1 include the availability of ‘quality’ essential medicines not only for primary health care, but also for secondary health care, otherwise it will exclude the treatment of all cancer patients. The cancer medicines we propose to include in the ‘core set of relevant essential medicines’ are 26 inexpensive essential cancer medicines, and 2 more expensive biosimilars, that are used in the treatment of 83% of adult cancers. These 28 medicines:

- Are all generics or biosimilars listed on the WHO Model List of Essential Medicines.
- Are included in the evidence-based ESMO Clinical Practice Guidelines because they have a high level of benefit for patient outcomes, either alone or in combination with innovative expensive medicines, and some can cure cancer patients.

5. In the Results Framework Table on page 26, we propose that Target 2 includes an increase in the availability of oral morphine from 25% to 80%, with an ideal target of 100%. This requires changes in national legislation to ensure the availability of opioids for legitimate medical and scientific use, and to protect against their diversion for use as narcotic drugs.

ESMO stands ready to collaborate with WHO on the topic of access to medicines, which is so vital to achieving universal health coverage and leaving no one behind. Thank you.
Table 1. List of 28 essential medicines on the WHO Model List of Essential Medicines used in the treatment of more than 83% of adult tumours

<table>
<thead>
<tr>
<th>Medicines on the WHO EML</th>
<th>Tumour Type</th>
<th>Percentage of Cancers Globocan 2012 (incidence)</th>
<th>ESMO Guideline</th>
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<tr>
<td>S-FU</td>
<td>Breast</td>
<td>12.0%</td>
<td>4th ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 4) - 2018</td>
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<tr>
<td>S-FU</td>
<td>Colorectal</td>
<td>10.0%</td>
<td>Rectal cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up (2017); ESMO consensus guidelines for the management of patients with metastatic colorectal cancer (2016)</td>
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<tr>
<td>S-FU</td>
<td>Oesophagus</td>
<td>3.2%</td>
<td>Oesophageal cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up (2016)</td>
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<tr>
<td>S-FU</td>
<td>Pancreas</td>
<td>2.4%</td>
<td>Cancer of the pancreas: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up (2015)</td>
</tr>
<tr>
<td>S-FU</td>
<td>Stomach</td>
<td>6.8%</td>
<td>Gastric cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up (2016)</td>
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<tr>
<td>Anastrozole</td>
<td>Breast</td>
<td>10.0% #</td>
<td>4th ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 4) - 2018</td>
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<td>Bisalutamide</td>
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<td>Cancer of the prostate: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up (2015); e-update ESMO (2017)</td>
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<tr>
<td>Bleomycin</td>
<td>Testis</td>
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<td>ESMO Consensus Conference on testicular germ cell cancer: diagnosis, treatment and follow-up (2018)</td>
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<td>Bleomycin</td>
<td>HL</td>
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<td>Hodgkin Lymphoma: ESMO Clinical Practice Guidelines (2018)</td>
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<td>Calcium Folinate</td>
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<td>Rectal cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up (2017); ESMO consensus guidelines for the management of patients with metastatic colorectal cancer (2016)</td>
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<td>Calcium Folinate</td>
<td>Oesophagus</td>
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<td>Oesophageal cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up (2016)</td>
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<td>Calcium Folinate</td>
<td>Pancreas</td>
<td>2.4%</td>
<td>Cancer of the pancreas: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up (2015)</td>
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<td>Calcium Folinate</td>
<td>Stomach</td>
<td>6.8%</td>
<td>Gastric cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up (2016)</td>
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<td>Carboplatin</td>
<td>Cervix Uteri</td>
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<td>Cervical cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up (2017)</td>
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<td>Carboplatin</td>
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<td>Carboplatin</td>
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<td>Cisplatin</td>
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<td>ESMO-ESGO-ESTRO Consensus Conference on Endometrial Cancer: diagnosis, treatment and follow-up (2016); e-update ESMO (2017)</td>
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<td>Paclitaxel</td>
<td>ovarian</td>
<td>1.7%</td>
<td></td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>Sarcoma</td>
<td>1.0%</td>
<td></td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>Testis</td>
<td>0.4%</td>
<td></td>
</tr>
<tr>
<td>Prednisone</td>
<td>NHL, HL</td>
<td>2.7%</td>
<td></td>
</tr>
<tr>
<td>Prednisone</td>
<td>Leukaemia</td>
<td>2.5%</td>
<td></td>
</tr>
<tr>
<td>Rituximab</td>
<td>NHL</td>
<td>2.7%</td>
<td></td>
</tr>
<tr>
<td>Tamoxifen</td>
<td>Breast</td>
<td>10.0% #</td>
<td></td>
</tr>
<tr>
<td>Trastuzumab</td>
<td>Breast</td>
<td>4.0% §</td>
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<tr>
<td>Vinblastine</td>
<td>HL</td>
<td>0.5%</td>
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<tr>
<td>Vincristine</td>
<td>NHL</td>
<td>2.7%</td>
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<tr>
<td>Vincristine</td>
<td>Sarcoma</td>
<td>1.0%</td>
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</tr>
<tr>
<td>Vincristine</td>
<td>Leukaemia</td>
<td>2.5%</td>
<td></td>
</tr>
<tr>
<td>Vinorelbine</td>
<td>Breast</td>
<td>12.0%</td>
<td></td>
</tr>
<tr>
<td>Vinorelbine</td>
<td>Lung</td>
<td>13.0%</td>
<td></td>
</tr>
</tbody>
</table>

The table represents a selection of 28 medications from the WHO Essential Medicines List (EML). These medicines are used in the curative (adjuvant, neoadjuvant, induction, pre- perioperative) and advanced settings of cancer treatment. **Legend**: * intended as relative incidence per tumour type compared to the global cancer burden. # considering 80-85% of breast cancer as hormone receptor positive. ° lip, oral cavity, oropharynx, larynx carcinoma. ^ intended as GIST, gastro-intestinal stromal tumour. § considering 25% of breast cancer as HER2- overexpressing. **Burkitt lymphoma. NHL is Non-Hodgkin lymphoma. HL is Hodgkin lymphoma. H&N is Head and neck tumours. CML is Chronic myeloid leukaemia. BTT is Biliary tract and Gallbladder cancer. Biological agents are indicated in **orange**, Hormonal agents are indicated in **blue**, Anastrozole, bicalutamide and leuprolaein represent compounds of a particular class (aromatase inhibitors, anti-androgen agents, LHRH agonists).
Figure 1. Global distribution of new cancer cases (Globocan, 2012).

N.B. ‘Other’ (17%) is intended as cancers excluded from treatment coverage when considering the selection of essential medications for 83% of tumours. BTT is Biliary tract and Gallbladder cancer. NHL is Non-Hodgkin lymphoma. HL is Hodgkin lymphoma. H&N is Head and neck tumours.

References
IAHPC thanks the Secretariat for inviting us to participate in the consultation and for the Draft Roadmap. We submitted our detailed analysis during the comment period and hope that it has been integrated into the next draft.

We support UNODCs comments about the importance of increasing access to internationally controlled essential medicines, in particular workforce training, and supply chain strengthening.

We believe that local, sustainable production at the regional level is a helpful approach for countries needing to improve access – the vast majority of low and middle income countries.

IAHPC urges the Secretariat to continue interfacing with NSAs such as who work with national and regional providers on the ground in order to maximize information and technical support for implementation of the roadmap in regard to this aspect of controlled medicines. IAHPC is always at your service to help with improving access to controlled medicines, as well as training and education of providers.

Sincerely,

Profesor Lukas Radbruch, MD
Chair

Roberto Wenk, MD
Past - Chair

Liliana De Lima, MHA
Executive Director

Katherine Pettus, PhD
Advocacy Officer
Many thanks for the invitation to the consultation meeting on Monday. The comments I made on behalf of ICN in summary were:

- ICN welcomes and supports the Roadmap for access and improving access to vaccines and medicines and this is also a key ICN priority given the central role that nurses play in medications administration, monitoring, surveillance, compliance and increasingly prescribing.
- In section 5 the surveillance, compliance and monitoring role that nurses and other health care professionals play could also be specifically recognised.
- It is because of the roles and responsibilities that healthcare professionals have right across the continuum of medicines management that we advocate for active engagement of health care professionals in governance arrangements. We propose that a reference to the involvement of clinical leaders in good governance in order to help bridge the policy/practice divide and this could be referenced in section 8.
- We welcome and support section 10 with its focus specifically on the health workforce. The scale of the projected health workforce shortage has recently been identified by the UN high level commission on health employment and economic growth as 18m by 2030 half of which are Nurses. We would like to see the scale of the shortage referenced in the document and the fact that this extends to health care professionals beyond Pharmacists.
- Section 10 also refers to interventions such as training that can increase capacity and access to medicines. Supporting healthcare professionals such as nurses to extend their scope of practice and removing barriers to nurse prescribing would assist greatly. Where new cadres are trained to support medicines management and administration the vital role that health professionals play in terms of providing support and supervision should be acknowledged as this is critical to ensuring safety.

I hope that’s helpful and any further queries do just let me know.

Best wishes,

Howard Catton
Director, Nursing, Policy & Programmes

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IFPMA High-Level Comments to the WHO Consultation on the Roadmap for access 2019–2023: Comprehensive support for access to medicines and vaccines

We appreciate the opportunity to provide additional information to complement the IFPMA statement on the WHO Roadmap, made in the WHO informal consultation of the 10 September 2018.

IFPMA represents global R&D-based pharmaceutical industry and welcomes the WHO’s ambitious 13th General Programme of Work (GPW), particularly around delivery of UHC. A broad range of policies are required to holistically address real barriers to access to medicines, particularly “domestic investment in coverage schemes that reduces out-of-pocket payments”, while simultaneously ensuring sustainability of future medical innovation.

