# 16.4 Global vaccine action plan

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# In focus at WHA68

The Assembly will have before it <u>A68/30</u> which was considered and noted by the EB in January. In line with resolution <u>WHA65.17</u>, the report describes the progress made towards the achievement of the global immunization targets, using the monitoring and accountability framework approved by the Sixty-sixth World Health Assembly, and conveys also the assessment report of the GVAP by the Strategic Advisory Group of Experts on immunization (SAGE), which met in October 2014.

The Assembly will be invited to take note of the report and to consider the recommendations (of the SAGE) for actions to be taken by the various stakeholders of the <u>global vaccine action plan</u> (GVAP) (adopted in May 2012) in particular by Member States.

There may be a resolution committing to the SAGE recommendations.

# Background

<u>A68/30</u> provides a summary report of the <u>2014 Assessment Report by the Strategic Advisory</u> <u>Group of Experts (SAGE) on immunization</u> which itself was based on the <u>GAVI Secretariat 2014</u> <u>Draft Report</u>. <u>A68/30</u> is a very summarised version of the <u>SAGE report</u> which is much more hard hitting and useful.

The SAGE report finds that progress, with respect to the implementation of the GVAP is 'far off track'. Five of the six goals set by the <u>GVAP</u> with deadlines at the end of 2014 or 2015 still require substantial progress to get the goals on track (poliovirus transmission interruption, maternal and

neonatal tetanus, measles and rubella elimination, and DTP3 coverage targets). Most have seen very little progress. Some have been missed multiple times before.

The SAGE report recommends that action focus particularly on addressing five priority problems:

- 1. Weak implementation,
- 2. Poor quality and use of data,
- 3. Vaccine affordability and supply,
- 4. Failures of basic integration, and
- 5. Situations disrupting immunisation.

Specific recommendations under each of these headings are briefly summarised in <u>A68/30</u> and but are elaborated more fully in the <u>SAGE report</u>.

See notes of the discussion of this item at EB136 here.

# PHM Comment

The SAGE report is unequivocal: 'stagnant vaccine coverage' and 'eradication and elimination goals repeatedly missed'.

In the following commentary PHM highlights:

- the limitations of vertical funding programs as compared with investing in health systems strengthening based on comprehensive primary health care;
- the significance of the continuing underfunding of WHO in relation to immunisation and the need for real WHO reform;
- the need for WHO action on pricing, affordability and procurement;
- the need for more critical attention to the opportunity costs associated with the introduction of expensive new vaccines;
- the need for all of WHO's regional and country offices to work with ministries of health to
  encourage the full implementation of the GVAP and regional and national plans and to
  provide technical support especially in relation to information systems and national policy
  making.

# Health systems strengthening and primary health care

Under the heading, 'failures of basic integration', the SAGE report regrets the lost opportunities to immunise where primary health care providers are not sufficiently conscious of the importance of immunisation. The report comments, "This is how programmatic silos at global and national level can unfortunately affect what happens in health care facilities."

Elsewhere in the report the SAGE comments on the failure to progress maternal and neonatal tetanus elimination. The report speaks of "gross underfunding" and notes that tens of thousands of babies die each years with 20 or more countries still affected.

Elimination of maternal and neonatal tetanus depends on real health system strengthening with comprehensive primary health care provision and strong referral and support relationships to secondary and tertiary facilities.

Surprisingly there is no reference in this report to comprehensive primary health care as a model which highlights the whole of population responsibility of primary health care providers and which explicitly promotes integration of services.

The <u>2013 SAGE meeting</u> noted "the importance of improved coordination and integration of immunisation initiatives with other critical public health interventions such as clean water and sanitation programs to ensure universal health coverage. Social determinants of health should be taken into consideration when integrating routine immunisation into primary health care...". This insight is lacking from the 2014 evaluation report.

It is surprising that the (2014) SAGE report recommends giving civil society organisations (CSOs) 'substantially more formal involvement in the delivery and improvement of vaccination services'. This is the route for further disintegration of primary health care systems. The priority should be for the development of strong public health systems based on the comprehensive primary health care model, not out-sourcing to NGOs.

PHM notes also the ambivalence of GAVI in relation to the need for health systems strengthening (HSS). On the one hand GAVI's CSO HSS Platform promotes the role of CSOs in advocacy for HSS but the direction of such HSS is largely focused on strengthening health system capacity to delivery immunisation.

### 'Programmatic silos'

PHM appreciates the recognition by the SAGE of the fragmenting impact of vertical programmatic silos. Clearly the continued domination of vaccination assistance by GAVI illustrates, reflects and perpetuates the fragmentation which the report criticises.

The gross underfunding of WHO, which does promote a coherent integrated approach to health care and public health, is part of the cause of the stagnation of the 'Decade of Vaccines'.

In this context it is not clear why the SAGE recommends that the GVAP secretariat agencies (Bill & Melinda Gates Foundation, GAVI Alliance secretariat, UNICEF, US National Institute of Allergy and Infectious Diseases and WHO) approach World Economic Forum to seek help in the implementation of the Decade of Vaccines. It may be that such an approach will yield more funding for GVAP (although DAH funding generally appears to be declining) but it is also likely to further entrench the vertical programmatic silo approach to global health priorities.

## WHO Reform

The SAGE report aims some legitimate criticism at WHO's regional offices and regional committees for failing to establish regional and national verification committees regarding measles, rubella and CRS elimination and for delays in adopting regional vaccine action plans.

The report doesn't repeat the criticism in <u>EB134/13</u> that, "many countries are still lagging behind in the establishment of [National Immunisation Technical Advisory Groups], particularly in the African and Western Pacific regions". This issue was underlined also in the <u>Action Plan</u> where Para 34 urged the establishment of national TAGs "that can guide country policies and strategies based on local epidemiology and cost effectiveness".

