

**EB140 (23 January-1 February 2017)**  
**Member State proposals for additional agenda items**

Proposal	Title	Proposed by	Last discussed by the Board or Health Assembly
<b>Agenda item 7. Preparedness, surveillance and response</b>			
New point under item 7.1	Coordination of humanitarian emergencies of international concern (to be included under item 7.1, Health emergencies)	Spain	WHA67 (2014) WHA69 (2016)
<b>Agenda item 8. Health systems</b>			
New point under item 8.1	International recognition of credits in development of the continuing education of health professionals (to be included under item 8.1, Human resources for health)	Spain	WHA64 (2011); WHA66 (2013); document A69/36 (2016)
Amendment to item 8.1	Amend the title of item 8.1 to read: Human resources for health and implementation of the outcomes of the United Nations High-Level Commission on Health Employment and Economic Growth	France	The Commission had its first meeting on 23 March 2016 in Lyon, France
Amendment to item 8.4	GSPOA, follow-up of the CEWG report and MSM on SSFFC medical products should be listed as separate agenda items	India, supported by all Member States of the South-East Asia Region	
New item 8.5	Improving access to assistive technology	Pakistan	EB139 (2016)
New item 8.6	Sepsis	Austria, Germany, Ireland, Israel, Luxembourg, Serbia, Switzerland, supported by Jamaica and Japan	Newborn health action plan (WHA67.10) (2014)
New item 8.7	"Kids Save Lives" in the context of improving quality of health care and patient safety	Sudan	EB138 proposed:• that, despite the importance of the proposed new item entitled ""Kids Save Lives" in the context of improving quality of health care and patient safety," the relevant work should be taken forward through other means, including technical briefings and seminars, as the initiative had already received the Organization's official endorsement and was under way.
New item 8.8	mHealth	India, supported by all Member States of the South-East Asia Region	EB139 (2016)
New item 8.9	Access to medicines	India, supported by all Member States of the South-East Asia Region	WHA67 (2014) (WHA67.22); WHA69 (2016) (WHA69.23)
New item 8.10	Regulatory system strengthening for medical products: acceleration and follow up of implementation	Mexico	WHA67 (2014) (WHA67.20)
New item 8.11	Promoting health of fragile and vulnerable populations, communities and individuals, such as migrants	Italy	WHA69 (2016)
New item 8.12	Migration and health	Sri Lanka	WHA63 (2010)
New item 8.13	Global snakebite burden	Costa Rica	Document EB131/8 (2012)
<b>Agenda item 9. Communicable diseases</b>			
New item 9.3	Accelerated action for global measles and rubella eradication	Colombia	Measles: WHA63 (2010) Measles and rubella included in global vaccine action plan WHA69 (2016)

Proposal	Title	Proposed by	Last discussed by the Board or Health Assembly
<b>Agenda item 10. Noncommunicable diseases</b>			
New item 10.5	Revitalizing physical activity for health	Thailand	Included in the report of the Commission on Ending Childhood Obesity WHA69 (2016)
New item 10.6	Cancer prevention and control: support for an updated WHA resolution	Jordan	WHA60 (2007)
New item 10.7	Rheumatic heart disease	Cook Islands, Ethiopia, Fiji, Namibia, New Zealand	EB114 (2004)
<b>Agenda item 11. Promoting health through the life course</b>			
New item 11.3	Developing a global action plan for the management and treatment of health care waste	Kuwait	WHA64 (2011)

## **BACKGROUND NOTE FOR OFFICERS OF THE EXECUTIVE BOARD**

### **CRITERIA FOR DECISION-MAKING DURING REVIEW OF ITEMS FOR INCLUSION IN THE DRAFT PROVISIONAL AGENDA OF THE BOARD**

There are two sets of criteria that Officers of Board may apply to support their decision-making on the items to be included in the provisional agenda:

1) established by the Board in 2007 and 2) by the Health Assembly in 2012.

- 1) In resolution EB121.R1 the Board decided on three criteria to apply in considering items for inclusion on the agendas:

“The Executive Board ...DECIDES:

...to endorse criteria for inclusion of proposed additional items in the provisional agenda of Executive Board sessions, namely, proposals that address a global public-health issue, or involve a new subject within the scope of WHO, or an issue that represents a significant public-health burden...”

- 2) In decision WHA65(9) on WHO reform, the World Health Assembly decided, as a means of improving governing body meetings...

“(7) (a) that the Officers of the Board use criteria, including those used for priority setting in the draft general programme of work, in reviewing items for inclusion on the Board’s agenda;...” (see the relevant extract from document A65/40 below)

### **WHO REFORM: MEETING OF MEMBER STATES ON PROGRAMMES AND PRIORITY SETTING (document A65/40)**

#### **CRITERIA FOR PRIORITY SETTING AND PROGRAMMES IN WHO**

The priorities of WHO should be aligned with its Constitution, particularly the principles of the preamble and the objective of the Organization of the attainment by all peoples of the highest possible level of health, and the functions for achieving that objective as contained in Article 2 of the Constitution. This includes the mandate “to act as the directing and co-ordinating authority on international health work”, giving due emphasis to countries and populations in greatest need, and taking into account gender equality, universal coverage, as well as the economic, social and environmental determinants of health.

The specific criteria are:

- (1) **The current health situation** including: demographic and epidemiological trends and changes, urgent, emerging and neglected health issues; taking into account the burden of disease at the global, regional and/or country levels.
- (2) **Needs of individual countries** for WHO support as articulated, where available, through the country cooperation strategy, as well as national health and development plans. (*agreed*)

- (3) **Internationally agreed instruments** which involve or impact health such as declarations and agreements, as well as resolutions, decisions and other documents adopted by WHO's governing bodies at the global and regional levels.
- (4) The existence of **evidence-based, cost-effective interventions** and the potential for using knowledge, science and technology for improving health.
- (5) The **comparative advantage of WHO**, including:
- (a) capacity to develop evidence in response to current and emerging health issues;
  - (b) ability to contribute to capacity building;
  - (c) capacity to respond to changing needs based on ongoing assessment of performance;
  - (d) potential to work with other sectors, organizations, and stakeholders to have a significant impact on health.

**SUGGESTION OF HOW TO APPLY THESE CRITERIA TO DECISION-MAKING ON AGENDA CONTENT**

In considering the composition and content of the draft provisional agenda, Officers of the Board may wish to test items against the following question:

*"Does a proposed agenda item align with at least the first element of the four reform priority-setting criteria and, at the same time, would action on it be consistent with the comparative advantage of WHO as an institution?"*



## **Annex**

### **Explanatory memorandum**

#### **1. Coordination of humanitarian emergencies of international concern**

Since the late 1990s, and in a very significant way since 2003 following the earthquakes in Bam (Islamic Republic of Iran) and Burmerdés (Algeria), Spain has dispatched health teams to the site of humanitarian emergencies in various contexts. While the response has always been appropriate and the commitment and dedication of the teams exemplary, in recent years, and especially since the earthquake in Haiti in 2010, certain weaknesses have become evident in international humanitarian response efforts; nor are Spain's contributions immune from these shortcomings.

An analysis of events following the earthquake in Haiti showed that, as in previous emergencies, although the response was commensurate and the medical teams did sterling work in saving many lives, many of them came unprepared to provide appropriate medical care for patients.

The health response in Haiti showed the need to develop principles, criteria and standards for the deployment of medical teams in emergencies and disasters, in line with global processes to improve humanitarian norms and standards.