WHO Strategy, Mandate & Coherence

It is important for the WHO Roadmap for “Access” to be connected, aligned, consistent and coherent with the broader WHO Strategic Priorities, as detailed in the GPW. Particularly, this Roadmap should fit in with this broader strategy, mandate and the individual work programmes on UHC and strengthening heath systems, addressing health emergencies, pandemic preparedness and other WHO norm setting activities that have a fundamental connection to medicine and vaccine access.

Sustainable Access through Effective Prioritization and Measurable Impact

A WHO Roadmap on access to medicines and vaccines can be useful if it facilitates a collective understanding of the key issues and catalyses actions that result in tangible benefit to patients worldwide. Creating this understanding of the wider context and key enablers for access - such as, effective health systems, sufficient and sustainable treatment financing, supply chain efficiencies, investment in the health workforce, suitable regulatory systems - is fundamental to achieving innovation and access to safe and effective diagnosis and treatment.

The Zero Draft identifies these issues but there needs to be a clear and coherent plan on how these objectives should be prioritized and delivered - with meaningful timelines and outcomes assessment. It must also be based on the guiding principle in the GPW and WHA document A71/12 “…though many activities contribute to improving access to medicines and vaccines, there is a need to prioritize and invest in those where WHO has an advantage compared with other organizations and that provide value for money, are fit for purpose, and lead to achievable and sustainable improvements”. Once such an ‘impact framework’ is defined there can be a sound basis for further substantive discussion.

The Importance of Partnerships

IFPMA continues to underscore the value of partnership - a vision strongly shared by Dr. Tedros as evidenced in his speech in the 2018 WHA: “By leveraging the experience, the skills, resources and networks of our partners, our impact can be exponentially larger than if we were acting alone…To truly fulfil our mandate, we
must make our partnerships even deeper and stronger”. Partnerships are a fundamental component for access to medicines and vaccines, but unfortunately, an integrated vision of collaboration is largely absent from the Roadmap.

In line with this, engagement with the private sector is also largely missing from the current version of the Roadmap, despite the GWP specifically detailing the critical role and importance of the private sector in achieving UHC including through innovation and investment. IFPMA and its members remain fully committed to achieve the goals as defined in the GWP, which draw upon and pursue health-related SGDs and we look forward playing an active role with WHO and other stakeholders, both in terms and innovation and access. IFPMA members are currently engaged in over 900 health partnerships, many of which focus on health system strengthening, and hence much experience can be shared.

Innovation, R&D & IP

Continued innovation is vital for global health. Intellectual Property remains the key incentive for health R&D and is an enabler for cooperation and collaboration between small and large companies, academia and public research institutes. Effective intellectual property systems stimulate investment, innovation and economic growth for the benefit of society as a whole. It sustains a business model which also enables further investment by industry in other aspects of the pharmaceutical and vaccines value chains, including but not limited to strengthening supply chains, maintaining manufacturing capacity and quality, and training healthcare workers.

Recent evidence illustrates that the current IP-based model is successfully incentivising R&D, and in particular R&D by the pharmaceutical industry, that is necessary to deliver products to address unmet needs and thus improve access to medicines and vaccines. The success of the current R&D model needs to be acknowledged in the Roadmap.

IFPMA welcomes the Global Observatory on health research and development that aims to set up R&D priorities. This should be coupled with the development R&D incentives for unmet medical need and hence should also be reflected in Roadmap.

Industry is committed to developing R&D and financing models supporting both innovation and access. The challenges encountered in certain diseases areas where there can be market inefficiencies (such as AMR, NTDs and pandemic preparedness) are often very different from one another (mechanism of resistance, limited ability to pay, unpredictability of emerging pathogens). Therefore, there is no “one-size-fits all” solution. It is important that any new R&D and/or financing model responds to identified and prioritized R&D gaps, and is mutually complimentary of existing models, including market-based solutions.

While undertaking technical training, it is important that WHO remains within its mandate and areas of expertise and refrain from interpreting key treaties or decisions by other international organizations. IP law is complex and effective implementation needs to be tailored to the individual country based on a long-term coherent view in order to maximize benefit for national prosperity. Depending on the economy, a range of
flexibilities, including strengthening IP rights to facilitate access to new therapies for all patients in particular markets, should be considered. WIPO (often in cooperation with WTO) is highly active in providing education around the effective implementation of IP, and WHO should tap into their expertise by including WIPO officials in training activities. IFPMA also stands ready to lend its expertise in R&D, financing models, and IP to support the collaborative work ongoing in this area.

WHO must not use the recommendations of the UN High Level Panel Report on Access to Medicines as a basis for further action. The report was not endorsed by Member States, as it lacked a robust empirical evidence base, had an overly narrow mandate, failed to consider the wider access landscape, and therefore does not serve as a basis for long-term and sustainable solutions.

**Fair Pricing, Financing Policies & Transparency**

Patient access and affordability is most effectively addressed through improved financing and reimbursement policies to reduce out-of-pocket expense and should be prioritized. Pricing policies, *per se*, do not effectively address affordability and should be viewed within this broader context of policies for sustainable access for patients. Critical to ensuring affordability are policies such as sufficient financing by the public sector and insurance coverage by public and private sectors. More generally, deliverables should be prioritized based on their assessed effectiveness for achieving better access and health outcomes (e.g. including new patient relevant quality of life endpoints) across the healthcare system.

As proposed in the Director General’s report, the definition of “fair pricing” should reflect “sufficient market incentive for industry to invest in innovation and the production of medicines” in addition to considerations of affordability. Furthermore, “fairness implies positive incentives/benefits for all stakeholders” thus pricing policies should be based on the therapeutic and societal value of a medicine, and not on the cost-of-production which do not incentivize benefits to patients or the healthcare system.

IFPMA supports more transparent, inclusive processes to encourage better policies. However, increased transparency in “prices” (e.g., disclosure of confidential discounts) would likely lead to lower access to medicines in countries that today get discounts/rebates due to their lower income levels/ability to pay. Ensuring the confidentiality of net prices allow governments to get an optimal price arrangement tailored to the country’s needs.

**Improving Health Systems Performance**

The attention provided to good procurement and supply chain management in the roadmap is welcome and timely as suboptimal procurement policies and supply chain management remains a major barrier to access to medicines in many countries. IFPMA supports prioritizing procurement and supply chain management processes that ensure high quality and sustainable supply of medicines and vaccines to the community.

The Roadmap states that “an estimated half of all medicines in the world are inappropriately prescribed, dispensed or sold” – this is a concerning statistic which demonstrates a priority area for greater efforts and
action. If addressed, this could have a substantial impact on improving health outcomes. This is an area which would require a multi-stakeholder approach between governments, payers, health care professionals, pharmaceutical manufacturers, distributors, wholesalers, retailers, and national regulatory and enforcement agencies.

IFPMA strongly supports WHO efforts around patient adherence, such as the new WHO handbook on digital technologies to support TB treatment adherence, which is critical to ensuring an effective access to medicines strategy. However, the Roadmap does not appear to have a specific plan for patient adherence. Solving the patient adherence problem will require a multi-stakeholder approach between governments, payers, health care professionals, pharmaceutical companies and patient groups. The roadmap should provide a strategy of how member states and other stakeholders can work together to eliminate the biggest contributor to health system waste, cost and ineffectiveness today and ensure patients enjoy the benefits of the medicines they receive.

An increasing volume of information and data is being generated with the digitalisation of healthcare systems and services, and the increasing use of new devices and technologies. The advancement of data collection, data science and analytics offers the potential to profoundly change our healthcare systems by achieving efficiency gains and minimization of waste through effective outcomes/impact measurement. The Roadmap needs to include these elements as a fundamental prerequisite for impact assessment – demonstrating improvement to health outcomes and wellbeing, as defined in the GPW and the WHA 71.1 resolution on Digital Health.

IFPMA agrees that a shortage in health workforce capacity is a major access barrier. With the global current shortage of over 7 million health workers expected to rise to 13 million by 2035, this is a pressing problem. The pharmaceutical industry has substantial experience in partnering with and training skilled health care workers.

**Regulatory Systems Strengthening**

IFPMA supports WHO efforts to ensure robust and science-based regulatory systems are developed and implemented more broadly. It is important to ensure that the resulting regulatory systems are harmonized or converged regionally; designed to reduce complexity; and include elements for reliance & work-sharing across NRAs.

For more effective outcomes, the Roadmap should link with the existing ICDRA recommendations and support the WHO Prequalification Programme for its stated purpose of assuring the quality of medicines and vaccines supplied through UN agencies to LMICs. Further clarification on the evolution of PQ as depicted in the draft Roadmap is required.
Emergency preparedness

The 13th General Program of Work took stock of the high-impact of health emergencies and prioritized it as one of the three interconnected strategic goals. A public health emergency requires decision-making in a context that is different to “business as usual”. Being prepared with the necessary plans and tools is just as essential for countries as for other actors like the biopharma industry in an emergency situation.

The biopharma industry is an essential player in epidemic and pandemic preparedness but the uncertainties around the pathogen, the timing of outbreaks, patient cohort for investigational purposes, and limited market serve as a disincentive for research and development.