PHM appreciates the recommendation that DG asks ministries of health of countries with less than 80% DTP3 coverage to report on challenges, plans and timelines to improve coverage.

PHM calls for meaningful action on WHO Reform: lift the freeze on assessed contributions; reform the regions; and strengthen the accountability of individual member states to the full membership.

# Pricing, affordability, procurement and logistics

The SAGE is critical of the lack of public information regarding vaccine prices. It notes particular concern regarding the affordability of newer vaccines for middle income countries who are not eligible for GAVI support. The clear implication is that there may be price gouging by some vaccine manufacturers and that the availability of more comprehensive price information could strengthen market pressures for more reasonable pricing. PHM supports the urgent need for transparent pricing of vaccines and clearer documentation of price barriers to the introduction of priority vaccines. We note the support expressed at several of the regional committee meetings for this initiative. (At the WPRC Korea asked the committee to guarantee transparency in vaccine costs in each country).

See also recently released MSF report on vaccine pricing (here). The report shows that between 2001 to 2014, the introduction of new vaccines – including those against pneumococcal and diarrhoeal diseases, and cervical cancer – has pushed the cost of a full vaccines package up by 68-fold in the poorest countries, with the pneumococcal vaccine accounting for 45% of the total cost.

PHM urges the EB to act on this set of recommendations from the SAGE but to include an assessment of the scope for further support for technology transfer, local production and pooled regional procurement.

The SAGE was shocked to find that, "In 2013, more than 40% of low and middle-income countries suffered a national level stockout of at least one vaccine that lasted at least one month. ... If anything, 40% may be an under-estimate." Even worse, it appears that the extent and root causes of the problem are not clearly known. This is an issue for the EB to take immediate

action to assess "(i) the extent to which the reported national-level stockouts are affecting local vaccine supply and delivery, and (ii) the root causes of these stockouts".

## Introduction of new vaccines

The GVAP recognises that national strategies for vaccination should respond to priorities and needs of local populations and the efficacy and cost effectiveness of vaccines and immunization campaigns have to be evaluated case by case in the specific country context. This is particularly important as new and increasingly sophisticated vaccines have become available in the last decade. As recognised in the Action Plan (p20), "New and more complex vaccines will bring new funding requirements and countries will be confronted with difficult decisions in dealing with competing health priorities. Resources will need to be allocated more efficiently, with the relevant decisions guided by national priorities, capacity, clear information on the costs and benefits of choices, and improved financial management. Expenditures must be linked to outputs and impacts, showing a clear investment case for immunization."

The opportunity costs of introducing new vaccines, measured in terms of cash and health outcomes forgone, can only be assessed in the specific context of local epidemiology, local health care expenditure and vaccine delivery capacity. Even powerful vaccines have opportunity costs: other ways of spending the same monies which might also contribute to health outcomes. Cost effectiveness comparisons of this sort require consideration of vaccine, disease, health systems and current health expenditure patterns. In health care systems which cannot deliver DTP3 to more than 50% of infants it might make sense to allocate additional resources to primary health care, including basic vaccination and effective treatment of diarrhoea.

Effectiveness depends on absolute risk reduction (ARR) which depends on the burden of disease in each country. The low incidence of invasive Hib disease in Asia is an example. We need country-specific ARR to calculate numbers needed to treat (NNT = 1/ARR) and find cost per case avoided. The inclusion of vaccines like Hib in the immunization schedules of countries with low disease burdens is associated with high opportunity costs.

Many new vaccines target only specific strains of the causative pathogen and their use is limited by the ability of pathogens to mutate and take up the space ceded by strains that are sensitive to vaccines. The country-specific evaluation of cost-effectiveness of new vaccines is essential and has to be conducted through a transparent process that avoids conflicts of interests.

PHM calls upon WHO regional offices and country offices to provide the necessary support for fully informed decisions by countries on this issue, including guidance on the opportunity costs of expensive vaccines for low incidence conditions. This also requires that countries, which have not done so, proceed to establish and strengthen their National Immunisation Technical Advisory Groups.

We are aware that many MSs are also concerned to strengthen the capacity of MSs to undertake broadly based assessments of new vaccines before deciding to add them to the national immunisation schedule. (At the WPRC both China and Malaysia spoke firmly about the need for broadly based national assessments of new vaccines.)

WHO should be concerned about the introduction of new vaccines in the absence of surveillance and information systems covering epidemiology, delivery, and evidence of safety and efficacy. The introduction of HPV vaccination in the absence of properly functioning country-wide cancer registries illustrates the point.

## Data quality and use

The SAGE report argues strongly for action to improve the quality of information systems and the use of data to guide immunisation programs.

The lack of data about vaccine prices and the causes and effects of national stockouts illustrate the need; likewise the data systems needed to support decisions regarding new vaccines - see below.

There is no comment in the report on data regarding adverse events following immunisation (AEFI) but clearly this is another area where information and decision systems need to be strengthened.

We note the controversy over the safety of pentavalent vaccines which in essence is an example of the broader problem of post marketing surveillance. PHM urges WHO to give increased priority to the development of rigorous post-marketing surveillance systems including adverse events following immunisation.

# Clinical trial data reporting

The recent WHO statement on clinical trial data reporting (here) and the subsequent commentary in PLOS (here) not only re-affirms the ethical imperative of clinical trial results reporting, it also defines reporting timeframes, calls for results-reporting of older but still unpublished trials, and outlines steps to improve linkages between clinical trial registry entries and their published results. It states that 'it is unethical to conduct human research without publication and dissemination of the results of that research. In particular, withholding results may subject future volunteers to unnecessary risk'.

Open reporting should extend to post marketing surveillance of vaccines and the confidential disclosure of manufacturers data to the regulator must be deprecated.

# Rubella and congenital rubella syndrome (CRS)

The SAGE report notes that progress on the elimination of rubella and rubella/congenital rubella syndrome (CRS) lags far behind targets.