Accordingly, the Pan American Health Organization convened an expert meeting in Cuba in 2010 to revise the Guidelines for the use of Foreign Field Hospitals in the aftermath of sudden impact disasters, which had been published by WHO/PAHO in 2003. That meeting formed the basis of what is now known as the Emergency Medical Teams (EMT) initiative.

Aligning itself with this process and with the European Union Civil Protection Mechanism, and based on the Master Plan for Spanish Cooperation 2013-2016 which seeks to improve the quality, effectiveness and coordination of the humanitarian response in the international framework, Spanish Cooperation published its operational guidelines for direct health response in disasters in July 2013 and developed a system for responding to international humanitarian emergencies called Spanish Technical Aid Response Team.

This system establishes an official mechanism for registering, selecting and mobilizing health workers from the Spanish national health system, based on a compendium of human resources that are available and properly trained for health emergencies, thereby facilitating operational planning in emergencies and enabling Spain to respond immediately in any humanitarian crisis.

The purpose of the compendium is to provide a coordinated register of medical, health and support personnel from Spain's various autonomous communities, assigned to the national health system, who would be deployed to third countries in humanitarian emergencies whenever the Spanish Agency for International Cooperation for Development decides to launch an operation. These health workers must apply to be included in the compendium, on a prior and voluntary basis, and will be accepted provided they meet the specified requirements.

WHO could develop similar strategies to appropriately coordinate the various humanitarian assistance teams deployed in a support capacity to needful areas and populations. The Organization would thus be able to manage the assistance it provides more efficiently and effectively, thereby enabling the affected areas – which as a rule are economically impoverished – to cope with the emergency as quickly as possible by matching the deployed

resources to the various needs arising in the field, and thus avoid omissions, gaps or duplication of effort.

## **2. International recognition of qualifications in the development of ongoing training for health workers**

Health workers have a decisive role to play in upholding quality standards in health care. Obviously, therefore, they must be subject to continuous improvement processes in their work, thus enabling them to develop a meaningful professional career in which their qualifications are properly valued and translating into better care for their patients.

It is thus vitally important to develop instruments to incentivize, promote and recognize health workers' professional development with a view to raising the quality of care and setting more stringent safety criteria in clinical practice, which ultimately will lead to better outcomes for patients.

Significant international population flows – including of health professionals – are an intrinsic reality of the globalized world we live in. Nowadays, professional mobility is certainly not limited to free movement of people and services within the European Union, where this is a fundamental tenet. Professional opportunities exist globally and relationships are multidirectional.

Thus, in order to secure the requisite quality standards for the health professions, it would be desirable to establish a system of international recognition of qualifications in ongoing training for health workers, to be validated according to a set of minimum requirements that would guarantee safety and quality in the exercise of the health professions, and thereby ultimately benefit patients.

Permanent Mission of France  
to the Office of the United Nations at Geneva

MAM/cda  
No. 2016-649479

The Permanent Mission of France to the Office of the United Nations and the international organizations in Geneva presents its compliments to the World Health Organization and has the honour to inform it that in response to note verbale CL 26-2016, France hereby requests that item 8.1 of the agenda of the 140th Executive Board should be amended to read as follows :

8.1 : Human resources for health and implementation of the outcomes of the United Nations High-Level Commission on Health Employment and Economic Growth

An explanatory memorandum is attached.

The Permanent Mission of France to the Office of the United Nations and the international organizations in Geneva takes this opportunity to convey to the World Health Organization the renewed assurances of its highest consideration.

Geneva, 9 September 2016

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Secretariat of the World Health Assembly  
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**Explanatory memorandum concerning the request to amend an item on the agenda of the 140th Executive Board.**

France requests that the implementation of the recommendations of the United Nations High-Level Commission on Health Employment and Economic Growth be examined at the 140th Executive Board of WHO.

The Commission's work demonstrates that health can be a lever of equitable growth that should attract priority investment rather than being viewed as a cost to be reduced, ensuring meanwhile that the poorest countries can build health systems that offer greater resistance to epidemics such as Ebola and Zika.

This view applies equally to countries and to bilateral and multilateral development agencies (in connection with the Addis Ababa Conference). The proposals in the report could be presented as a significant contribution to the Sustainable Development Goals, given the universal and intersectoral nature of the recommendations.

The report of the United Nations High-Level Commission on Health Employment and Economic Growth will be transmitted to the Secretary-General of the United Nations on 20 September 2016 by the presidents of the French Republic and the Republic of South Africa. The conclusions will therefore have been adopted before the Executive Board in January. In its current form, the report of the United Nations High-Level Commission on Health Employment and Economic Growth proposes a series of measures to be taken within 18 months of the report's adoption and advocates immediate implementation of its recommendations.

A draft resolution is also in preparation, drawing on the contributions of the United Nations High-Level Commission on Health Employment and Economic Growth, under the auspices of the Diplomacy Health group currently chaired by South Africa.

To adhere to this schedule and fulfil the commitments, discussion of the implementation of the recommendations must get under way in January 2017.





## Permanent Mission of India

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### URGENT

No.GEN/PMI/WHO/2016

The Permanent Mission of India to the United Nations Office and other International Organizations presents its compliments to the World Health Organization and, with reference to it Note C.L.26/2016, has the honour to make the following comments/submissions on the provisional agenda of the 140<sup>th</sup> Executive Board (EB) Session.

2. First, the Permanent Mission notes that the agenda items on Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA), Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (Follow up to CEWG) and Member States Mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products (MSM on SSFFC medical products) have all been clubbed together and listed as one agenda item (8.4) for review and evaluation.

3. The Permanent Mission of India wishes to highlight that these issues are distinct and have always been discussed as separate agenda items by WHO Governing Bodies. Moreover, there is NO such pending review of CEWG. In fact, as part of the follow up to the CEWG resolution (WHA 69.23) adopted at the 69<sup>th</sup> World Health Assembly in May 2016, a number of substantial issues, including the terms of reference of the new WHO Expert Committee on Health R&D are up for consideration and adoption by the EB140 Session. Even the agenda item on SSFFC medical products goes beyond just the review of MSM and includes

consideration of the outcome of the 5<sup>th</sup> MSM meeting scheduled to take place in November 2015. The Permanent Mission of India, therefore, requests WHO to correct this discrepancy and list the above issues as separate agenda items delinking them from review and evaluation of GSPOA.

4. Secondly, the Permanent Mission of India notes that the agenda item on 'mHealth' does not figure on the provisional agenda of EB140. A preliminary discussion on mHealth took place at the EB139 session in May 2016. During those discussions, the Indian delegation had proposed to introduce a draft resolution on mHealth for adoption at the next World Health Assembly in May 2017. India's proposal was supported by many countries. A member of the Executive Board from South East Asia Region even formally proposed that mHealth should be included again on the agenda of EB140 session to enable the consideration of a resolution on the subject. The Permanent Mission of India, therefore, requests WHO to list 'mHealth' on the agenda of EB140 session to carry forward the discussion on mHealth and also facilitate the adoption of the first ever resolution on mHealth.

5. Finally, the Permanent Mission of India has the honour to propose a new agenda item entitled "Access to Medicines: Report of the UN Secretary General's High Level Panel on Access to medicines" for inclusion on the agenda of the EB140 session. An explanatory memorandum in this regard is enclosed. The UN Secretary General had appointed a High-Level Panel in November 2015 with a mandate to review and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies. The High-Level Panel is expected to come up with some actionable recommendations for promoting access to innovation and access to medicines, vaccines and diagnostics and thus contribute to Member States efforts in realizing the health related Sustainable Development Goals. Its final report is expected to be released by end of September 2016. Considering the constitutional mandate of WHO to promote global health R&D efforts to meet health needs of all and its central role in achieving the health related Sustainable Development Goals, it would be only appropriate that the recommendations of the High Level Panel are discussed by WHO Governing Bodies.