IFPMA and its members remain fully committed to play an active role is contributing to pandemic preparedness and response in partnership with WHO, national authorities, and other key health actors. IFPMA believes that there are five key areas that need to be addressed to foster research, development, and rapid deployment:

- **Funding** - Robust models that ensure adequate funding and sustainable solutions to vaccine, medicines and diagnostic research and development, and access are needed.
- **Regulatory** – Clarity in use of specialized regulatory pathways, agreed upon in advance, which recognize the unique challenges of developing a vaccine or a treatment for use in an emergency setting in the absence of an outbreak, would be a significant enabler of the field.
- **Indemnification** - Mechanisms are needed to indemnify companies for use of a vaccine pre-license in an emergency setting, to protect the developer for any liability claim and to compensate individuals if harm is done. It is encouraging that WHO is leading an effort with support from CEPI, WEF, Harvard Global Health Institute to establish an indemnification protection.
- **Optimize use of existing Emerging Infectious Diseases (EIDs) vaccines** – Optimized use of underused and under-valued vaccine tools for existing EIDs should be pursued. Vaccine-preventable disease outbreaks are ultimately best combatted through strong and resilient national routine immunization through the life span and reaching the threshold rates of coverage needed.
- **Interconnectivity** – We encourage interconnectedness and transparency across how emergencies preparedness mechanisms (e.g., R&D blueprint, CEPI, Gavi VIS) relate to one another concretely.

More specifically for pandemic influenza vaccines - A supply security roadmap is needed to solve critical roadblocks for sustainable optimal manufacturing capacity and timely development, production, deployment of pandemic influenza and emerging infectious diseases (EID) vaccines, including:

- **Switch** - Development of a set of IHR rules of engagement with manufacturers to ensure vaccine response at the time an influenza pandemic is declared and switching from seasonal influenza vaccine production to pandemic vaccine production (“Switch”)
- **Nagoya Protocol** - Provide as appropriate, upon request, in collaboration with other competent international organizations, technical support to ensure the health-sensitive implementation of
CBD/the Nagoya protocol in relation to using biological material in the development of vaccines or treatments, especially during a public health emergency

- **Deployment** - Development or improvement of processes / systems that facilitate timely access to quality-assured vaccine and antivirals (from both demand and supply side).

**Good Governance and Engagement with Private Sector**

IFPMA welcomes the WHO’s strong focus on the need for effective governance as a critical aspect if countries are to move towards UHC, as noted in the GPW. IFPMA welcomes WHO’s support for policy dialogue between government and the private sector in countries working to introduce and build universal health coverage. Recognizing these exchanges and partnership as a pillar of sustainable solutions for improved health outcomes.

IFPMA looks forward to continuing, constructive and evidence-based discussions on the Access to Medicines Roadmap, which will add value by creating greater clarity and focus by the WHO in its important effort to increase access to medicines and vaccines over the next 5 years for the benefit of patients worldwide.
ISN welcomes the draft roadmap on access to medicines and vaccines 2019-2023 and the opportunity to participate in this consultation.

One in ten adults worldwide has chronic kidney disease, many of those affected are unaware of this given lack of awareness and access to diagnosis. Major risk factors include diabetes and hypertension. CKD DALYs and deaths have increased by 24% and 32% respectively over the past decade. CKD is a major risk factor for heart disease and cardiac death and is a major complication of other preventable and treatable conditions including HIV and hepatitis. The costs of dialysis and transplantation consume 2–3% of the annual health-care budget in high-income countries, even though this represents under 0.03% of the total population countries. The economic burden from milder forms of CKD is more than twice the total cost of treated ESKD. Access to effective and sustainable kidney care is highly inequitable across the world.

Care of NCDs like kidney disease requires reliable access to affordable medication of good quality.

Patients with kidney disease are highly vulnerable under when UHC is not in place because:

- kidney disease is often asymptomatic until late stages because of lack of access to basic diagnostics
- kidney disease is preventable with simple public health strategies and access to essential medicines, but for example one month’s supply of essential medications for chronic kidney disease can cost up to 18 days’ wages when paid for out-of-pocket (OOP) in low-income countries despite these medicine being included in the WHO Best Buy’s and Essential Medicines lists.
- patients must take medicine every day to control risk factors effectively and prevent progression of disease and its complications

Kidney disease is preventable and controllable by simple and integrated treatment of hypertension, cardiovascular disease and diabetes, as outlined in the WHO Hearts Packages for example.

In terms of access to essential medicines is clear that:

- Lack of adequate access and high cost of essential NCD medicines and technologies in many countries increases morbidity and mortality and cost of care that forces people and families into poverty due to disability and out-of-pocket expenses
- Governments are responsible for ensuring equitable reliable access to efficacious, safe and quality assured NCD essential medicines and technologies
- All countries, no matter how poor, can implement effective strategies and approaches that promote access to essential medicines for NCDs

We call for:

- Effective policies and strategies to promote equitable access at all levels of the health system, including rational selection, evidence-based clinical practice guidelines, and policies to promote generic products
• Fair and transparent pricing and reliable quality of medication which is crucial to sustain affordable and effective treatments
• Policies should promote integrated care to rationalize medication access and use
• Universal access to essential diagnostics which is key for early diagnosis and optimal management of NCDs
• Building capacity amongst health workers and the health system to manage NCDs which is a cornerstone of addressing the increasing burden of these conditions
• Involve expert patients in developing country NCD strategies
Intervention on the WHO roadmap on access to medicines & vaccines 2019-2023

MEETING WITH WHO AND THE STAKEHOLDERS

Speaker: Ms Zuzana Kusynová, from the International Pharmaceutical Federation (FIP)

Honourable Chair, Distinguished Delegates,

Thank you for the opportunity to speak on behalf of the International Pharmaceutical Federation (FIP), the global organisation representing over four million pharmacists worldwide.

Under Figure 2 describing the order of the Activities to undertake, we suggest the neglected areas listed as Activity 5 (“appropriate prescribing, dispensing and use”) and Activity 9 (collecting, monitoring and using key data) need immediate attention and deserve to be prioritised.

Under Activity 2, it should be acknowledged that the environment has a substantial impact on the health of the population. Environmental impact regulation strengthening and environmentally sustainable financial models should be addressed.

In Activity number 4, we encourage adding an additional goal related to supporting countries for efficient procurement and supply chain management, namely “to assist countries with processes and procedures which include community pharmacies as part of the supply chain process, due to local pharmacies’ more likely refrigeration capabilities in both urban and rural communities.”

We also encourage WHO to strengthen language regarding the essential nature of prevention strategies, especially vaccines. Specifically, in Activity 5, we would request that WHO recommend that countries adopt the recommendations outlined by FIP’s global report assessing the status of pharmacy-based immunisations globally. This report determined that an additional 655 million people globally just in countries where pharmacists are authorised to administer vaccines may be immunised if access to care barriers were removed.¹

Finally, as highlighted by the Report, the development, production, procurement, distribution and appropriate use of medicines, as well as the supportive functions of regulation, all require a competent, equitably distributed pharmaceutical workforce. FIP can continue providing technical expertise in this area.

Thank you for your attention.

(300 words)

Universal health coverage should serve as the overarching theme that underpins the vision for the WHO’s roadmap on access to medicines and vaccines.

The WHO’s draft roadmap on access to medicines and vaccines acknowledges that “some of the greatest challenges to achieving UHC stem from persistent barriers to accessing health services and to accessing affordable and quality-assured health products.” With a view of bridging these barriers, in early August 2018, 16 groups including KEI, HAI, and Oxfam wrote to the Director-General framing our vision for the WHO roadmap. I will present some key points from our joint letter (/https://www.keionline.org/wp-content/uploads/2018/08/Letter-to-Dr.-Tedros-on-the-WHO-Roadmap-on-Access-to-Medicines-and-Vaccines-2019-2023.pdf)

A roadmap with robust language on transparency would reinforce the WHO’s authority to explore norms and mechanisms to enhance the transparency of R&D costs, prices and revenues.

The lack of transparency currently impedes or delays many of the policies that would otherwise be available as policy measures to reduce the price of medicines and vaccines. In particular, without reliable information regarding the cost of R&D, the cost and results of clinical trials, private sector expenditure on the development of products, expenditures on marketing and revenues, it is hard to design alternative policy measures to reduce the current prices on excessive pricing, we request the WHO secretariat to develop a best practices manual on the subject of the control of and remedies for excessive pricing by December 2020. The manual should compile expertise on various legal and technical aspects of excessive pricing, including the context specific methodologies employed by Member States for determining if prices are excessive, and the mechanisms to remedy and control pricing abuses.

With respect to the overarching theme of achieving universal health coverage (UHC), access will always be constrained and unequal without the delinkage of R&D costs from the prices of drugs, vaccines and other health technologies.
As countries wrestle with affordability and financial sustainability issues, they can seek technical assistance from the WHO or other entities in order to use lawful pathways to ensure treatments are affordable and widely available — including through the granting of compulsory licenses and/or through the use of competition law or other means to remedy excessive prices.

Finally, in multilateral settings such as the high-level meetings of the United General Assembly on non-communicable diseases and tuberculosis, WHO should be more vocal in pushing a public health agenda where UHC depends on timely and affordable access to health technologies by, among other means, making use of TRIPS flexibilities and other public health safeguards.
Dear WHO-EMP team

Please find here below the statement of Medicines for Europe provided this morning, in writing:

“Medicines for Europe thanks WHO for inviting the NSAs to this informal discussion and congratulates the WHO for the crucial work on access so far. WHO will now start a pilot Pre-Qualification (PQ) procedure for biotherapeutics, including biosimilar medicines with the aim to increase access to essential biological products. However for the time being, only the Prequalification of Medicines programme related to generic medicines is mentioned in the zero draft of the Roadmap on Access to Medicines and Vaccines. We invite WHO to revise the road map and include also the PQ procedure for biotherapeutics, including biosimilar medicines. Thank you.”

Best regards,
Suzette

Suzette Kox
Senior Director International - Biosimilar Medicines Group

MPP Statement

The Medicines Patent Pool (MPP) welcomes the opportunity to provide inputs to the Draft Roadmap on access to medicines and vaccines and supports the idea of a comprehensive roadmap with clear goals, activities and timelines.