Unfortunately there is no discussion of the risks of low coverage infant rubella immunisation, in particular the risk that partial population immunity will push the age profile of new cases into the

child-bearing years. In such circumstances a strong case can be made for focusing on adolescent immunisation rather than young child. If countries are unable to deliver high coverage in both infancy and adolescence the focus should be on adolescence.

Rubella by itself is a mild disease and it will help reduce chances of CRS if rubella is allowed to spread in the community. The priority must be to eliminate congenital rubella. Further reduction of CRS can be achieved by adolescent rubella vaccination. In countries with uncertain coverage of infant immunisation there is a risk that the WHO strategy of eliminating rubella in childhood by immunization in the 2nd year of life will actually increase the incidence of CRS.

# Report of discussion at WHA68

Provisional summary records

- <u>Second meeting of Committee A</u>, suspended
- Fifth meeting of Committee A, suspended
- <u>Eleventh meeting of Committee A</u>, suspended
- 12th meeting of Committee A, finalised.

[WHA journal 3, summary: The agenda subitem was opened and the Chairman invited comments from the floor. Discussion of the subitem was suspended]

#### Documents:

- A68/30 Secretariat report on global vaccine action plan
- <u>A68/A/CONF./4</u> Draft resolution proposed by Libya

### Libya: Thank you, Mr Chairman

Libya is pleased to have the opportunity to speak on this item. The recommendations of the Strategic Advisory Group of Experts to address the five (5) priority problems challenging the GVAP's success are well noted.

The EMRO region recently celebrated World Immunization Week under the banner of Closing the Gap. In Libya we are proud to be able to report a 98% coverage of children receiving their 3rd dose of DTP-containing vaccine.

As the 2014 assessment report warns, the GVAP is far off track and urgent

To start, it is urgent that we find a way to continue immnnization services during crises and epidemics. Many countries in our region are facing disruption of routine vaccination services due to conflict. In addition to disrupted EPI activities, some countries of the EMRO region are absorbing significant refugee populations, which sees increased demand on EPI programmes; we should try to extend the vaccines package to these groups.

As recommended in the 2014 assessment report, WHOis guidance on vaccinating in humanitarian crises should be expanded; we also ask that WHO double their efforts to assist countries in implementing the existing guidance.

The aim of GVAP is to extend vaccination to all, and to reduce inequities in immunizatian. Fundamental to this is ensuring access to vaccines themselves. As noted in the 2014 assessment report, "the affordability and supply of vaccines need to be urgently examined." Libya has introduced a Resolution for the member states' consideration as an active step towards advancing this issue. The Assembly repetitively hears from governments , that vaccine affordability is a challenge to introducing and sustaining vaccines, in particular the newest vaccines.

We applaud the effort by donors and Gavi, The Vaccine Alliance, to provide subsidies for initial introduction of new vaccines in the lowest. income countries but governments which do not benefit flom donor support, nor lower negotiated prices, need solutions as well. Countries that receive donor support today will face similar challenges like us in the future as they'inherit the full cost of vaccines and immunization programmes.

The Resolutiontherefore invites memberrstates and the Director General to take forward actions that have been proven to increase affordability. These include increased price transparency which must start with us, governments.

Utilizing procurement strategies, such as pooled'procurement, are also included.,And other steps, such as enabling a healthy and competitive new vaceines'mar,ket that meels WHO pre-qualifieation standards are included. tibya believes this is in the interest of all governments wishreg to foster an affordable and sustainable supply of vaccines.

It is critical that in nnoving fonvard we pause, as govefilments and'as,the ' custodians,of,our peoptres" health, to critically think,aboutthese challenges outlined in \*te 20!.4 assessment report and what is needed to overcome them.'We are encorrraged by the'increasing momentum to address vaccine afflordability and thank the Secretariat for its leadership,in this area, \Ye hope thatthe Assembly wiltr positively considerthis:Reso,lution.

**Iceland:** Thank you chair, Denmark, Estonia. Iceland, Latvia,,,,, informed on progress of vaccine plan, one of 5 children is still not receiving routine immunization we urge the D to give importance to solve that, important not to miss opportunity to vaccinate, healthcare workers is a key, members take our responsibility to share all the data we have with healthcare workers, healthcare workers should understand the importance of the data, we have a problem of not evidenced based information, un evidenced information can create legends, we need consistency in evidence based knowledge.

**Panama:** speaking on behalf of Americas region: importance of immunization as most cost-effective action, access is key to UHC and universal access to care, through prevention and contribution to socio-economic development. Eliminated smallpox and polio, also recently free of rubella. Pneumonia, diarrhea and certain types of cancer will be major steps forward to

prevent deaths. Bring down costs of vaccines, then progress will be made. We do not have entitlement to bring down price. Essential to strengthen alliances to bring down financial inequity levels. Promote and strengthen efforts in vaccine against dengue. Pool national resources to buy equipment to buy equipment and vaccines at lowest cost. Develop model and tools to access guality and safe vaccines and tools.

**Chile:** Thank you, ladies and gentlemen, we would like to endorse what was said by Panama and we want to add, the summary of 2012 on vaccines, We want to highlight:

1- the recommendations made by the experts, designing national plans based on diagnosis of the situation of every participating country

2- need for coordinated work to finances measures ensure that all immunisation is given according to guidelines

3- states should take responsibilities, guaranteeing of financing and provision of immunisation free of charge to their population, advocacy and lobbying. Cost effectiveness of vaccines should be included in the plan.

**AU:** remain concerned that progress is patchy and slow. Urge MSs to focus on routine immunization as cost-effective intervention. Support draft resolution, commit to further actions. Share concerns of sustainable financing, for LAMICs. Particular for Pacific region where Immunization rates remain low. Unable to comply with call to vaccine price transparency, but investigating to make price info available in future. Call for collective prioritization to focus on countries with DPT<80%. Core business of WHO is to improve vaccination rates.