6. The Permanent Mission of India has the further honour to inform that all the above three submissions have the support of all Member States of the South East Asia Region and have been endorsed by the Regional Committee of WHO South East Asia Region at its 69<sup>th</sup> annual meeting held in Colombo from 5-9, September 2016.

7. The Permanent Mission of India avails itself of this opportunity to renew to the World Health Organization the assurances of its highest consideration.

Geneva, 12 September 2016

World Health Organization,  
[Kind Atten : Mr. Timothy Peter Armstrong,  
Governing Body Section],  
Geneva



4/2

## **Provisional agenda of 140<sup>th</sup> Session of Executive Board of WHO**

### **Proposal to include a new agenda item entitled 'Access to Medicines: Report of the UN Secretary General's High Level Panel on Access to Medicines'**

**Proposed by: India (supported by member states of South East Asia Region and endorsed by the Regional Committee of WHO South East Asia Region)**

#### **Explanatory Memorandum**

In November 2015, UN Secretary General, Ban Ki-moon, appointed a UN High-Level Panel on Access to Medicines ('the High-Level Panel') to examine various incentives and propose solutions to promote health technology innovation and access.

The establishment of the High-Level Panel is a timely initiative to comprehensively address some of the persistent barriers to access to medicines. Its work assumes significance for all countries particularly in the context of the launch of the Agenda 2030 for Sustainable Development. The ambitious health related SDGs cannot be achieved if we do not address the critical issue of access to essential health technologies in a comprehensive and systemic manner.

The High-Level Panel is co-chaired by Festus Mogae, former President of Botswana and Ruth Dreifuss, former President of Switzerland and consists of 16 eminent individuals with a deep knowledge and understanding of a broad range of trade, public health, human rights and legal issues associated with the promotion of innovation and access to medicines, vaccines, diagnostics and related health technologies. Its work has been informed by submissions from a wide range of stakeholders, including but not limited to Member States, academia, civil society, private sector and patient rights groups. All stakeholders invited to submit their contributions including through participation in two global dialogues.

The High Level Panel is examining various solutions that promote research, development, innovation and access to health technologies



with a view to support member states efforts in achieving the SDGs. Its mandate is quite comprehensive covering

- All diseases, in order to give full meaning to SDG 3;
- All technologies recognizing that the right to health entails having access to medicines, vaccines, diagnostics and related health technologies; and
- All populations in low, middle and high-income countries, in the spirit of leaving no one behind.

The main objective of the High-Level Panel is to “remedy the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”

The right to medicines is a key component of the right to health as guaranteed under international human rights law. There is increasing recognition of the inherent conflict between government obligations under human rights law to ensure access to medicines and obligations under intellectual property law to grant medicines patents.

Recent developments such as the 1000 dollar pill, excessive price gouging etc have demonstrated that access to medicines impacts everyone. Similarly, the debate on access to medicines can no longer be confined to so called Neglected Tropical Diseases. The emergence of Anti-microbial Resistance, Ebola and Zika virus outbreaks have demonstrated the failure of current R&D model and highlighted the importance of achieving policy coherence. Access to Hepatitis C, new anticancer drugs and other non-communicable diseases assumes equal importance if we are to achieve the health related SDGs. A global public policy response that rebalances obligations under human rights law with obligations under IP law and address the needs of all countries, in particular those of developing countries, is urgently needed.

The World Health Assembly in its resolution WHA69.23 noted the establishment of the UN Secretary General’s High Level Panel on Access to Medicines and expressed particular concern that even today for millions of people the right to the enjoyment of the highest attainable standard of physical and mental health, including access to medicines, remains a distant goal, that especially for children and those living in poverty, the likelihood of achieving this goal is becoming increasingly

remote. It also requested the DG, WHO to promote policy coherence within WHO on its research and development-related activities.

WHO has a constitutional mandate to set and lead global R&D efforts and promote access to medicines to meet the health needs of all. WHO has produced some landmark reports on access to medicines and has also submitted its inputs to the High-Level Panel. While multiple players have emerged within and outside the UN system attempting to address issues related to health innovation and access, WHO should be the main UN agency that is at the forefront of access to medicines agenda. This subject also assume importance in the context of the follow up to the WHA resolution (WHA 67.22) on Access to Essential Medicines, which urged member states, inter alia, to identify key barriers to access to essential medicines and to develop strategies to address these barriers. In its progress report on this resolution to the 69th World Health Assembly, WHO noted that access to essential medicines for non-communicable diseases and for other diseases including Hepatitis C remains problematic for large proportion of patients in many countries and highlighted the continued importance of ensuring access to medicines as reflected in Sustainable Development Goal 3.

The report of the High-Level Panel is expected to be released by end of September 2016. It is highly anticipated that the High Level Panel will come up with some actionable recommendations that will support Member States efforts to promote access to health technologies including access to medicines, vaccines and diagnostics. In view of the continued importance of promoting access to medicines and its inclusion in the Sustainable Development Goals, the report of the High Level Panel is also expected to have a material impact on the attainment of the 2030 Development Agenda.

Considering the constitutional mandate of WHO on health R&D and access and its central role in coordinating global efforts for the realization of health related Sustainable Development Goals, it is only appropriate that the findings and recommendations of the UNSG's High Level Panel are discussed formally by Member States within WHO. Hence, it is proposed to include a specific agenda item on 'Report of the UN Secretary General's High Level Panel on Access to Medicines' on the agenda of the 140<sup>th</sup> Executive Board Meeting. Such an informed discussion on will allow Member States to consider potential innovative approaches to address some of the persistent challenges to access to

medicines and provide appropriate directions to WHO to carry forward its work on health innovation and access.

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**Subject:** FW: Request for an additional Agenda Item on Sepsis  
**Attachments:** 3 Memorandum\_Sepsis\_FINAL.docx

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**From:** Consul [<mailto:consul@jamaicamission.ch>]  
**Sent:** Sunday, 4 September 2016 12:52 PM  
**To:** 'VEA, Gina Rene' <[veag@who.int](mailto:veag@who.int)>; 'armstrongt@who.int' <[armstrongt@who.int](mailto:armstrongt@who.int)>  
**Subject:** Request for an additional Agenda Item on Sepsis

WHO Secretariat

**Request for an Additional Agenda Item on Sepsis**

Reference is made to attached Memorandum regarding the proposal put forward by Austria, Germany, Ireland, Israel, Luxembourg, Serbia, Switzerland to include an item on “Sepsis” to the Agenda of the 70th Session of the World Health Assembly. In this regard, the Permanent Mission of Jamaica has been directed to advise that the Ministry of Health is pleased to support the proposal looks forward to this inclusion as it will assist in raising the awareness and knowledge of Sepsis globally.