We note that one of the deliverables considered as potentially having significant impact on access to safe, effective and affordable medicines is supporting the expansion of the MPP to essential medicines under patent. This expansion is in fact already in process.

The MPP was established by Unitaid as a mechanism to promote innovation and access to medicines through public health-oriented licensing. It is a concrete example in moving towards Universal Health Coverage by enabling over 100 countries get faster access to the latest treatments at affordable prices and in suitable formulations. Currently, the MPP holds licenses on 16 HIV, HCV or TB medicines with 9 patent holders. 25 partner generic companies develop, register, manufacture and supply WHO-recommended products in LMICs.

With the support of the Swiss Development and Cooperation Agency, the MPP recently undertook a feasibility study to assess the potential for the MPP’s patent pooling model to be applied to patented essential medicines in other therapeutic areas. The study, along with the MPP’s new 5-year strategy, was launched last May, with the participation of the WHO, Unitaid and the governments of India, South Africa and Switzerland. We were encouraged by the overwhelming support for expansion received from member states during the recent discussions at the EB and WHA. As a next step, the MPP, in cooperation with the WHO is beginning to work on the prioritization of candidate products for licensing. Discussions with member states and other stakeholders will be important to understand access gaps.

As we implement the expansion, we will need to engage with other “deliverables” mentioned in the roadmap. For example, we will need to explore appropriate mechanisms for quality assurance for products that are not currently in the WHO Prequalification list. This may be facilitated by the WHO’s support for strengthening national regulatory capacity or through the development of new routes for WHO Prequalification or expansion of the Prequalification Program.

MPP is also working closely with WHO to facilitate transparency around the patent status of essential medicines in low and middle-income countries which is another of the priority actions of the roadmap. Our Patents & Licenses database (known as MedsPaL) is a free platform that provides patent, licensing and regulatory data exclusivity information in over 100 LMICs. This has been possible thanks to collaboration with national patent authorities of many countries.

Finally, we also support the development of best practices for licensing of publicly-funded R&D results, which can contribute to ensuring that licensing takes into account innovation and access needs in LMICs. We would be happy to share our experience with public health oriented provisions as this work progresses.

Thank you Chair
Roadmap for access 2019 – 2023 ‘Comprehensive support for access to medicines and vaccines’
Statement by Médecins Sans Frontières International. Speaker: Katy Athersuch

Médecins Sans Frontières welcomes the decision of the Seventy-first World Health Assembly to elaborate a roadmap outlining the programming of WHO’s work on access to medicines and vaccines. As an international medical humanitarian organisation, our teams see the devastating impact that widespread lack of access to essential health technologies has on people’s lives. Inadequate access to affordable health technologies and the failures of the global research and development (R&D) system are crises of international concern that touch on our operations every day. With this experience in mind and having reviewed the zero draft, we would like to highlight the following points:

1. In line with commitments in the Global Strategy and Plan Of Action on Public Health and Intellectual Property (GSPOA) and previous resolutions, we urge WHO to include a deliverable on the provision of technical assistance and capacity building to countries to implement health needs-driven R&D that is evidence based and guided by the core principles of affordability, effectiveness, efficiency, equity and the principle of delinkage.

2. We urge WHO to fix the Roadmap’s definition of fair pricing. It is not about finding an algorithm that will mechanically give a fair price for each medicine. It is about the conditions of the price negotiations between public health and commercial interests in order to achieve a balance. It requires management of exclusive rights to avoid undue or abusive monopolies, and far more transparency and disclosure on public and private investments in a product’s development from basic research through to the delivery to people. This also requires disclosure on the real clinical benefits of the products for people in comparison to existing therapeutic options, and of course about the price agreed on itself. We urge WHO to include specific deliverables on transparency and disclosure within the work on fair pricing and under the ‘good governance’ pillar.

3. Regarding the application and management of intellectual property from a public health perspective, we are particularly concerned that the Roadmap weakens existing mandates given to WHO through the GSPOA. The Roadmap’s deliverables should reflect the GSPOA, and the qualifications that have been introduced to weaken this mandate should be removed.

4. In the area of supply chain, we urge WHO to provide technical assistance to donor-transitioning countries for the procurement of quality-assured medicines in national programmes. In its work on ‘supporting collaborative approaches’, WHO should reject the vertical supply chain model driven by pharmaceutical corporations.

5. We welcome the emphasis the Roadmap places on quality and safety of medicines, support to global procurement through the WHO Prequalification Programme (PQP), and strengthening national medicines regulatory systems to ensure and monitor the quality and safety of medicines in their countries. We urge WHO to provide the additional, sustained resources required to support and strengthen the quality assurance of medicines, vaccines and diagnostics that meet public health needs – specifically through additional investment in the WHO PQP.

6. Finally, accountability is key. The Roadmap must include more specific deliverables and timelines so that success can be measured.

We look forward to seeing a bold roadmap that ensures patient-centred innovation – and access to medicines, vaccines and diagnostics for all people.
MSF Access Campaign Comments on the WHO Roadmap for access 2019 – 2023: Comprehensive support for access to medicines and vaccines ‘Zero Draft’

In May 2018, the World Health Assembly adopted decision 71(8) requesting you ‘to elaborate a roadmap report, in consultation with Member States, outlining the programming of WHO’s work on access to medicines and vaccines, including activities, actions and deliverables for the period 2019–2023.’¹ We are writing to provide our initial feedback on the Secretariat’s zero draft document of the Roadmap on Access to Medicines and Vaccines 2019-2023, created for consultation with Member State in response to this decision.

Médecins sans Frontières (MSF) is an international medical humanitarian organisation providing medical assistance to people affected by armed conflict, epidemics, natural disasters and exclusion from healthcare in more than 60 countries. We bear witness to the devastating impact that widespread lack of access to affordable and suitable medicines, vaccines and diagnostics has on peoples’ lives. With this experience in mind, we raise the following key points we believe will help strengthen the Roadmap.

1. Building Local Capacity for Research and Development

WHO has been requested to build and strengthen local capacity for research and development (R&D), including through the provision of technical assistance, in a number of WHA resolutions.¹ Element 2 of the GSPOA, ‘Promoting research and development’ also strongly highlights the importance of building local capacity for research. However in its current form, the draft Roadmap does not cover this mandate in sufficient detail. It includes a ‘mid-term’ commitment to support policy options for designing R&D models that promote innovation and access in line with the CEWG principles, and a ‘long-term’ commitment to developing sustainable financing mechanisms models for R&D where the market does not attract sufficient investments. Both these deliverables are important, but they are insufficient. WHO should also provide technical assistance and build local capacity for the implementation of health needs-driven R&D in line with the CEWG principles.

MSF urges WHO to actively pursue a comprehensive health needs-driven R&D agenda that fosters sustainable innovation and access to medicines, including promoting R&D approaches that will end the reliance on high prices and monopolies to finance R&D and that address innovation and access concerns for all diseases (types I, II and III) and health technologies for all countries.

In line with commitments in the GSPOA and previous resolutions: include a deliverable on the provision of technical assistance and capacity building to implement health needs-driven R&D in line with the CEWG principles. This falls under the first activity pillar: ‘Research and development for medicines and vaccines that meet public health needs’.

2. **Fair Pricing and Financing Policies**

The Roadmap sets out important work in the area of fair pricing and financing policies, particularly in relation to supporting processes for selection and health technology assessment and implementation in countries; and the work to reduce out of pocket payments including the adoption of generics and biosimilar selection, procurement and use. However the definition of a ‘fair price’ provided in the document is problematic and should imperatively be revised and there is an insufficient focus on measures to increase transparency.

‘Fair pricing’ should be considered a dynamic concept applying to the negotiations taking place with the pharmaceutical industry with the objective of reaching a balanced and acceptable outcome for society – that is affordable and reasonable prices. It is only possible to reach a ‘fair price’ if fair negotiating conditions are established. This includes prioritizing efforts to increase transparency on all aspects of the research, development, production and marketing processes of medicines as well as preventing undue or abusive monopolies that put the public authorities in a weak negotiating position, delay price lowering-competition and keep prices high – through unwarranted patents, evergreening, data exclusivity and trade secrets. The limitation of all unnecessary monopoly situations should be a guiding principle of public policies in order to achieve fair pricing.

The widespread secrecy related to various aspects of the R&D, manufacturing and marketing processes provide fertile ground for unchecked high medicine prices. Transparency is needed throughout the biomedical R&D chain; from the initial step of basic research to the delivery of medicines to patients. This is necessary so that public authorities negotiating with pharmaceutical companies have the data they need to negotiate with the private sector, and an informed vision about the real investments made by public and private sectors.

In its current form, the Roadmap only contains one deliverable on transparency in the activity area of ‘fair pricing and financing policies’, and that is to promote global and regional collaboration to increase price transparency and to facilitate dialogue between public payers, government decision makers and industry. While such measures are welcome, promoting fair pricing will require a more proactive role for WHO in promoting transparency and will need to be far more comprehensive than simply focusing on end product prices.

- Under the second activity area of ‘Fair pricing and financing policies’, WHO should:
  - Remove the simplistic definition of ‘fair pricing’
  - Expand the work of WHO on transparency throughout the lifecycle of medicines from research, development to manufacturing and marketing.
3. **Strengthening the Public Health Perspective in National Intellectual Property Systems**

   **Global Patent Databases**

Element 5.1.e of the GSPOA provides a clear mandate for WHO to, ‘strengthen education and training in the application and management of intellectual property from a public health perspective, taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights.’ However, the draft Roadmap introduces several caveats to this work which serve to unduly diminish this mandate. Rather than establishing this commitment as a clear deliverable, WHO waters this down claiming it will, ‘provide as appropriate, upon request, in collaboration with other competent international organizations, technical support, including, to policy processes to countries that intend to make use of the provisions contained in the Agreement on TRIPS, including the flexibilities recognized by the Doha Declaration...’