#### Discussion of the sub-item was suspended; resumed in Committee A on Wed 20 May

[From <u>Jour 4</u> report: The Chairman reopened the subitem and invited the Committee to consider the report Global vaccine action plan as contained in document A68/30. The Chairman invited comments from the floor on the draft resolution Global vaccine action plan as contained in document A68/A/CONF./4. The Secretariat then responded to issues raised. Discussion of the subitem was suspended to allow Member States more time to consider the draft resolution.]

**Brazil:** is undeniable that preventive measures for preventive disease are more efficient and efficacious to ensure the safeguard of PH in the world. Importance of vaccines in the health of population, disease as polio began to present new challenges in places where it was eradicated. Brazil urges access to vaccines for pops in all countries, such measures are a challenge especially considering cost of vaccine. Articulation mechanisms are important such as Rotary fund in Panamerican region. Transparency and ...pricing, in order to provide quality safety and efficacy features. Congratulate MS efforts for broadening access coverage especially the ...group. Continue with strong emphasis in order to avoid any setback.

**Iran:** importance of national action plans. responsibility with countries. role of civil society and academia. advisory group role in evaluating situation. Iran considers high priority. new vaccines to all including migrants and refugees is priority for india. talking of national situation.

**Japan:** welcome intro of new vaccine but concern of not reaching target of existing routine vaccines. Intro of new vaccines is expected to have health benefits but implementation of basic vaccines through strengthening of health systems and delivery of routine vaccine is more important. IP essential to promote R&D but can cause cost increase. Is it a real barrier for national immunisation program? We need further analysis. Proposes to delete phrase "an IP barrier" in par 12. Japan able to obtain approval including report epi studies comprehensive testing etc. Japan will continue support of WHO GLobal vaccine plan

**Ethiopia:** on behalf of AFRO. immunisation along with PHC important to decrease mortality of children. however, africa still sees too many deaths. GCAP was adopted by all. emphasis on hard to reach areas. every child a VIP (vaccinated, immunised and Protected). EVD outbreak teaches to protect health system, and build robust them so that they can withstand disasters. but vulnerable in the region. lack of data and other gaps are challenges for HS strengthening. WHO to shape market of vaccines so that they are affordable to developing countries. affordability, supply, management are important. appreciate role of GAVI. parallel campaigns should be promoted. cross border areas too. shortage of traditional vaccines to be addressed. AFRO commitment to decade of vaccines.

Morocco: supports resolution by Libya. vaccine priority for PH. resources deployed have produced results, 11 targets with 95% improvement. In the last decade 86% reduction of meningitis since vaccine intro in 2006, 95% from tetanus. The goals identified should be reviewed taking into account the health security and health situation. New mechanisms in order to be put in place in each country to achieve the goals. Technical and financial support, plus implementation of strategies from WHO needed, coordination mechanisms with EMRO and AFRO, importance of surveillance and post vaccine care also reinforcement of international and national partnerships for vaccines and also support of research.

Merci monsieur le Président Mesdames et messieurs Le Maroc soutient le projet de résolution proposé par la Libye. Nous considérons la vaccination comme une action prioritaire de santé publique. Les efforts déployés dans le cadre du Programm National d'Immunisation ont donné leurs fruits comme en témoigne les constats ci-dessous - La couverture vaccinale contre les 11 maladies ciblées a enregistré des taux dépassant les 95%. - Aucun cas de poliomyélite et de diphtérie n'a été enregistrê depuis respectivement 1987 et 1991. - La validation de l'éliminotion du tétonos néonatol au Maoc en 2002. - La réduction des cas de méningites à plus de 85 % apres l'introduction du vaccin contre l'haempphilus influenza type b en 2007. - La réduction de la mortalité infanto-juvénile qui a régresse de 95% pour le ïétanos, de 84% pour la rougeole et de 86% pour la coqueluche chez les enfants de un à 12 mois. Par ailleurs, la lecture du rapport du secrétariat de l'OMS concernant l'évaluation du plon d'action mondial pour les vaccins 2010-2020 répond à notre vision pour atteindre les objectifs fixés por le plan. Toutefois, - Les objectifs fixés au départ doivent être revus tenant compte de la situation mondiale actuelle économique,

sanitaire et sécuritaire. - Concernant l'accessibilité économique des vaccins et les I es systèmes d'approvisionnement notamment pour l'introduction de nouveaux vaccins, un appui de l'OMS et de ses partenaires pour la mise en place des mécanismes d'achafs groupés des vaccins s'avère essentiel. Aussi, en vue d'atteindre les objectifs escomptés , nous souhaitons que l'OMS et les Organisations Internationales appuient les pays, notamment le Maroc, sur le plan technique mais aussi financier en particulier pour les domaines suivants: - la mise en oeuvre des stratégies de contrôle et d'élimination et d'éradication des maladies à prévention vaccinale - la mise en place de plateforme d'achats groupés des vaccins -le renforcement des mécanismes de coordination AFRO-EMRO dans la mise en oeuvre et le suivi du plan mondial pour les vaccins - le renforcement du système de surveillance epidemiologique des maladies cibles et des effets indésirables post-vaccinal -l'évaluation de l'impact de l'introduction des nouveaux vaccins - le renforcement du partenariat national et international en faveur de la vaccination - le développement et la recherche Merci monsieur le Président

**Egypt:** speaks about national programs and data. sustainable immunisation financing is lacking. High prices of new vaccines means that they can not be included. Urge access and support action plan.

Korea: Thank you, Mr. Chair. The Republic of Korea would like to commend WHO's leadership and enormous endeavor of the international society to eliminate vaccine- preventable diseases (VPDs) and to reduce their global burden, including WHO member states as well as the SAGE, UNICEF, and GAVI.