Kindest Regards

**Lishann Salmon (Miss)**  
**First Secretary/Consul**  
**Permanent Mission of Jamaica to the UN and its Specialized Agencies at Geneva/**  
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## MEMORANDUM

To: WHO Director-General Dr. Margaret Chan

Re: Proposal put forward by Austria, Germany, Ireland, Israel, Luxembourg, Serbia, Switzerland to include an item on “Sepsis” to the Agenda of the 70th Session of the World Health Assembly

### 1. OVERVIEW

Sepsis, commonly known as blood poisoning, is a syndromic response to infection and the final common pathway to virtually all deaths from infectious diseases of all origins worldwide. Despite medical progress with use of better vaccines, antibiotics and acute care, hospital mortality rates of sepsis in the best healthcare systems in high-income countries range between 10 and 50%. Sepsis arises when the body's attempt to fight an acute infection leads the immune system into overdrive which causes damage to multiple organs and circulatory shock. That is why appropriate treatment of sepsis requires not only treatment of the underlying infection with antimicrobials, but in parallel requires life-saving medical interventions such as fluid resuscitation or vital organ support. The majority of sepsis cases are caused by infections targeting the respiratory, gastrointestinal and urinary tract and may also be triggered by wound/skin infections. Most types of microbes can cause sepsis, including bacteria, fungi, viruses and parasites such as those causing malaria. Sepsis may result from a healthcare related infection, however, even in the developed world the majority of sepsis is community acquired. Bacteria are by far the most common culprit, but sepsis is also the fatal common pathway of viral infections with seasonal influenza viruses, Dengue viruses and infections that have emerged as pathogens of public health concern such as avian flu, swine flu, SARS, MERS-CoV and most currently Ebola Virus disease. For most of these emerging pathogens there are no effective antiviral agents and supportive sepsis care is the only therapeutic option.

Enormous progress has been made through the introduction of and improved access to vaccinations which save an estimated 2 -3 million lives a year by preventing infections which can lead to sepsis. However, an estimated 18.7 million infants worldwide are still unimmunized.

There is a lack of awareness among the general public and public health authorities that vaccinations against influenza, *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Neisseria meningitidis* are lifesaving. Vaccinations against *Haemophilus influenzae* and *Streptococcus pneumoniae* are recommended for all children worldwide and meningococcal vaccines depending on regional epidemiology. Furthermore, all 4 vaccines are recommended for certain groups such as immunocompromized patients being at special risk of sepsis. In many developing countries, however, there is no vaccination program for elderly people or people at risk. Vaccines are not only an important tool to prevent sepsis but also essential to hinder the emerge of multiresistant pneumococcal strains.

Health care-associated infections (HAIs) are the most frequent adverse events in health-care delivery worldwide and a major patient safety issue. Hundreds of millions of patients are affected by health care-associated infections worldwide each year, leading to significant mortality and financial losses for health systems. Sepsis is the common cause of death from health care associated infections. HAIs are amenable to infection prevention and control measures, such as appropriate hand hygiene and the correct application of simple and low-cost basic precautions during invasive procedures.

Currently the word sepsis is largely unknown to the general public and media. Most people are unaware of early signs and symptoms of sepsis. It is poorly known that every acute infection may progress to life threatening sepsis, for which an effective cure requires not only treatment of the



underlying infection but rigorous acute care interventions to stabilize the cardio-respiratory system and other organ functions. Lack of awareness and knowledge about sepsis can have disastrous results: a) health care professionals can miss the diagnosis and delay onset of treatment. b) Mortality and morbidity due to delay in seeking appropriate medical care. There is increasing evidence that all these factors make sepsis worldwide the number one cause of preventable deaths.

## 2. A PUBLIC HEALTH ISSUE

Accurate data on the incidence of sepsis in low and middle-income countries are virtually non-existent, however, if we extrapolate from data in high income countries conservative estimates suggest more than 30 million new sepsis cases throughout the world each year. At least 8 million people including 5 million neonates and young children die from sepsis. More than two million of these deaths are preventable. Estimates on the global burden of sepsis are limited due to the absence of reliable population-based data from low- and middle-income-countries. The true global burden of sepsis in low-income countries remains uncertain and may be much higher because infectious diseases are more prevalent and most likely carry a much higher mortality rate than in the high-income-countries.

Sepsis affects all age groups; most vulnerable are women in the postpartum period, new-borns, elderly above age 60, and children under five years of age in resource poor areas. The incidence of sepsis is higher in males than in females, and higher in socio-economically disadvantaged groups. Sepsis is the leading cause of death from lower respiratory tract infections (LRTI). Death from LRTI was ranked as the number one cause of global years of life lost in the Global Burden of Disease Report 2010, yet LRTI *per se*, at least in the developed world, rarely results in death; deaths occur when the LRTI causes sepsis and sepsis is the cause of death. The elderly with chronic disease and weakened immune systems, patients who have had their spleen removed surgically or through disease, and those under treatment with immunosuppressive medications are at increased risk for sepsis. HIV-positive individuals have an up to tenfold higher incidence of sepsis. Patients with diabetes, cancer, chronic kidney or liver disease are also at increased risk, as are pregnant women and those who have experienced a severe burn or physical injury. In the developing world, sepsis accounts for 60-80% of lost lives per year, accounting for the deaths of 5 million newborns and children annually. It is estimated that puerperal sepsis causes at least 75,000 maternal deaths every year, mostly in low-income countries. In these countries, malnutrition, poverty, lack of access to vaccines and timely treatment all contribute to death from sepsis. In the developed world, the reported incidence of sepsis is increasing by an annual rate of between 8-13 % over the last decade. This increase can be partly attributed to improved documentation of sepsis. However, other reasons to explain the increase are an aging population, increasing use of high-risk medical and surgical interventions in all age groups, the development of drug-resistant and more virulent varieties of infections.

In resource rich countries with adequate intensive care unit availability, treatment for sepsis often involves a prolonged stay in the intensive care unit and complex therapies, which incur high costs. In some countries sepsis is ranked as the most expensive medical condition accounting for approximately 3% of the national health care expenditures. The costs related to long-term impacts of sepsis have not been quantified but are likely substantial, including subsequent medical care: the true fiscal burden, considering delayed return to work, the need for families to adjust lifestyles to support, and rehabilitation cost is likely to be huge..

### 3. ...THAT MUST BE A GLOBAL HEALTH PRIORITY

**Coordinating programmes for the prevention and control of sepsis with other related programmes will contribute to the strengthening of health systems in all countries.** To date, efforts and educational programmes on sepsis prevention and treatment by the WHO have been successful but fragmented and were triggered primarily by outbreaks and pandemics with highly virulent and easily transmissible pathogens. WHO does not yet have a comprehensive strategy for sepsis that embraces the broad spectrum of the burden in the community as well as in health care setting in all parts of the world. Thus, the time is right for WHO and national governments to set in place a comprehensive strategy which creates new opportunities for prevention, increases early recognition by appropriate educational programmes and improves access to appropriate rehabilitation and after-care for sepsis survivors. The impact of these efforts on mortality and morbidity will be significant because of the tremendous burden of disease.

### 4. ...AND REQUIRES JOINT ACTION FROM WHO AND ITS MEMBER STATES

The WHO is in a position to provide coordinated global support and leadership in the development of a comprehensive approach spanning the entire health system for the prevention and control of sepsis. A resolution on sepsis would be a formal next step to engage in concerted global action. It would be an opportunity to bring on board low- and middle-income countries, for which sepsis is a challenge, and to ensure global action. A resolution will contribute

- To raise awareness globally that sepsis is more common than heart attacks and kills more people than any cancer.
- To highlight that sepsis is the most common cause of death from community acquired and health care associated infections.
- To convey the message that sepsis can be prevented by simple measures such as hand hygiene and vaccines
- To highlight that sepsis can be effectively treated by better education of health care workers and lay people on early recognition of the symptoms of sepsis and access to simple, low-cost and effective diagnostic and treatment interventions.
- To highlight that prevention and management of sepsis plays an important role in patient safety and in reaching major targets of the United Nations sustainable development goals by 2030, in particular reducing maternal and neonatal mortality as well as achieving Universal Health Coverage.