It is well acknowledged that developing countries come under significant pressure when seeking to make use of the public health safeguards in the TRIPS agreement. Given this, and in light of the clear mandate WHO has through the GSPOA; MSF strongly urges WHO to remove all additional qualifications to this work. We urge WHO instead to proactively assess the needed resources to implement training and support for countries in order that they can apply and manage intellectual property from a public health perspective, and further to take up the recommendation in the UN HLP report for WHO to strengthen the capacity of patent examiners to apply public health sensitive standards.

Further, MSF urges WHO to include a clear deliverable in the Roadmap reflecting the GSPOA mandate to WHO to develop global databases containing public information on the administrative status of health-related patents. Currently the draft roadmap contains a commitment to ongoing work to facilitate the assessment of the patent status of essential medical products at national and regional level in collaboration with competent partners, but does not outline plans to develop global databases for health-related patents that permit both to establish a clear correlation between patents and health products and the level of constraint patents exert on generic production according to patent quality.

- Under the third activity area, ‘Application and management of intellectual property to contribute to innovation and promote public health’:
  - Change the deliverable on the provision of technical support and capacity building to reflect the commitment of the GSPOA, ‘Provide education and training in the application and management of intellectual property from a public health perspective, taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the Agreement on Trade-Related Aspects of Intellectual Property Rights.’
  - Include a clear deliverable reflecting the GSPOA mandate to WHO to develop global databases containing public information on the administrative status of health-related patents.
Include a deliverable reflecting the UNHLP recommendation for WHO to strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability taking into account public health needs.

4. **Procurement and Supply Chain Management**

MSF welcomes the acknowledgement in the Roadmap of the critical challenges facing countries transitioning from donor support for specific vertical programs. Countries’ national procurement systems may not have the negotiating power, transparency, forecasting, or the legislative and regulatory policies in place which are necessary to ensure that quality, supply and price don’t suffer as a result of the transition.

While MSF also welcomes the Roadmap’s action on collaboration and support in procurement and supply chain management, such partnerships must be transparent, balanced and strategic. The pharmaceutical industry, for example, has recently driven discussions at WHO on the integration of national Supply Chains, while at the same time launching their own treatment-specific, vertical “access programmes” in various LMICs globally.

- MSF urges WHO to give technical assistance to transitioning countries for the procurement of quality-assured medicines for their national programmes.

- When “supporting collaborative approaches for strategic procurement”, WHO should ensure its independence from industry.

5. **Regulatory systems to ensure quality, safety and efficacy of medicines and vaccines**

MSF welcomes the emphasis that the Roadmap places on quality and safety of medicines, support to global procurement through the WHO Prequalification Programme (PQP), and strengthening national medicines regulatory systems.

- Additional, sustained investment is needed to allow the PQP to (i) assess more essential health products, (ii) improve the efficiency of product registration through regulatory reliance initiatives (including the expansion of the WHO Collaborative Registration Procedures) and regional regulatory convergence initiatives, and (iii) support its efforts to strengthen pharmacovigilance and postmarket surveillance.

6. **Strengthening Transparency Tools in Good Governance**

Under the eighth activity area on ‘Good governance’ WHO commits to ‘develop and maintain tools and platforms for facilitating transparency and accountability regarding access to essential health products.’ This is welcome especially given the important work WHO have led in the area of transparency including establishing the Vaccine Product, Price, Procurement (V3P) Project, which promotes transparency on vaccines prices worldwide; and the recently launched International
Clinical Trials Registry Platform (ICTRP), which aims to improve transparency in clinical trials – a critical component of R&D.

- These initiatives should be strengthened and expanded in line with recommendations of the UN HLP which further calls on WHO to establish an accessible international database of prices of patented and generic medicines and biosimilars.⁷
- The Roadmap should be more explicit as to which specific tools and platforms it will develop and maintain. The above mentioned tools will require sustained investment to ensure they continue to be updated and useful.

7. The importance of comprehensively including work on diagnostics within the Roadmap

MSF’s work on access to medicines covers drugs, diagnostics and vaccines. Currently the Roadmap focuses on vaccines and drugs, and it is unclear how comprehensively the Roadmap covers the work currently being undertaken and planned in the area of improving access to diagnostics. We note that diagnostics and ‘other health technologies’ are referred to at various points in the narrative and deliverables of the Roadmap, but it would be worth explicitly mentioning work on diagnostics across the board.

8. Accountability, Timelines and Target Indicators

The draft roadmap contains no commitment to the production of technical reports or progress reports detailed in WHA resolutions. These reports, which are key deliverables for the WHO and form a core component of monitoring and evaluation mechanisms, should be outlined in the roadmap.⁶

The draft roadmap establishes timelines for each of the deliverables in its ten strategic areas, categorising these as ‘ongoing’, ‘mid-term’ or ‘long-term’. While ‘ongoing’ is a useful designation for certain continuous activities; ‘mid-term’ and ‘long-term’ are unspecific and risk creating a document that does not serve to hold the WHO accountable to the work it is mandated by Member States to undertake. It is worth noting that the GSPOA, agreed in 2008 and 2009 by all Member States, sought to provide a ‘medium-term’ framework and yet many of the elements have not yet been fulfilled. We therefore urge WHO to include specific timelines for the completion of the outlined deliverables.

The draft roadmap sets out five key targets and indicators for assessing success. This list is clearly non-exhaustive, and omits a number of targets established in WHA resolutions. Omitted targets include those relating to the elimination and eradication of malaria, poliomyelitis, measles, rubella and neonatal tetanus. Targets relating to vaccine coverage, measured by coverage for diphtheria-tetanus-pertussis-containing vaccines are also omitted.

Furthermore, the roadmap does not include the targets laid out in the SDG framework. SDG target 3b stresses the importance of supporting R&D for diseases primarily affecting developing countries, the importance of access to affordable medicines and vaccines in accordance with the Doha Declaration on the TRIPS Agreement, and the need to provide access to medicines for all.⁸ The two indicators for measuring the achievement of this target are the proportion of the population with access to affordable medicines and vaccines on a sustainable basis, and the total net official development assistance to medical research and basic health sectors. The roadmap presented by WHO should
outline the ways in which target 3b will be achieved and integrate SDG indicators as a measure of success.

1 In WHA resolution 61.15, ‘Global immunization strategy’, WHO is mandated ‘to take measures, as appropriate, to assist developing countries to establish and strengthen their capacity for vaccine research, development and regulation, for the purpose of improving the output of vaccine production with the aim of increasing the supply of affordable vaccines of assured quality.’

In WHA resolution 69.21, ‘Addressing the burden of mycetoma’, WHO is mandated ‘through the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, to support the strengthening of research capacity in order to meet the need for better diagnostics, treatments and preventive tools for mycetoma.’

In WHA resolution 70.14, ‘Strengthening immunisation to achieve the goals of the global vaccine action plan’, WHO is mandated ‘to continue to strengthen the WHO prequalification programme and provide technical assistance to support developing countries in capacity building for research and development, technology transfer, and other upstream to downstream vaccine development and manufacturing strategies that foster proper competition for a healthy vaccine market.’

ii UN HLP recommendation to WHO:
2.6.1 (a)(ii) These multilateral organizations [UNCTAD, UNDP, WHO, WIPO, WTO] should strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability taking into account public health needs.

iii The GSPOA mandates WHO to:

‘facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases that contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents.’ (GSPOA, element 5.1.c)

iv UN HLP recommendation to WHO:

‘4.3.4 (b) Building on the Global Price Reporting Mechanism (GPRM), V3P and others, WHO should establish and maintain an accessible international database of prices of patented and generic medicines and biosimilars in the private and public sectors of all countries where they are registered.’

v for example under the first activity area, ‘Research and development for medicines and vaccines that meet public health needs’ there is a deliverable on analysing and publishing ‘a list of prioritized research and development needs... [including] in-vitro diagnostics’..

vi For example, in WHA resolution 70.12, ‘Cancer prevention and control in the context of an integrated approach’, WHO is mandated ‘to prepare a comprehensive technical report to the Executive Board at its 144th session that examines pricing approaches, including transparency, and their impact on the availability and affordability of medicines for the prevention and treatment of cancer, including any evidence of the benefits or unintended negative consequences, as well as incentives for investment in research and development on cancer and in innovation of these measures, as well as the relationship between inputs throughout the value chain and price setting, financing gaps for research and development on cancer, and options that might enhance the affordability and accessibility of these medicines.’

vii Sustainable Development Goals Target 3b:
‘Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.’
OXFAM’ COMMENTS ON
THE WHO ROADMAP FOR ACCESS 2019-2023
COMPREHENSIVE SUPPORT FOR ACCESS TO MEDICINES AND VACCINES

The roadmap is an important step to define WHO work on medicines. It defines ten critical issues that are essential for access to medicines and identifies the deliverables under each issue. Clearly, intensive work has gone into designing the roadmap building on WHO’s past and on-going work and taking into account the challenges in global health. However, WHO needs to elaborate on a number of issues in order to make the roadmap effective in achieving its goals.

GENERAL COMMENTS: THE ROADMAP NEEDS TO:

1. Highlight how the current changes in global health such as the epidemiological changes, impact access medicines in the introduction.
2. Focus the 10 topics as clear objectives- what would the deliverables intend to achieve by 2020 (see ideas below).
3. Emphasise the importance of diagnostics: New technology has increased the value and importance of diagnostics in public health. However, there is a huge need for R&D for new diagnostics for many health conditions including the rising antimicrobial resistance, NCDs in addition to neglected diseases. The high price of available diagnostics is a barrier for people to get correct diagnosis.
4. Emphasise the gender dimension of access to medicines. Gender differentiation goes well beyond maternal health. For example, women bear the brunt of out-of-pocket spending by their extra unpaid healthcare.
5. Incorporate specific recommendations from the High Level Panel on access to medicines.
6. Clarify the deliverables that have specific timeframe and those that require continuous work.