Since 2002, the Republic of Korea has been operating the web-based integrated immunization information system. We believe that this system may serve as one of the best practice models for coping with the issue of poor data quality and use, which was highlighted in the 2014 assessment report on the Global Vaccine Action Plan by SAGE. The system allows vaccine providers to register the vaccination records online, using user-friendly web tools and resident registration numbers. This data is monitored on a real- time basis by public health centers as well as provincial and central government agencies, making it possible to trace individuals' immunization records permanently. Furthermore, public health centers use the system to identify unvaccinated people in each jurisdiction, and encourage them to get vaccinated. As a result, the Republic of Korea has achieved vaccination coverage of 99.8% among all young children regarding the national immunization program vaccines, and we'd be pleased to share our experience with other member states.

Also, the Republic of Korea supports the adoption of the draft resolution for vaccine affordability proposed by Libya. Infectious diseases are a serious health issue that goes beyond national boundaries. They have become global health security issues relating to high global mobility, as witnessed in the spread of measles and polio recent days. Thus, the adoption of this resolution will contribute to maintaining high population immunity in all nations. I thank Mr. Chair.

**China:** support the report, recognize the efforts of the secretariat and recommend WHO. financial should be strengthen. to improve the quality of data collected.

**Ecuador:** Supports statement made by panama and supports resolution made by Libia. Points: economies of scale, PAHO fund one of the pillars of PH in the americas this could be an example for others, Also point principle of solidarity, promoting immunisation campaign in our region and that's why we were the first to eliminate polio and other diseases, countries in the region have to be able to work together and put together efforts, that's why we support mechanism that make the process more transparent. Ecuador just promoted the Third vaccination week in the Americas. commitment to GVAP, improve surveillance in order to improve coverage and project above the 95% coverage

Gracias Sr. Presidente. Ecuador acoge el informe presentado por la Secretaría sobre el "Plan de acción mundial sobre vacunas", permitiendo con ello, dar una mirada global de la ejecución del Plan por parte de los Estados Miembros. Manifestamos nuestro respaldo a la intervención realizada por Panamá a nombre de la Región de las Américas sobre este punto.

De igual manera, acogemos con beneplácito el proyecto de resolución presentado por Libia, dentro de la cual quisiéramos resaltar algunos aspectos de vital importancia.

El primer aspecto es la invitación a los estados miembros a mancomunar esfuerzos, con miras a aumentar la asequibilidad mediante economías de escala. Como muchos de ustedes saben, el Fondo Rotatorio de la Organización Panamericana de la Salud, se ha convertido en un pilar de los sistemas de salud de la Región de las Américas, este es un ejemplo a ser replicado en otras regiones. El Ecuador apoya y comparte firmemente los principios del mismo, basados en equidad, solidaridad y panamericanismo. Y reconocemos los beneficios generados a través del mismo a lo largo de su existencia.

Estas características han sido claves en el éxito de los programas de inmunización de la región de las Américas, logrando ser la primera en el mundo en la eliminación de la poliomielitis y del sarampión autóctono, y la más avanzada en la eliminación de la rubéola y el síndrome de rubéola congénita (SRC).

En esta misma línea, la resolución hace referencia a otro tema clave: los precios de las vacunas. Es de suma importancia que los países, en las diferentes regiones, actuemos unidos y coordinados, para hacer contrapeso a los interés comerciales que desgastan la capacidad de los estados para garantizar el derecho a la salud. Es por esto que apoyamos todo mecanismo mediante el cual podamos transparentar los procesos, y de esa manera asegurar una de las prestaciones más eficaces del sector salud.

En el mes de Abril pasado el Ecuador fue sede del lanzamiento de la Decimo Tercera Semana de Vacunación de las Américas y Cuarta Semana Mundial de Vacunación, por esta razón quisiéramos reiterar el compromiso del país con el "Plan de Acción Mundial de Vacunas", y ratificar que seguiremos trabajando en un sistema de información para registro de coberturas y actividades de vigilancia, de tal manera de que podamos mantener coberturas de vacunación iguales o superiores al 95%. Mantendremos las campañas de seguimiento para asegurar la sostenibilidad de la eliminación de la Rubeola, la consolidación de la eliminación del sarampión y mantener la erradicación de la poliomielitis. Muchas gracias Sr. Presidente,

**Pakistan:** Immunization is an important part of primary healthcare which can significantly lower healthcare costs especially in resource constrained developing and least developed countries. Affordable accessible vaccine supplies are imperative for strong efficient national health systems to provide optimal health care. Universal health coverage cannot be achieved until all countries have universal access to vaccines. National efforts are often limited. Y financial constraints especially in developing countries. Pakistan supports the draft resolution on vaccine affordability introduced by Libya which we believe is an important step forward in ensuring accessible, affordable health for all.

**Lebanon:** *Mr Chair I would like to thank the Secretariat for the report on the Global Vaccine Action Plan. In view of the unrest that our Eastern Mediterranean Region is still passing through, we would like to stress once again the importance of maintaining immunization activities despite disruptive situations such as wars and people's displacements. The massive influx of displaced Syrians to Lebanon since 2011 led to an increase, by 30%, of the number of children to be vaccinated. Syrians are receiving the same routine vaccinations as the Lebanese according to our national immunization calendar.* 

The financial burden, however, is becoming unbearable with the deficient international assistance to the displaced population and considering that Lebanon is still not eligible for GAVI. And this despite the social and economic hardship that is prevailing in the country for the fourth consecutive year. High prices of vaccines combined with the increased needs due to Influx of refugees are causing delays in introducing Pneumococcal, rotavirus and hepatitis A vaccines in our calendar of routine immunization. We believe that armed conflicts and political instability deserve more attention, and hampered immunization is only an example to highlight the gravity of their effect on the health system.