**From:** ASHFORTH, Nicolas Cameron  
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**To:** CIPRIOTT, Denise Claire  
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Fyi

Envoyé de mon iPhone

Début du message transféré :

**Expéditeur:** "ARMSTRONG, Timothy Peter" <[armstrongt@who.int](mailto:armstrongt@who.int)>  
**Date:** 10 septembre 2016 19:27:31 UTC+2  
**Destinataire:** "ASHFORTH, Nicolas Cameron" <[ashforthn@who.int](mailto:ashforthn@who.int)>  
**Objet:** TR : Additional Agenda Item Sepsis EB 140

FYI

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Begin forwarded message:

**From:** NISHIZAWA HIDEAKI  
<[hideaki.nishizawa@mofa.go.jp](mailto:hideaki.nishizawa@mofa.go.jp)>  
**Date:** 10 September 2016 at 18:44:16 GMT+2  
**To:** "ARMSTRONG, Timothy Peter" <[armstrongt@who.int](mailto:armstrongt@who.int)>, "VEA, Gina Rene" <[veag@who.int](mailto:veag@who.int)>  
**Cc:** "[wi-1-io@genf.auswaertiges-amt.de](mailto:wi-1-io@genf.auswaertiges-amt.de)" <[wi-1-io@genf.auswaertiges-amt.de](mailto:wi-1-io@genf.auswaertiges-amt.de)>, Chariklia Balas <[Chariklia.Balas@bmg.bund.de](mailto:Chariklia.Balas@bmg.bund.de)>, 駒田 謙一(komada-kenichi) <[komada-kenichi@mhlw.go.jp](mailto:komada-kenichi@mhlw.go.jp)>  
**Subject:** FW: Additional Agenda Item Sepsis EB 140

Dear Timothy and Gina,

We, Japan would like to support proposal from Germany to include sepsis into EB Agenda and add ourselves to co-sponsors.  
Best regards,

Hideaki



差出人: .GENFIO WI-1-IO Jarasch, Cornelia  
送信日時: 2016年9月5日 11:45  
宛先: NISHIZAWA HIDEAKI  
CC: Chariklia Balas  
件名: Additional Agenda Item Sepsis EB 140

Dear Hideaki,

Together with several other Member States we proposed an additional agenda item for the next EB that would deal with Sepsis. Please find attached the Memorandum with the background and the rationale.

We would greatly appreciate your support for this issue. If Japan decides to support the inclusion of this item, we would be most grateful if you could communicate it to GBO ([armstrongt@who.int](mailto:armstrongt@who.int); [veag@who.int](mailto:veag@who.int)) before September 12.

Looking forward to hearing from you,

Best regards,

Cornelia

Cornelia Jarasch

*First Secretary (Health / WHO)*  
*Ständige Vertretung der Bundesrepublik Deutschland*  
*Permanent Mission of the Federal Republic of Germany*  
*28 C, Chemin du Petit-Saconnex*  
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*[www.genf.diplo.de](http://www.genf.diplo.de)*

**Von:** .GENFIO WI-1-IO Jarasch, Cornelia  
**Gesendet:** Dienstag, 23. August 2016 15:49  
**An:** HERNANDEZ, Lindsey Caroline; SMITH, Ian Michael; ARMSTRONG, Timothy Peter  
**Cc:** VEA, Gina Rene ([veag@who.int](mailto:veag@who.int)); Chariklia Balas; Dagmar Reitenbach -Z23 BMG ([Dagmar.Reitenbach@bmg.bund.de](mailto:Dagmar.Reitenbach@bmg.bund.de)); Guinote Hendrik-Schmitz; OR-G-L Bergner, Tobias; BMG-Z23 ([z23@bmg.bund.de](mailto:z23@bmg.bund.de)); 'kelleye@who.int'  
**Betreff:** Letter German MoH Größe - DG: Agenda Item Sepsis EB 140

Dear Ian, Dear Timothy,

please find attached the copy of a letter from MoH Gröhe to DG Chan regarding the proposal of an additional Agenda item for EB 140 / WHA70. This letter is accompanied by an explanatory memorandum. The proposal is put forward jointly by Austria, Germany, Ireland, Israel, Luxembourg, Serbia, Switzerland. We expect additional MS to support it and will ask them to express their support via email to GBS.

The original of the letter is currently transmitted to the Director General's Office.

With kind regards

Cornelia Jarasch

*First Secretary (Health / WHO)*  
*Ständige Vertretung der Bundesrepublik Deutschland*  
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## MEMORANDUM

To: WHO Director-General Dr. Margaret Chan

Re: Proposal put forward by Austria, Germany, Ireland, Israel, Luxembourg, Serbia, Switzerland to include an item on “Sepsis” to the Agenda of the 70th Session of the World Health Assembly

### 1. OVERVIEW

Sepsis, commonly known as blood poisoning, is a syndromic response to infection and the final common pathway to virtually all deaths from infectious diseases of all origins worldwide. Despite medical progress with use of better vaccines, antibiotics and acute care, hospital mortality rates of sepsis in the best healthcare systems in high-income countries range between 10 and 50%. Sepsis arises when the body's attempt to fight an acute infection leads the immune system into overdrive which causes damage to multiple organs and circulatory shock. That is why appropriate treatment of sepsis requires not only treatment of the underlying infection with antimicrobials, but in parallel requires life-saving medical interventions such as fluid resuscitation or vital organ support. The majority of sepsis cases are caused by infections targeting the respiratory, gastrointestinal and urinary tract and may also be triggered by wound/skin infections. Most types of microbes can cause sepsis, including bacteria, fungi, viruses and parasites such as those causing malaria. Sepsis may result from a healthcare related infection, however, even in the developed world the majority of sepsis is community acquired. Bacteria are by far the most common culprit, but sepsis is also the fatal common pathway of viral infections with seasonal influenza viruses, Dengue viruses and infections that have emerged as pathogens of public health concern such as avian flu, swine flu, SARS, MERS-CoV and most currently Ebola Virus disease. For most of these emerging pathogens there are no effective antiviral agents and supportive sepsis care is the only therapeutic option.

Enormous progress has been made through the introduction of and improved access to vaccinations which save an estimated 2 -3 million lives a year by preventing infections which can lead to sepsis. However, an estimated 18.7 million infants worldwide are still unimmunized.

There is a lack of awareness among the general public and public health authorities that vaccinations against influenza, *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Neisseria meningitidis* are lifesaving. Vaccinations against *Haemophilus influenzae* and *Streptococcus pneumoniae* are recommended for all children worldwide and meningococcal vaccines depending on regional epidemiology. Furthermore, all 4 vaccines are recommended for certain groups such as immunocompromized patients being at special risk of sepsis. In many developing countries, however, there is no vaccination program for elderly people or people at risk. Vaccines are not only an important tool to prevent sepsis but also essential to hinder the emerge of multiresistant pneumococcal strains.

Health care-associated infections (HAIs) are the most frequent adverse events in health-care delivery worldwide and a major patient safety issue. Hundreds of millions of patients are affected by health care-associated infections worldwide each year, leading to significant mortality and financial losses for health systems. Sepsis is the common cause of death from health care associated infections. HAIs are amenable to infection prevention and control measures, such as appropriate hand hygiene and the correct application of simple and low-cost basic precautions during invasive procedures.