SPECIFIC COMMENTS

1) Research and development for medicines and vaccines that meet public health needs

Objective: R&D and financing for medicines, vaccines and diagnostics that meet public health needs.

The roadmap needs to include a strong WHO role in:
1. Investigating models of delinking financing of R&D from the price of resulting products in relation to neglected diseases and AMR and across a broad spectrum of diseases.
2. Advocating and supporting countries to increase their funding for R&D including investing in national research institutions.
3. Including NCDs as a priority for R&D especially medicines and diagnostics appropriate for poor settings.
4. Supporting countries to prioritise financing for medicines, vaccines and diagnostics through increasing their health budget.
5. Prioritising setting global standards for R&D and undertaking preliminary work for a global convention on R&D.

2) Fair pricing and financing policies

Objective: Fair pricing policies and practices that result in affordable medicines, vaccines and diagnostics.

Comments:
1. The focus on cost effectiveness in the document ignores the fact that high price makes many medicines/vaccines/diagnostics “not” cost effective. Therefore, the focus of the deliverables should be on how to decrease price in order to make a health product cost effective. Balancing “health gain” with “cost" requires challenging the high prices and not taking the current price as a given in calculating such balance.
2. Need to include specific actions for middle income countries. MICs have been excluded from global deals on low prices on medicines and vaccines. Some countries changed status overnight from low to middle income without real change in poor people’s income or in the country’s spending on health.

3. Given that high price is a global challenge even in high income countries, WHO should be promoting initiatives that address the fundamental causes of high prices.

4. The definition of “fair price” needs further work to clarify because “sufficient market incentive” can actually mean high price.

5. Transparency on pricing and prices needs to be emphasised. Price reporting mechanisms such as the WHO reports on medicines for specific diseases should be expanded to include all medicines. This will require supporting the countries to enhance their capacity in data collection and in setting up transparency standards to make the prices publicly available.

6. WHO’s new work on biosimilar medicines needs to be prioritised.

3) Application and management of intellectual property to contribute to innovation and promote public health

Objective: Intellectual property application that prioritises public health and access to medicines.

The roadmap needs to:
1. Emphasise and clarify WHO role in bilateral and regional free trade agreements. The role should include supporting the assessment of the health impact of an agreement during the negotiation and after it comes into effect. It is critical that WHO warns against provisions that can have negative impact on public health.

2. Support countries facing pressure when implementing any TRIPS flexibilities.
3. Protect the inclusion of TRIPS flexibilities in international arena, such as in relevant UN processes and high level meetings.

4) Procurement and supply chain management

Objective: Effective procurement systems that cover both public and private sectors.

The roadmap needs to emphasise:
1. Prioritising market intelligence to predict shortages and establish mechanisms to deal with shortages.
2. Supporting governments’ actions to regulate the private sector involved in procurement and dispensing health products.

5) Appropriate prescribing, dispensing and use

Objective: Health products are prescribed, dispensed and used in a way to enhance public health.

The roadmap needs to emphasise WHO role in:
1. Supporting countries to ensure continuous in-service training for health workers for the appropriate prescribing and dispensing of medicines.
2. Supporting countries to enhance public awareness of the proper use of medicines.

6) Regulatory systems to ensure quality, safety and efficacy of medicines and vaccines

Objective: Safe quality medicines, vaccines and diagnostics via effective regulatory systems, policies and practices.

The roadmap should emphasise WHO strong role in:
1. Ensuring that global initiatives that target private sector role in procurement and dispensing medicines guarantees the quality of medicines by, for example, not allowing the sale of medicines by the informal sector.
2. Expanding the pre-qualification program to include needed health products starting with the essential medicines list and including training and supporting national and regional regulators.
3. Supporting national capacity for effective regulation and monitoring the quality of products across private and public sectors.

7) **Preparedness for emergencies**

Objective: Health products are available and affordable to respond to health emergencies.

The roadmap needs to:
1. Clarify the general stream of work that responds to any general emergency e.g. the health products supply during an earthquake differ from specific medical emergencies such as Ebola.
2. Include actions to make products affordable and to secure systems of coordinated international support in purchasing products that strengthen national systems during health emergencies.

8) **Good governance**

Objective: good governance is implemented through the whole chain of health products from R&D to patients’ use.

The roadmap needs to include:
1. Supporting countries to regulate the private sector especially the informal sector.
2. Advocating for civil society involvement in monitoring and accountability mechanisms.
3. Including specific targets on transparency in all aspects of the chain of health technologies from R&D to dispensing.

9) **Collection and use of key data on medicines and vaccines**

Objective: Countries implement and use good data collection systems for health products.

The roadmap needs to include:
1. Supporting countries to include data from private sector procurement and dispensing of health products
2. Supporting countries to collect gender-differentiated data.

10) **Health workforce capacity for access to medicines and vaccines**

Objective: Health workers have enhanced capacity in all aspects of access to medicines, vaccines and diagnostics.

The roadmap needs to emphasise WHO role in:
1. Supporting mechanisms to ensure that health workers have easy access to evidence-based un-bias medical information that is free from market incentives.

Finally, WHO should ensure appropriate funding for the implementation of the roadmap.
Access to medicines and vaccines roadmap consultation – Save the Children feedback

Geneva, 10 Sept 2018
(submitted to roadmapaccess@who.int)

Introduction and overview:

- Importance of also looking at the enabling environment for affordable medicines and vaccines
- Under each of the activity areas, beyond deliverables, what will be the expected outcomes (including intermediary outcomes), timelines and milestones and how will success of the roadmap be measured – this is important not only for the overall roadmap but also under each activity area

Activity area 1 – R&D for medicines and vaccines that meet public health needs:

- First sentence should read “…improving availability of and affordable access to medicines and vaccines.”
- Should also look at product formulations and administering devices that meet the needs of LICs as well as rural and remote areas
- How will the list of prioritised R&D be used and what kind of dissemination will be done? How will it be used to push for response/action to the unmet need (e.g. with industry, innovative funding and partnerships, academia, etc)?

Activity area 2 – Fair pricing and financing policies:

- Good to see a strong focus in the roadmap on fair pricing.
- In addition to eliminating out-of-pocket costs to individuals, need to also address the high cost to governments in purchasing medicines and vaccines, which undermines progress to increase and sustain coverage. This is coupled with many countries transitioning from bilateral and multilateral aid whereby they will face the double burden of fully financing their health programmes and without access to negotiated prices (e.g. as in the case of Gavi transitioning countries).
- It is important to also provide technical and capacity support through the roadmap to help build countries’ price negotiating capacity. This is particularly important in light of many countries’ transition from bilateral and multilateral aid, such as countries transitioning from Gavi support, as well as for many MICs. This should be linked with the MIC strategy and carried out in collaboration with other partners.
- Good to see a focus on improving price transparency. How will this leverage and improve the use of existing mechanisms, while also learning lessons from them (such as the V3P database)? How will you engage industry around this so that they are not a barrier to improved price transparency?
- In addition to transparent prices, a healthy medicines and vaccines market is also needed with sufficient competition to dive down prices, while also preventing medicines and vaccines shortages. What work will be done to support and accelerate entry of new suppliers (e.g. for PCV), to support a healthy market (working together with other partners)? There should also be a focus on emerging market production and generics.
- With regard to developing and revising policy guidance for more effective pricing policies, who is the target of this – countries? Suppliers? How will it be enforced?
Activity area 4 – procurement and supply chain management:

- Similar to the point under activity 2, it is important to also provide technical and capacity support through the roadmap to help build countries’ procurement capacity. This is particularly important in light of many countries’ transition from bilateral and multilateral aid, such as countries transitioning from Gavi support, as well as for many MICs. This should be linked with the MIC strategy and in collaboration with other partners.
- Good to see support around pooled procurement in the road map (e.g. this has been on the RITAG agenda but without progress). How will WHO (together with partners and linking with the MIC strategy) move forward on this, e.g. a pooled procurement mechanism for Africa? How can WHO play a convening role to make progress on this agenda?

Activity area 6 – Regulatory systems to ensure quality, safety and efficacy of medicines and vaccines:

- This should also look at enhancing capacity to accelerate the entry of new vaccines to the market (e.g. PCV from emerging market producers), including improving regulatory capacity.

Activity area 9 – Collection and use of key data on medicines and vaccines

- There is a need for accountability around this, not only for countries, but also manufacturers, technical agencies, etc.
- Will price transparency databases also come under this activity area and how will you ensure that systems are being better used (in terms of inputs) and then utilised (to inform decisions)?

10 September, 2018

Thank you Chair,

Stichting Health Action International (HAI) welcomes the opportunity to contribute to the discussions on the World Health Organization’s (WHO) Roadmap for Access 2019–2023. We note positively the document under discussion here today, and appreciate the efforts of the Secretariat in translating the mandate of Member States in addressing the global shortage of, and access to, medicines and vaccines into a workable strategy.

Access to medicines is a cornerstone of the promotion and defence of public health, plays a crucial role in the fulfillment of the human right to health, and is essential for the achievement of Universal Health Coverage (UHC).

Improving access and avoiding shortages of medicines is a collective effort. Across all HAI’s areas of work, such as strengthening health systems, addressing the challenges of access to insulin, promoting the use of TRIPS flexibilities to improve and secure access to medicines, and in supporting technology transfer to combat neglected tropical diseases (NTDs), we have seen first-hand the importance of stakeholder collaboration, transparency and political will.