Chairperson, As we have mentioned on several occasions, the situation has been complicating in countries where immunization relies to some extent on the private sector. This sector, in middle income countries, is still experiencing sudden acute shortages in several vaccines including MMR, Penta and DPT. We call upon WHO to monitor more closely the global supply of vaccines, and strive to avoid that developing, middle income countries bare the highest burden of the international shortfalls in vaccines.

Finally Mr. Chair, in line with the recommendation of the Strategic Advisory Group of Experts emphasizing that transparency of vaccine pricing is required to improve affordability, Lebanon would like to support and co-sponsor the draft resolution proposed by Lybia.

Brunei: importance of laboratories in identifying viruses.

**USA:** Implementation has been disappointing. Polio legacy into action now . Surveillance is the foundation of pH programs. We support the development of guidance on immunisation, that

would be useful in times of disruption. Affordability and delivery of the vaccines is considered in the plan and we appreciate it. Monitor supply and Meningococcal, rota, expand influenza. Partnerships needed.

**Russia:** Russia welcomes report, including global action plan for vaccination 2014. Many areas still difficult for countries to resolve, namely unstable funding for vaccination programmes - Russia is continually increasing funding to expand vaccination. Rendering assistance to fight HIV, measles, rubella, and polio. Extraordinary situations worthy of particular attention: cross-border issues, where international support required, with WHO guidance. We support technical manuals from WHO.

**UK:** welcomes report and fully supports recomm etc including eradicate polio globally. internationally UK is largest donor to GAVI, 1.44 billion £ of funding 2016-2020. we fully support GAVI model, until countries can afford programs it enhances sense of ownership. also major donor to Polio plan.

**Cape Verde:** recognises WHO leadership on this issue and welcomes global vaccine action plan GVAP, and supports statement made by ethiopia on behalf of African countries. Vaccines key tool to prevent diseases, but some of our African countries are not able to acquire vaccines at an affordable price and this undermines our health efforts - particularly to acquire NEW vaccines. Even if these countries are qualifiers to low and middle income countries, they are very vulnerable. We ask that WHO and MS show leadership to make vaccines affordable to our countries.

**Thailand:** appreciation to DG for report, implementation of GVAP, contribution of strategic advisory group on vaccination, 2011-2015 slow progress unlikely MDG goal will be achieved. Propose comment: 1 effective and equitable distribution of health delivery systems, this improves health workforce, esp costly vaccines. One of the weakest links is the migrant populations, urban populations. Capacity to produce vaccines in developing countries, decrease in price, strengthen licensing, procurement etc crucial. Document proposed by Libya thailand fully supports resolution.

**Philippines:** Thanks secretariat for GVAP report - useful as shows how our efforts doing in comparison to global efforts to achieve vaccination goals. we support this draft resolution by Libya as provides equitable access to lifesaving new vaccines.

**Tanzania:** supports Statement by Ethiopia for AFRO, continuing support action plan, reach every child strategy, remarkable progress made, more 90% coverage for polio. High level of coverage, continue to cofinance for use and underused vaccine, Neonatal tetanus, coverage of pregnant women, MR routine vaccination at 9 and 18 months introduced, revised material plan of action, data quality assessment also performed, immunisation service integrated with health delivery system. Support action plan.

**Nigeria:** Supports resolution tabled by Libya. More than 6 million children each year needing access to vaccines. Pentavalent vaccine introduced - learning a lot from intro of these vaccines.

EPI programme: still face obstacles in rolling-out. Getting GVAP back on track. Crisis in North of country. Expanding WHO guidelines to immunisations in emergencies: most welcome by Nigeria. Vaccines remain a challenge, but Nigeria lucky to benefit of GAVI support. Wishes to accelerate use of vaccines in our country, but costing process.

**South Africa:** welcomes report, GVAP 2011-2020 decade of vaccines, end inequity of vaccinations and ensure vaccines vast future potential. Implementation has been patchy, necessary improvements must be made to achieve results. There has been some success in intro of new vaccines, but progress is far off track. Deadlines of 2014-2015, goals has to be on right track. support draft resolution proposed by Liba, important in reducing under 5 morb and mortality. Proposed amendments: point 9 read low and middle income not devel again on 10 same, point 16 noting with concern shortage of setting replace op 16 countries that request assistance, par ? to assist mobilizing....in accordance to national priorities. A few friendly amendments: not "developing" but "low and middle income countries" / instead of "low income countries" "countries that request assistance".

<u>Canada:</u> Thank you Chair. Canada welcomes the report of progress on the Global Vaccine Action Plan (GVAP). Canada is strongly supportive of immunization, as a key component of our top development priority; Maternal, Newborn and Child Health.

Given the importance of immunization in reducing preventable child mortality, Canada is however concerned that the implementation of GVAP is off track. We therefore strongly support the recommendations put forward by the Strategic Advisory Group of Experts (SAGE), and would welcome WHO's views on how to support GVAP stakeholders in successfully addressing them.

We suggest that future GVAP reports highlight priorities, risks and mitigation measures for the upcoming year to ensure objectives and targets are reached within established timeframes. In addition, we would propose that clarity be provided on how efforts to implement GVAP are being tied to overall health systems strengthening activities.

We would also recommend that future GVAP reports address strengthened access to affordable medicines, which will be critical to achieving the GVAP's objectives. Within this context, we would welcome clarity on how the GVAP is, or could address tiered pricing that seek to secure the lowest possible vaccines prices.

Finally, Canada would be interested in better understanding the leadership roles of key stakeholders involved in implementing the GVAP, and whether dedicated funds will be set aside to address recommendations.

We appreciate Libya's introduction of the resolution and share concerns with advancing the GVAP progress. However, we have comments to provide on the text and seek direction on the best way to provide them. Thank you.