Currently the word sepsis is largely unknown to the general public and media. Most people are unaware of early signs and symptoms of sepsis. It is poorly known that every acute infection may progress to life threatening sepsis, for which an effective cure requires not only treatment of the



underlying infection but rigorous acute care interventions to stabilize the cardio-respiratory system and other organ functions. Lack of awareness and knowledge about sepsis can have disastrous results: a) health care professionals can miss the diagnosis and delay onset of treatment. b) Mortality and morbidity due to delay in seeking appropriate medical care. There is increasing evidence that all these factors make sepsis worldwide the number one cause of preventable deaths.

## 2. A PUBLIC HEALTH ISSUE

Accurate data on the incidence of sepsis in low and middle-income countries are virtually non-existent, however, if we extrapolate from data in high income countries conservative estimates suggest more than 30 million new sepsis cases throughout the world each year. At least 8 million people including 5 million neonates and young children die from sepsis. More than two million of these deaths are preventable. Estimates on the global burden of sepsis are limited due to the absence of reliable population-based data from low- and middle-income-countries. The true global burden of sepsis in low-income countries remains uncertain and may be much higher because infectious diseases are more prevalent and most likely carry a much higher mortality rate than in the high-income-countries.

Sepsis affects all age groups; most vulnerable are women in the postpartum period, new-borns, elderly above age 60, and children under five years of age in resource poor areas. The incidence of sepsis is higher in males than in females, and higher in socio-economically disadvantaged groups. Sepsis is the leading cause of death from lower respiratory tract infections (LRTI). Death from LRTI was ranked as the number one cause of global years of life lost in the Global Burden of Disease Report 2010, yet LRTI *per se*, at least in the developed world, rarely results in death; deaths occur when the LRTI causes sepsis and sepsis is the cause of death. The elderly with chronic disease and weakened immune systems, patients who have had their spleen removed surgically or through disease, and those under treatment with immunosuppressive medications are at increased risk for sepsis. HIV-positive individuals have an up to tenfold higher incidence of sepsis. Patients with diabetes, cancer, chronic kidney or liver disease are also at increased risk, as are pregnant women and those who have experienced a severe burn or physical injury. In the developing world, sepsis accounts for 60-80% of lost lives per year, accounting for the deaths of 5 million newborns and children annually. It is estimated that puerperal sepsis causes at least 75,000 maternal deaths every year, mostly in low-income countries. In these countries, malnutrition, poverty, lack of access to vaccines and timely treatment all contribute to death from sepsis. In the developed world, the reported incidence of sepsis is increasing by an annual rate of between 8-13 % over the last decade. This increase can be partly attributed to improved documentation of sepsis. However, other reasons to explain the increase are an aging population, increasing use of high-risk medical and surgical interventions in all age groups, the development of drug-resistant and more virulent varieties of infections.

In resource rich countries with adequate intensive care unit availability, treatment for sepsis often involves a prolonged stay in the intensive care unit and complex therapies, which incur high costs. In some countries sepsis is ranked as the most expensive medical condition accounting for approximately 3% of the national health care expenditures. The costs related to long-term impacts of sepsis have not been quantified but are likely substantial, including subsequent medical care: the true fiscal burden, considering delayed return to work, the need for families to adjust lifestyles to support, and rehabilitation cost is likely to be huge..

### 3. ...THAT MUST BE A GLOBAL HEALTH PRIORITY

**Coordinating programmes for the prevention and control of sepsis with other related programmes will contribute to the strengthening of health systems in all countries.** To date, efforts and educational programmes on sepsis prevention and treatment by the WHO have been successful but fragmented and were triggered primarily by outbreaks and pandemics with highly virulent and easily transmissible pathogens. WHO does not yet have a comprehensive strategy for sepsis that embraces the broad spectrum of the burden in the community as well as in health care setting in all parts of the world. Thus, the time is right for WHO and national governments to set in place a comprehensive strategy which creates new opportunities for prevention, increases early recognition by appropriate educational programmes and improves access to appropriate rehabilitation and after-care for sepsis survivors. The impact of these efforts on mortality and morbidity will be significant because of the tremendous burden of disease.

### 4. ...AND REQUIRES JOINT ACTION FROM WHO AND ITS MEMBER STATES

The WHO is in a position to provide coordinated global support and leadership in the development of a comprehensive approach spanning the entire health system for the prevention and control of sepsis. A resolution on sepsis would be a formal next step to engage in concerted global action. It would be an opportunity to bring on board low- and middle-income countries, for which sepsis is a challenge, and to ensure global action. A resolution will contribute

- To raise awareness globally that sepsis is more common than heart attacks and kills more people than any cancer.
- To highlight that sepsis is the most common cause of death from community acquired and health care associated infections.
- To convey the message that sepsis can be prevented by simple measures such as hand hygiene and vaccines
- To highlight that sepsis can be effectively treated by better education of health care workers and lay people on early recognition of the symptoms of sepsis and access to simple, low-cost and effective diagnostic and treatment interventions.
- To highlight that prevention and management of sepsis plays an important role in patient safety and in reaching major targets of the United Nations sustainable development goals by 2030, in particular reducing maternal and neonatal mortality as well as achieving Universal Health Coverage.



**To: World Health Organization**  
Department for Governing Bodies and External Relations

The Permanent Mission of Mexico has the honor to make reference to the note C.L.26.2016 regarding the draft provisional agenda for the 140<sup>th</sup> meeting of the Executive Board, to be held in Geneva from January 23 to February 1, 2017.

In this regard, the Permanent Mission has the honor to convey the request of the Government of Mexico for the addition of an agenda item in the aforementioned draft provisional agenda entitled **“Regulatory system strengthening for medical products: acceleration and follow up of implementation”**. The Permanent Mission encloses to this message the concept note explaining the proposal and request.

The Permanent Mission would like to appeal the WHO Secretariat to transmit the aforementioned request of the Government of Mexico to the Members of the Bureau of the Executive Board, for the corresponding consultation and decision making by that Bureau and the preparation of the provisional agenda by the WHO Director-General which will be adopted during the 140<sup>th</sup> meeting of the Executive Board.

The Permanent Mission encloses also to this message the official note dated on September 12<sup>th</sup> which has been sent by post.

**Permanent Mission of Mexico**



MISIÓN PERMANENTE DE MÉXICO

OGE02988

La Misión Permanente de México ante la Oficina de las Naciones Unidas y otros Organismos Internacionales con sede en Ginebra saluda muy atentamente a la Organización Mundial de la Salud (OMS) y tiene el honor de hacer referencia a la 140ª sesión del Consejo Ejecutivo de la OMS, que tendrá lugar del 23 de enero al 1º de febrero de 2017 en Ginebra.

Al respecto, y en seguimiento del contenido de la nota C.L.26.2016, la Misión Permanente tiene el honor de transmitir la solicitud del Gobierno de México para la inclusión de un punto en el orden del día provisional de dicha reunión, con el título ***Regulatory system strengthening for medical products: acceleration and follow up of implementation***. Se anexa el respectivo memorándum explicativo.

La Misión Permanente de México ruega a la Secretaría de la OMS que la presente solicitud sea transmitida a los Miembros de la Mesa del Consejo Ejecutivo, para la correspondiente consulta y toma decisión por dicha Mesa y posterior preparación por la Directora General de la OMS del orden del día que deberá ser adoptado en la reunión.