In partnership with the international health community, WHO must prioritise closing the gap and addressing existing imbalances effecting access to medicines and vaccines. In particular, it has a crucial role in monitoring and promoting the use of TRIPS flexibilities and other IP management tools for the betterment of access to medicines. WHO is the only United Nations agency with the knowledge, capacity and mandate to evaluate the impact of free trade agreements on public health. It is imperative that technical cooperation on the matter be resourced and reinforced.

Transparency is not only a prerequisite for good governance; it can also provide a major boost to efficiency and accountability of public actions, policies and programmes. We welcome the importance the Roadmap places on increased transparency in critical domains, including medicine pricing and clinical trials. However, we need WHO to go beyond this and include figures for the cost of research and development (for example, to ascertain the specific amount of public and private investments), and procurement schemes (to assess rebates and discounts). On the latter, WHO could provide technical assistance to civil society and national authorities to develop joint tools and platforms for accountability in health spending, including on pharmaceuticals.

We remain confident that Member States will fully engage in this exercise, not only through the contribution of ideas and suggestions, but that they will also commit resources and provide the necessary political support for WHO to be able to respond adequately to short-sighted unilateral actions aimed at defending private interests, and other threats to a shared global health agenda.
Roadmap for access 2019 – 2023; comprehensive support for access to medicines and vaccines

Thank you for the opportunity to deliver this statement on behalf of UICC.

We welcome the roadmap for access by the secretariat and the concerted efforts undertaken by Member States, the WHO and other key international partners to improve access to essential medicines and vaccines.

As recognised within the roadmap, a consistent emphasis on building strong and resilient health systems, with timely access to quality vaccines and medicines, will be essential to successfully deliver the target of universal health coverage (UHC). This target is in line with the 2017, World Cancer resolution, the WHO’s 13th General Programme of Work (GPW) and objective 4 of the Global Action Plan for the prevention and control of Noncommunicable Diseases (NCDs).

NCDs are the leading cause of premature mortality globally; cancer alone was responsible for approximately 8.8 m cancer deaths and 14.1m new cases in 2015, and this figure is forecasted to increase significantly to 21.6 m new cases annually by 2030. Access to essential medicines and vaccines will significantly reduce premature mortality from cancer.

The global burden of NCDs constitutes a major public health challenge that undermines social and economic development throughout the world. Therefore, we urge member states to reflect on the specific activities, actions and deliverables identified within the roadmap to address the multiple determinants of access and:

- Ensure the affordability and availability of safe, effective and quality medical products through appropriate selection based on clinical evidence, for inclusion on national essential medicines lists (NEMLs), effective regulatory systems, efficient procurement strategies, such as joint or pooled procurement at regional and global levels, and policies that encourage fair pricing
- Build capacity, in collaboration with WHO, WTO, WIPO and other organisations and partners, for the proper implementation of intellectual property laws that are in line with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and that make adequate use of its flexibilities to improve access to medicines
- Address the training needs of the health workforce with regard to strengthening supply chain management, while also addressing the issue of inadequate data management systems
- Engage civil society in the contribution to and monitoring of the progress towards these deliverables.

UICC supports the target of increasing availability of essential medicines at the primary health care level, but would also recommend this be extended to include the secondary and tertiary levels to ensure access to effective treatment which can’t be delivered at the primary health care level.

UICC would like to commend Members States for their work thus far, and we stand ready to support countries to reduce the burden of cancer through the delivery of effective UHC.

Honourable Chair, distinguished delegates,

On behalf of the World Heart Federation we thank the WHO Secretariat for its Roadmap Report. People living with cardiovascular disease, or CVD, suffer acutely from poor access to medicines. The 2011 PURE Study shows that nearly 70% of patients living with CVD in LMICs do not receive medicines to manage their chronic conditions. This figure rises to over 80% for patients in LICs.¹

We therefore support the Roadmap’s 10 priority areas, and the over-arching goal of the Roadmap to help build resilient health systems to progress towards universal health coverage. We would like to make comments on three key areas:

1. We acknowledge the need to strengthen Governance to reduce waste as highlighted in priority area 8, which notes the costs of corruption in the supply chain. Nevertheless it is important to emphasize that spending on health systems and medicines should be regarded as an investment, not a cost. The recent Lancet Taskforce on NCDs and Economics estimated that investing just $1.50 more per person per year in the SDG era in the 20 countries with the highest NCD burden – including many pharmaceutical interventions – would result in a benefit-cost ration of over 10 to 1.² We therefore urge WHO to include advocacy to Member States on the long-term economic and social benefits of UHC as a core element of the Roadmap.

2. Benzathine penicillin G, or BPG, the essential treatment for syphilis and for prevention of rheumatic fever, has been present on the WHO Essential Medicines List since the first edition in 1977. However, shortages and market failure have combined to cause stockouts worldwide. We urge WHO to pursue plans to develop a global reporting system for shortages and stockouts as part of the Roadmap to alleviate this problem.

3. We commend WHO’s emphasis on increasing the number of pharmacists to strengthen health workforce capacity. We suggest adding a recommendation to increase the role of nurses and allied health workers to include prescription of some essential medicines; many settings lack sufficient doctors to meet demand, and studies have shown improved adherence to medications among patients through interventions led by non-physician health workers.³

Thank you for your attention.

¹ https://www.ncbi.nlm.nih.gov/pubmed/21872920
² Lancet Taskforce on NCDs & Economics, 2018 p53; https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30665-2/fulltext
³ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5143810/
Comments on Zero draft v2 of the
Roadmap for access 2019-2023 – Comprehensive support for access to medicines and vaccines
Thomas C. Baghai (section secretary), Norman Sartorius (past president WPA, president Association for the Improvement of Mental Health Programmes), Siegfried Kasper (section president), Helen Herrman (WPA president)
on behalf of the World Psychiatric Association (WPA), Section of Pharmacopsychiatry

The WPA fully supports the goal of the document to support global access to essential medicines. Therefore the publication of the roadmap and the WHO support for equitable and easy access to medicines and vaccines will be an important step forward to approximate this goal.

Nevertheless, from a psychiatric view, the roadmap and the list of essential medicines do not reflect the impact of psychiatric disorders on global mental health adequately. According to WHO reports e.g. depression is and will be a major, if not the leading cause for disability affecting to date more than 300 million people. Despite ongoing awareness programs and anti-stigma campaigns only 10-50% of affected patients receive treatment due to the fact that depression is still both underdiagnosed and undertreated while the burden of the disease is still rising. Even in high income countries an inequity for people needing medicines for the treatment of psychiatric disorders compared with those needing treatment for somatic disorders is known, but in low and middle income countries the situation is known to be even worse. Moreover, this treatment gap includes also people suffering from psychotic disorders in low and middle income countries where antipsychotic medication often is not available in the needed amount and quality.

Therefore, in our view it is essential, to update the psychopharmacologic part of the list of essential medicines considering not only clinical effectiveness and actual prices of the mentioned medicines, but also safety and tolerability of the treatments, because the actual list of essential medicines for psychiatric indications does not allow treatment according to several national or international guidelines. Treatment for mood disorders does not include modern antidepressants with better side effect profiles. Antipsychotics should include more atypical and better tolerable substances in addition to depot preparations of atypical antipsychotics. Standard emergency medications such as rapid dissolving tablets of benzodiazepines are not included, even if their application is connected to reduced risks for the patients in comparison to i.v. formulations.

Our suggestions would not cause significant increases in treatment costs, but would improve predominantly the availability and tolerability of psychopharmacological treatments. This leads usually to better adherence to the treatment, to better treatment outcomes and to an increasing use of relapse-preventing treatments.

Detailed recommendations for the list of essential medicines

Antidepressant medications should be extended to modern selective serotonin and noradrenaline reuptake inhibitors (SNRIs) such as venlafaxine extended release (standard dose treatment costs: 1.33$ per week) or duloxetine (1.75$) useful especially in treatment resistant depression. Also more selective serotonin reuptake inhibitors (SSRIs) such as sertraline (1.35$) or (es)citalopram (2.60-3.60$) should be included.

Antipsychotic medications should include quetiapine and aripirazole for the treatment of schizophrenia, but also as an augmentation strategy for depression and for the treatment of bipolar disorder.

Some drugs are already listed, but more psychiatric indications in differential pharmaceutical forms should be mentioned (e.g. lorazepam rapid dissolving tablets for acute psychotic agitation, catatonia, acute suicidality, depressive stupor and mutism; biperiden extended release tablets for the treatment of extrapyramidal motoric side effects of neuroleptics).
Recommendations for the Zero draft v2 of the roadmap 2019-2023 document

Chapter 2 – Fair pricing and financing policies:

“Evidence based selection and priority setting” should include clinical effectiveness, safety and tolerability; each medical discipline including psychiatry should provide an expert consensus.

“Encourage more transparent and better policies and actions to ensure fairer pricing” should not only include an increase in price transparency provided by industry, but also an increasing “reimbursement transparency” from government decision makers.

Chapter 5 – Appropriate prescribing:

Provide support for “regular development and revision of national treatment guidelines” should include also globalization: It may be sufficient to adopt international treatment guidelines to national requirements and availabilities.

Support appropriate prescribing by supporting awareness and education programs for underdiagnosed and undertreated diseases (e.g. depression).
Re: WHO’s roadmap for access to medicines and vaccines 2019-2023

The World Stroke Organization (WSO) would like to congratulate the roadmap’s leadership for their comprehensive work and the rapid progress in the elaboration of this report.