**Columbia:** support Panama for statement, different vaccines introduced recently in Columbia, now quality certification state, interruption of measles and congenital rubella in particular, all of these thanks for funding from national level. Concern regarding price of vaccines increasing, listen carefully to recomm of group of experts in sharing supply and developing strategies to make recomm effective. Fully prepared for vaccination campaign but pressure from financial burden in developing countries. Support draft resolution from Libya, strengthen mechanism to ensure universal access. implement effective R&D strategies. Pricing mechanisms for supply of vaccines. Columbia fully committed to continue to step up vaccination campaign, but huge financial burden for developing countries, so we support draft resolution by Libya to ensure access at a global level to vaccines. Effective R& D strategies.

**Bangladesh:** appreciate report operationalizing GAPVI and enhances accountability. In Bangladesh HBV, haemophilus, pneumococcal, IPV, all introduced with support from GAVI (all?). Success in routine immunisation in Bangladesh is a good global example, and often cited / internationally recognised. Production of vaccines locally - stringent national regulatory authorities, control process. Sensitivity surveillance from all the districts. National stock outs affect local supply and delivery. WHO needs to help if any shortfall, WHO + other technical partners need to see as to vaccine pricing, and ensure production and supply. BCG and TD vaccines are a problem in Bangladesh due to supply chain interruptions.

#### Maldives: Thank you Mr Chair,

Maldives appreciates the report by secretariat. We believe there is an urgent need for more concerted action to accelerate the work to be on track to achieve some of the key immunization goals set by the Global Vaccine Action Plan.

Sustainable access to vaccines, especially the newer vaccines at affordable prices for all countries, especially the middle-income countries who are not eligible for funding support from the GAVI Alliance, calls for other collaborative mechanisms to facilitate the process for such countries.

Chair, Maldives urges countries with low coverage, to meet vaccination coverage targets; accelerate control of vaccine-preventable diseases. Further, even for countries like Maldives with high immunisation coverage focus need to shift to the population groups not being vaccinated, with the view of leaving NO ONE BEHIND. Also, for such countries maintaining high vaccine coverage, assistance on risk communication and effective public awareness programs including the need and impact of immunization as well as addressing the misinformation within communities on vaccine usage.

We urge member states to fully integrate vaccination into the operation of all aspects of the health care system and to reduce missed opportunities to vaccinate, through more equitable access to routine and other immunization services for people in all communities, despite disruptive situations, such as war and disease outbreaks.

Member states should invest in improving data quality at the local level, and use data to strengthen accountability and to improve understanding of what the programmatic issues are and to also address fundamental issue like ensuring all births are included in the denominator of immunization programs.

In conclusion Maldives appreciates the contributions of WHO, UNICEF and other health partners including GAVI in their efforts to supporting and strengthening global immunisation services. Thank you for your attention.

**Jamaica:** commends Secretariat on GVAP which outlines challenges so that goals met. Makes valid points for MS and donor agencies to consider. Jamaica urges WHO to help with advocacy and social support given popularity of anti-vaccination groups - this was not highlighted in the report. Development of messages advocating for vaccination. Much more resources needed for intro of new vaccines. Jamaica profits from PAHO revolving fund. Due to prohibitive cost of new vaccines (cf pneumococcal) Jamaica not able to fully roll-out, Jamaica has never been able to profit from GAVI support as GDP per capita too high. This does not reflect burden of disease or gap in vaccination - this needs addressed. Jamaica endorses draft resolution proposed by Libya.

**Bahamas:** thanks for protecting children every country's responsibilities, SAGE work shows as targets set are underachieved. WHO has not failed, we have failed because we are WHO. Immunisation are for all and not only for some. Financing crucial, also for combating. MDG impact on child mortality and adult morbidity, linked to the success of our economy. Immunisation best pH investment. SAGE and regional advisory group have given best advice and we have to follow. Poor low and high income countries we all have to immunise our children.

**Bahrain:** support draft resolution by Libya. Since 1995 tetanus eliminated notably alongside rubella measles, stopped contagion of rubella. Bahrain one of first countries in region to introduce new vaccines and follow recommendations as to polio both bivalent and inactivated. We conduct vaccine programmes supported by data surveillance etc. work in line with WHO recommendations. As regards complications produced by vaccines, public awareness raising programmes. Goes in direction of our work in alignment with devt goals.

**Saudi Arabia:** on behalf of EMRO thanks secretariat for report on GVAP, immunisation coverage low in several countries or decreasing, data inadequate, more investment needed in the countries supported by involved stakeholders, progress towards immunisation measles and rubella eradication far to be reached. Partners needed. Tetanus elimination target delayed. Countries hosting refugees need to access vaccines at lower price. specially measles and rubella. as part of commitment to support GAVPi, Saudi arabia supports draft resolution proposed by Libia.

**Qatar:** We support GAVI programme with 10 million \$ until 2020 in order to improve vaccination coverage. We support Libya's resolution.

<u>Malaysia:</u> Malaysia fully supports the recommendation on integration of health services. We have implemented it since early 2000. It encourages parents to take their children for immunization.

Global shortage of certain vaccines from certain manufacturer since end of last year could affect the immunization programme. Registration of vaccines from all manufacturers available will facilitate countries to overcome the issue.

**Argentina:** thanks WHO for GVAP and progress report. In accordance with intl programme of 19 vaccines, vaccination in Argentine free for all ages groups. We are not a high income country, but we finance this via an array of strategies. PAHO centralising purchase fund: importance can not be stressed, also so as to NOT interrupt vaccination campaigns. Equal fair access to vaccines should not be blocked. Stockouts frequent in more than 40 countries of low income. Supports draft resolution from Libya.

**Kuwait:** Thanks WHO for efforts around GVAP which is basis for all national vaccination programmes as in Kuwait. Happy to see this document which includes lots of dif data, happy to see involvement of CSOs in vaccination. Commend efforts of expert group. Specific information as to pricing necessary, Kuwait is with pooled procurement system.