La Misión Permanente de México ante la Oficina de las Naciones Unidas y otros Organismos Internacionales con sede en Ginebra aprovecha la oportunidad para reiterar a la Organización Mundial de la Salud las seguridades de su más alta y distinguida consideración.

Ginebra, a 12 de septiembre de 2016

A la Organización Mundial de la Salud,  
Ginebra

## MEMORANDUM

**TO:** WHO Director General Margaret Chan

**Re:** Proposal to include an item on the **“WHA67.20: Regulatory system strengthening for medical products: acceleration and follow up of implementation”** in the context of point 8. Health System of the EB 140 draft agenda

### OVERVIEW

WHO has made statement through the resolution WHA 67.20 and the leadership priorities that: “We will continue to improve access to safe, quality, affordable and effective medicines. We will support innovation for affordable health technology, local production, and national regulatory authorities”. As indicated in the resolution WHA 67.20 , the Director-General is requested to :

- (1) to continue to support Member States upon their request in the area of regulatory system strengthening, including, as appropriate, by continuing to:
- (12) to report to the Seventieth \*2017 and Seventy-second \* 2019 World Health Assemblies on progress in the implementation of this resolution.

### THE ISSUE

**NRAs:** National Regulatory Authorities (NRAs) are becoming a key and critical stakeholder of the national health system through their action towards ensuring quality, safety and efficacy of health products and technologies. Increasing health issues or emerging health matters called for these institutions to enlarge their mandate or have to deal with more complex issues related to health. Several NRAs are dealing not only with regulation of health products and technologies but also managing food, environment or emergencies. The gain obtained in the area of health products and technologies can be used to enhance the regulatory capacity in other areas. So the need for documenting best practices through a Good Regulatory Practices model is needed.

**Lack of global Good Regulatory Practice (GRP) model to guide development of NRAs:** Several functional or stringent regulatory system have already developed good regulatory practices, WHO has started the development of this model and we hope to have it endorsed in 2016, the issue however will be with the implementation. Existing harmonization efforts and existing networks of regulatory agencies are aiming to increase exchange among NRAs and related institutions. However only 35% of NRAs have been assessed by WHO as functional in the area of vaccines and WHO has documented almost the same figures for regulation of all other health products and technologies. The concept of functionality is used for vaccine regulation while the concept of stringent regulatory

authorities is used for medicine pre-qualification (mainly ICH members), nevertheless, Mexico believes the model and concept can be harmonized to determine the minimal regulatory capacity a country should aim for regulating and ensuring quality, safety and efficacy of all health products and technologies. Therefore, it is important to build up and disseminate the concept of minimal regulatory capacity using the above mentioned functional or stringent regulatory systems capacity and guidance.

**Access to health and minimal regulatory capacity of NRAs:** The industry is constantly developing new products that can increase or improve access to health. Nevertheless, most regulatory systems don't have enough capacity to assess independently and competently new products so they can speed access to new medicines. WHO established the prequalification programme which efficiently increased access, however, the scope and growth of health products is so wide that the current programme will not be able to address all health needs and products. One reason is that countries' needs and health issues require significant technical expertise to regulate these products and sustain high supervision through proper pharmacovigilance and inspections. Another reason is their lack or limited guidance to implement the GRP, limited staffing or expertise, or no access to relevant guidance on site to develop their capacity.

**Coordinated efforts using regulatory excellence to drive acceleration of the resolution WHA 67.20:** Among the functional or stringent regulatory system documented by WHO, there are already several NRAs that have developed international programme to support and exchange with other regulatory systems. A well-coordinated effort of existing regulatory excellence (regulatory sciences and GRP) can make a significant difference for supporting WHO goals to achieve the Universal Health Coverage and consequently the Sustainable Development Goals through the WHO 67.20's resolution.

Mexico like some other regulatory agencies has established under the APEC development programme in COFEPRIS a centre of excellence (CoE) in August 2016 with the objective to enhance and promote Regulatory Sciences (RS) and Good Regulatory Practices (GRP) including Good Regulatory Management (GRM). COFEPRIS has also contributed to the development of the WHO Good Regulatory Practice guidance that will be submitted for review and endorsement to the WHO expert committees (ECPP and ECBS) in October 2016.

## **1. PRIORITY FOR WHO**

As describe above this proposal meets the requirement for submitting the agenda items as it addresses a global public-health issue (ensuring and sustaining functional regulatory system of member states health systems), raises a new subject (using innovative model to implement a resolution) within the scope of WHO and that will impact or represents a

significant public health burden (addressing the quality safety and efficacy of health products and technologies).

Moreover the subject matter proposed is consistent with the World Health Organization leadership priorities such as: a) Universal health Coverage, b) increasing access to medical products and c) Sustainable Development Goals. It is also coherent and consistent with the current WHO global Programme of Work and it is not requesting more budget resources but helping to find out additional resources.

This proposal is firstly aimed to help WHO and member states to use an innovative mean to obtain resources that will ensure acceleration of implementation of the above mentioned resolution. The innovative mechanism proposed will allow to establish a WHO model of Center of Excellence (CoE) hosted within NRAs and to use existing WHO Collaborating Center (CC) or potentially new one to deliver and support WHO in achieving the WHA 67.20 resolution objectives. Secondly is also aimed to ensure that a meaningful report is submitted to Member States for the next WHA.

## 2. SIGNIFICANT BURDEN FOR THE HEALTH<sup>1</sup>

NRAs have to deal with all health products and technologies that have a significant impact on health of people through the quality, safety and efficacy. The lack of a competent regulatory system and the non-access to a WHO prequalification programme products leads to high risk products not meeting quality, safety or efficacy standards to be used and maybe harmful for the concerned population.

## CONCLUSION

Mexico would like to propose a new agenda item for the 140th Session of the World Health Organization (WHO) Executive Board on the **“WHA67.20: Regulatory system strengthening for medical products: acceleration and follow up of implementation”** in the context of point 8. Health System of the EB 140 draft agenda. Mexico is also contacting other Member States to support the above agenda item.





*Rappresentanza Permanente d'Italia  
presso le Organizzazioni Internazionali  
10, Chemin de l'Impératrice  
1292 Genève*

2111

The Permanent Mission of Italy to the United Nations and other International Organizations presents its compliments to the World Health Organization and, in view of the forthcoming 140th Session of the WHO Executive Board to be held in Geneva, from 23 January to 1 February 2017, has the honor to request the inclusion of a new agenda item on "Promoting health of fragile and vulnerable populations, communities and individuals, such as migrants".

This issue represents a Public Health challenge and a clear priority. Health issues related to population movements have been on the WHO agenda for many years. We must ensure that our health systems are adequately prepared to provide support to refugees and migrants while at the same time protecting the resident population's health. This requires cooperation among the countries of origin, transit and destination. The issue deserves a follow-up to the discussions which took place at EB 138 and WHA 66 when there has been a very successful Technical Briefing.

The Italian Authorities strongly believe awareness must be raised and documented and an appropriate response to the refugees and migrants' health needs must be formulated and implemented urgently. Actions are needed between and within countries as well as among sectors.

It is our responsibility as Member States to adopt measures in order to guarantee adequate standards of care for refugees and migrants as they are not only a global good but are also crucial for protecting and promoting their human rights as well as those of the host communities. No individual country, sector or organization can manage this theme alone.