Together with the WHF and Coalition for Circulatory Health, the WSO welcomes the fact that NCD are appropriately mentioned in the report. Stroke and heart diseases remain the world’s leading causes of death and disability, affecting disproportionately LMICs.

We have two comments on the current draft, one on the implementation of the Essential Medicines List and one on inclusion of other health products:

1) **Regarding the WHO Essential Medicines List and its implementation:**
WSO strongly supports the target to increase availability of essential medicines for primary health care, including the ones free of charge to 80%. For NCDs, this availability concerns medicines for hypertension, diabetes, hyperlipidemia, and smoking cessation, all of which are highly cost effective and still massively underused. WSO recommends that mechanisms for implementation of the WHO Essential Medicines List are spelled out more specifically. In addition to stressing UHC and a trained workforce, the roadmap should A) stress the already available HEARTS and PEN packages for NCDs, B) that member states establish explicit financing mechanism for the products on the Essential Medicines List; B) mention the importance of intersectorial collaborations with carefully selected partners that could allow essential medicine to reach the neediest populations.

2) **Regarding the inclusion in the report of other health products** such as diagnostics, interventions and devices: WSO recognizes that medicines and other health products are closely linked. Both areas are complex and have ambitious goals. In order to keep to the timetable of the roadmap and start implementing it in 2019, we encourage the leadership to focus this roadmap on medicine and vaccines, and then work in parallel on a similar roadmap for other health products and interventions.

Again, the WSO appreciates the opportunity given by the WHO to support the elaboration of this and other initiatives to improve circulatory health worldwide.

*Statement made on behalf of WSO by Prof. P. Michel, WSO Board Member*
Written submission of Knowledge Ecology International (KEI) and 15 groups: Comments on the WHO Roadmap on Access to Medicines and Vaccines 2019-2023

11 September 2018

This written submission is prepared on behalf of these following organizations: Alianza LAC – Global por el Acceso a Medicamentos, Asociación por un Acceso Justo al Medicamento, BUKO Pharma-Kampagne, Canadian HIV/AIDS Legal Network, Health Action International, Health GAP, Just Treatment, Knowledge Ecology International, KEI Europe, Misión Salud, Oxfam, Prescrire, Salud por Derecho, Stop AIDS, Union for Affordable Cancer Treatment, and Yolse.

Content

The secretariat report (A71/12) on Addressing the global shortages of, and access to, medicines and vaccines was published on 19 March 2018 and provides the foundation for the World Health Assembly decision to create a roadmap on access to medicines. The WHO report was a “comprehensive review of the major challenges to ensuring access to safe, effective and quality medicines and vaccines and analysed progress made to date.” (Source: A71/12).

On the basis of this review, the Secretariat identified twelve actions that could be prioritized for implementation. Two of these actions relate to transparency:

- “Support the development and implementation of systems at the national level for collecting and monitoring key data on medicines and vaccines, such as availability, price, expenditure, usage, quality and safety, and ensuring use of these data for better evidence-based policy-making.” (Source: Ibid)

- “Develop policies that promote and enhance transparency throughout the value chain, including the public disclosure of clinical trial data, research and development costs, production costs, procurement prices and procedures, and supply chain mark-ups.” (Source: Ibid)

A roadmap with robust language on transparency would reinforce the WHO’s authority to explore norms and mechanisms to enhance the transparency of R&D costs, prices and revenues.

Policies that influence the pricing of health technologies or the appropriate rewards for successful research outcomes can be better evaluated when there is reliable, transparent and sufficiently detailed data on the costs of R&D inputs (including information of the role of public funding and subsidies), the
medical benefits and added therapeutic value of products. The actual access or lack of access to products by patients is highly dependent on affordable prices.

The lack of transparency currently impedes or delays many of the policies that would otherwise be available as policy measures to reduce the price of medicines and vaccines. In particular, without reliable information regarding the cost of R&D, the cost and results of clinical trials, private sector expenditure on the development of products, expenditures on marketing and revenues, it is hard to design alternative policy measures to reduce the current prices.

**With respect to the overarching theme of achieving universal health coverage (UHC), access will always be constrained and unequal without the delinkage of R&D costs from the prices of drugs, vaccines and other health technologies.**

The WHO roadmap on access to medicines and vaccines should envision a pathway to evaluate and implement the alternative business models that are consistent with universal access to products. This means, in practical terms, progressive implementation of delinkage of R&D costs from the prices of products, something that is essential to reduce prices without undermining innovation.

As countries wrestle with affordability and financial sustainability issues, they can seek technical assistance from the WHO or other entities in order to use lawful pathways to ensure treatments are affordable and widely available — including through the granting of compulsory licenses and/or through the use of competition law or other means to remedy excessive prices.

The WHO should be much more active in this regard; rather than waiting passively for countries to approach the WHO for assistance, the WHO could organize a series of regional workshops to share expertise and best practices on various technical and practical aspects of compulsory licenses, and other related topics including the ability of Member States to implement limitations on remedies for patent infringement.

In multilateral settings such as the special sessions of the United General Assembly on non-communicable diseases and tuberculosis, WHO should be more vocal in pushing a public health agenda where UHC depends on timely and affordable access to health technologies by, among other means, making use of TRIPS flexibilities and other public health safeguards.

We note that UN Sustainable Development Goal Three seeks to “ensure healthy lives and promote the well-being for all at all ages” and Agenda 2030 target 3.B calls upon Member States to “provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.” The WHO has to take concrete actions to give effect to these goals and targets.

Given the global disparities of access to treatment and the challenge of promoting both innovation and access, it is imperative that the WHO roadmap address the policy incoherence between trade rules, international human rights law, and public health. It is critical for the WHO to stand at the vanguard of the
United Nations' (UN) response to the UN High-Level Panel on Access to Medicines (UNHLP) - including the convening of a special session of the UN General Assembly on Access to Medicines and Vaccines in 2019.

We propose the following operational language on: A) Transparency, B) Excessive Pricing C) Biologics drug competition, D) Intellectual Property rights and E) Delinkage, with clear timelines and milestones for key activities - something that is currently missing in the zero draft of the roadmap.

Proposed operational language on transparency for the WHO roadmap

During the period 2019-2023, the WHO secretariat is requested to:

A. Transparency

(1) Collect and analyse and disseminate data on health technologies of public health importance, including but not limited to:
   a. Actual costs of R&D on specific drugs and vaccines, including most importantly the enrollment and costs of individual clinical trials, and the degree to which specific products benefit from subsidies provided by governments and charities;
   b. Actual manufacturing costs of specific drugs, vaccines and health technologies;
   c. The landscape of patents, including information about patent oppositions and other disputes about the validity and/or relevance of asserted patents;

(2) Collect and analyse and make available data on clinical trial outcomes and adverse effects of health technologies;

(3) Create a web-based tool for national governments to share information on drug prices, revenues, R&D costs, the public sector investments and subsidies for R&D, marketing costs, and other related information by the third quarter of 2021;

(4) Create a web-based tool for governments and third parties to provide information on the landscape of patents on medical technologies, including information about disputes about the validity and/or relevance of asserted patents by the first quarter of 2021;

(5) Hold meeting in the first quarter of 2020 to consider measures including but not limited to standards for reporting prices, revenue, R&D and marketing costs;

(6) Create a biannual forum on the transparency of markets for pharmaceuticals, vaccines and diagnostics, to evaluate progress toward the progressive expansion and increasing operationalization of transparency starting in 2019;

(7) Make public any contribution, financial or in kind, from pharmaceutical companies and other for-profit actors, and philanthropic foundations in relation to events, programs and actions implementing this roadmap.
B. Excessive Pricing

The WHO Secretariat is requested to develop a best practices manual on the subject of the control of and remedies for excessive pricing by December 2020. In order to develop the manual, the WHO is requested to organize a series of workshops to share expertise on various legal and technical aspects of excessive pricing, including the context specific methodologies employed by Member States for determining if prices are excessive, and the mechanisms to remedy and control pricing abuses.

No later than the end of 2019, WHO should organize a technical meeting on drug pricing, with contributions from all stakeholders, including academia and civil society, reviewing the conclusions and implementation of recommendations from the Fair Pricing Forum held in Amsterdam in 2017, as well as subsequent work in other fora to address measures to curb excessive prices for medical technologies.

C. Biologic drug competition

The WHO Secretariat should organize workshops to consider new policies and guidelines that can enhance competition for biologic drugs, including greater transparency of know-how and access to materials in order to create highly competitive markets for biologic drugs.

D. Intellectual Property Rights

During the period 2019-2023, the WHO Secretariat is requested to provide remuneration guidelines in relation to the non-voluntary licensing of health technologies. To this end, the WHO is requested to organize a series of workshops to share expertise and best practices on various technical and practical aspects of compulsory licenses, and other related topics including the ability of Members to implement limitations on remedies for patent infringement, in the context of cases where courts may and often do deny permanent injunctions even involving medical technologies, but order a reasonable royalty to compensate for the non-voluntary use of the patented invention.

The WHO Secretariat is requested to produce a report by March 2020 on potential intellectual property and regulatory barriers for gene and cell-based therapies including but not limited to CAR T and CRISPR.

E: Delinkage

The WHO Secretariat is requested to conduct a feasibility study of creating a multi-country push and pull fund for cancer R&D to progressively delink the costs of R&D including the incentives borne by buyers of drugs from product prices, as an alternative to global norms that rely upon time limited monopolies and high prices to induce investments in R&D. The WHO Secretariat is requested to initiate this feasibility study in the first quarter of 2019 and submit the findings of the feasibility study to the Seventy-third World Health Assembly for its consideration in 2020, through the Executive Board at its 146th session.

The suggested operational language for the road map on access to medicines and vaccines would create a clear pathway to have a meaningful impact on the WHO’s programme of work for 2019-2023.