In light of the above, the Italian Authorities would highly appreciate if the Executive Board can consider this request favorably and include this item in the Provisional Agenda of its 140th Session.

The Permanent Mission of Italy avails itself of this opportunity to renew to the World Health Organization the assurance of its highest consideration.

Geneva, 9 september 2016

World Health Organization  
GENEVA





**Memorandum for an additional Item at EB 140 on “Promoting health of fragile and vulnerable populations, communities and individuals, such as migrants”.**

Direct and indirect health determinants influence **health outcomes, increasing or decreasing the vulnerability and resilience of individuals, groups and communities**. The lower a person's social and economic position is, the worse his or her health will be. Because determinants are not equally distributed the health divide between countries and the social gradient between people, communities and areas within countries are increasing.

Vulnerability in health results from exclusions from benefits and services, related to inequities in the distribution of power, money and resources, and the opportunities for life. The most vulnerable communities are those whose rights to access services are denied, neglected or are just difficult to ensure under the current paradigms.

Among them, migrants are possibly those at highest risk, as they are frail, have limited and often not acknowledged rights and have no organized health system capable to identify their needs and prevent and treat their diseases timely.

Member States should **address inequities** in the state of health of migrants, Roma and others ethnic minorities made vulnerable through exclusionary processes, ensuring access to quality health and social services delivered in a cultural sensible way. Many of the strategies for achieving this include **specific actions** such as training of health care workers in working with minority and marginalized populations, design, implementation and evaluation of health programmes, improvement of health information systems, and the formulation of integrated policy approaches designed to overcome the multiple causes of social exclusion.

The **current situation of migration in Europe** underlines the vulnerability of most migrants left alone in arranging their own hazardous migration. Only in 2015, over 1 million refugees and migrants reached European countries, adding to the over 2.5 million who had taken shelter in Turkey by the end of the year. In addition, throughout 2015, more than 3,700 refugees and migrants are known to have died or gone missing at sea. Up to July 2016, over 240,000 have arrived to Europe and over 2,900 have died or gone missing at sea. It must be underlined also that the migration process cannot grant adequate housing, labour and access to basic services, including food and nutrition.

**There are tools and resolutions that help** in achieving concrete health improvements. For example, the **WHO European health policy framework Health 2020** provides a tool to address the fact that overall health is improving but the poor and vulnerable all too often get left behind. This allows addressing the health of fragile and vulnerable population by engaging a variety of non-state and governmental actors, such as home and foreign affairs, justice, labour, social affairs, education and health, whose policies and interventions have implications across sectors.

Additionally, the **World Health Assembly resolution on the Health of migrants 61.17 of 2008** called for Member States to consider with particular attention the provision of health services sensitive to the needs of migrants, taking into consideration their cultural, religious, linguistic and gender requirements. This document underlines that special attention must be given to migrant women and children who are even more vulnerable on several grounds. The main principle is that **applying an equity approach** to health and non-health interventions, promoting understanding and scaling up dialogue among health and non-health sectors, will make countries' health systems more inclusive and will have a positive impact on the macroeconomic indicators of a country, benefiting the migrant population as well as society as a whole. This approach is equally in line with the scope of the 2030 Agenda for Sustainable Development, in which countries pledged that “no one should

be left behind”, and its Sustainable Development Goals, in particular Goal 3 on health, Goal 5 on gender equality, and Goal 10 on reducing inequalities within and among countries.

The work done by a number of Governments and by WHO EURO shows that **countries together can do more** to equip themselves to face the challenges posed by migration, including the preparation of a Strategy and action plan for refugee and migrant health in the WHO European Region, which has been developed in line with the above-mentioned documents and will be submitted for the approval of the WHO Regional Committee for Europe in September 2016. In order to achieve better health for vulnerable groups, policy makers need to use two types of strategies: action within each country, addressing the specific demographic and political challenges; and **action at transnational level**, harmonizing policies and improving preparedness.

**EB140** offers the opportunity to discuss the state of art, the relevance of the tools that are available, the status of implementation, and way forward to strengthen country capacity to deal with the challenges posed by migration at transnational level. The framework shall be updated and reconsidered in light of the current situation and the short and midterm foresights. In addition, **EB139** offers the opportunity to continue the discussion held during the World Health Assembly in May 2016, where multiple countries called for the scale up of WHO’s support in the area of migration and health, and agree on next steps. The development of a global strategy was mentioned by several delegations as means of bringing coherence to the health response to migration, a phenomenon of global nature. The Ministry of Health of Italy has widely supported WHO/Europe’s work in this area as well as the development to the European strategy and action plan; along the same lines, it stands ready to support action on migration and health at the global level.

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Ministry of Health, Nutrition & Indigenous Medicine

Dr. Margaret Chan  
Director General  
World Health Organization

Dear Madam,

**Proposal for inclusion of Migration Health into the agenda of the 140<sup>th</sup> Executive Board of WHO (reference to WHA61.17/2008)**

We would like to express our gratitude in recognizing Migration Health as an important determinant of health in the SEA region by the World Health Organization.

Based on our experience in promoting migrants' health, we would like to propose the attached amendments to the already available list of recommendations of the above Resolution (WHA61.17/2008) and to propose that they be discussed at the 140<sup>th</sup> Executive Board meeting of the WHO. The proposal is annexed.

Thanking you

Anura Jayawickrama  
Secretary/Health

Anura Jayawickrama  
Secretary  
Ministry of Health, Nutrition & Indigenous Medicine  
"Suvassiripaya"  
385/Rev. Baddegama Wimalawansa Thero Mawatha, Colombo 10, Sri Lanka.

CC: Dr. Ravinatha Ariyasinha, Permanent Representative for the United Nations for Sri Lanka  
Dr. Poonam Singh, Regional Director, SEA Regional Office  
Dr. Jacob Kumaresan, Country Representative, Sri Lanka

**Proposal for inclusion of Migration and Health into agenda of 140th Executive Board of WHO (reference to WHA61.17/2008)**  
**Proposed by Sri Lanka**

**Background**

More than eight years have passed since the adaptation of the resolution on Health of Migrants the 61<sup>st</sup> World Health Assembly in 2008. The resolution calls upon the Member States to promote migrant sensitive health policies and equitable access to health services, to gather and share information related to migration health and to build capacities of service providers to provide migrant sensitive health services. The resolution however does not urge the Member States or the Director-General to regularly monitor the progress of actions at regional and global levels. We see it as a gap that should be addressed in the purview of accelerating the progress made by the Member States in this regard.

As a country in the SEA region that have progressed in the field of migration health, we would also like to recommend two actions to be included in the resolution. We've learnt that identifying knowledge gaps by a national research agenda on migration is important and conducting rapid situation analyses facilitate prioritizing knowledge gaps to be addressed. Migration health involves coordination and collaboration between different sectors. Thus, a national level focal point and a steering committee is important in efficient inter-sectoral and inter-agency collaboration.

Based on the above, we would like to propose to include the following to the already available list of recommended actions of the above Resolution and for this to be discussed at the 140th Executive Board meeting of the WHO

**1. CALLS UPON Member States:**

- 1) to conduct rapid situation analyses and identify the knowledge gaps to be addressed by a national research agenda
- 2) to identify national focal points and establish national level steering committees and task forces to facilitate and implement evidence based strategies on promoting and protecting migrants' health

**2. REQUESTS the Director-General:**

- 1) to review and regularly monitor the progress of the member states at least bi-annually, at the regional and global levels in implementation of the recommended strategies to protect and promote migrants' health