**Gabon:** One of few countries in sub saharan africa who fully immunise children from 0-11 months age. Despite our efforts, objectives remain below those set out in GVAP. Polio: outbreaks, required substantial efforts and coordination with neighbouring countries. Injected vaccine in order to meet GVAP, will increase spending by 30% - so we commend MS support in implementing GVAP. But as we get no GAVI support - very difficult for us to implement. We support draft resolution by Libya, so we can respect the vaccination goals.

**India:** GVAP coincides with plan for universal elimination if (??) in India. Web-system introduced in India to ensure timely immunisation of every child. Endeavor to protect every child from 7 vaccine preventable diseases so far. Take this opportunity to acknowledge support from technical partners. Happy to endorse draft resolution from Libya: add " low and middle income" countries to draft res instead of only "middle".

**Venezuela:** support comment by Panama. Our constitution requests us to invest heavily to combat child mortality, and since 1970s with intro of vaccines we have succeeded in reducing under 5 mortality in major fashion. Never the less if you look at coverage particularly in cities, some areas were below 95%! Remote areas/areas of migration from neighbouring countries etc, national programme needs to address these issues. Vaccination fully free and universal in our country. WHO needs to support permanent capacity building in staff of our countries, helping to guide future activities in our countries in relation the EPI activities.

**Latvia:** Draft resolution by Libya: EU group still discussing this amongst member states. Requesting time to allow this and align their position.

**Iraq:** Sustainable procurement of vaccines in crisis situations - certain security circumstances (Iraq with 3 million IDPs with increased vulnerability). Crisis situations entails campaigns for seasonal influenza, HAV, meningococcal disease. Prerequisite: gradual conversion from trivalent to bivalent inactivated polio vaccine. Timely and sustainable procurement without interruption which affects effectivement of elimination and eradication of poliomyelitis. Pertussis: active to inactive pertussis vaccine may lead to reactivation. World surveillance systems needed to combat any resurgences of diseases, should be included in this action plan. Vitamin A supplement with measles vaccination.

<u>Senegal</u>: We welcome report from Secretariat. Support draft resolution submitted by Libya. Our country has introduced all new vaccines in context of GVAP (pneumococcal, inactivated rubella, 2nd dose measles, pilot scheme HPV currently, and one-dose HBV as of july 2015 from birth).. Neonatal tetanus: elimination as of 2011.

Madame, Monsieur le Président, Excellences Mesdames et Messieurs les Ministres de la santé, Mesdames et Messieurs, J'ai le plaisir de prononcer cette déclaration au nom des 47 Etats membres de la Région africaine de l'OMS.

I- Introduction de nouveaux vaccins Le Sénégal a pratiquement introduit tous les nouveaux vaccins recommandés dans le cadre de GVAP. Cette introduction concerne les vaccins contre les infections à pneumocoque, la rubéole, les rota virus, le Vaccin Polio Inactivé, une deuxième dose de vaccin contre la rougeole et le vaccin contre le virus du papillome humain(HPV) sous forme de projet de démonstration. Il est également prévu d'introduction d'une dose de vaccin contre l'hépatite B dans le courant de 2015.

II- Vaccination pour tous Les couvertures vaccinales administratives sont encore faibles du fait d'une mauvaise complétude des données. Une enquête nationale de couverture vaccinale organisée dans le pays en mars 2012 a révélé des taux de 90% de couverture pour le pentavalent au niveau national et de 80% au niveau de plus de 90% des districts. Ces données ont été confirmées par les estimations OMS/UNICEF. La dernière estimation réalisée au cours de l'EDS continu 2013-2014 montre les mêmes tendances. Des efforts sont en train d'être fournis pour maintenir et améliorer les performances en termes de couverture notamment en généralisant la mise en œuvre de l'approche ACD dans tous les districts avec l'implication des organisations de la société civile.

III- Elimination du Tétanos Maternel Néonatal L'élimination du tétanos maternel et néonatal dans tous les districts du pays a été validée par l'OMS en 2011. Le risque évalué de tétanos en 2014 reste faible pour l'essentiel des districts du pays.

IV- Elimination de la rougeole Le pays dispose depuis 2012 d'un plan stratégique d'élimination de la rougeole et avait en même temps organisé en 2013, une campagne de vaccination de rattrapage combinée rougeole-rubéole pour les enfants âgés de moins de 15 ans, suivie de l'introduction du vaccin rougeole-rubéole dans la vaccination de routine puis d'une deuxième dose du même vaccin dans le PEV à partir du 15ièmemois. Un système de surveillance sentinelle du syndrome de rubéole congénitale est également mis en place et aucune épidémie de rougeole d'envergure n'a été notifiée dans le pays depuis 2010.

**Brazil:** In addition to previous comment, supports resolution presented by Libya. Following friendly amendment: and universal access to health, op1 4: "national regulatory standards including WHO prequalification"

**Algeria:** Supports statement by African group but underscores one issue core to implementation of GVAP: access! Price/cost should not be a barrier, is a real problem, not only for LOW income countries, also for MIDDLE income countries. We need to give greater transparency to pricing. Availability in sufficient quantity of these vaccines - for example for injectable poliovirus vaccine. Supports draft resolution of Libya.

Libya: India Brazil and so many others input appreciated.

- · PP9 line 4: replace
- · PP10 line 1: replace developing with low and middle income countries
- · PP16 (60?): noting with concerns shortage of certain traditional vaccines (BCG/)
- · PP?: immunisation gaps of low and middle income countries "that request assistance"
- PP2 line 2: access to health and / immunization as one of most effective measures in public health...and universal coverage
- PP?: to seek opportunity for establishing regional and national regulatory standard, including WHO prequalifications

Canada: 2 suggested deletions

- PP9: "mechanisms that lower price"
- PP 2: " delete to secure funding"

**Chinese-Taipei:** Applauds GVAP progress report. Shortages have affected overall vaccination coverage. Hold manufacturers to commitment of sustainable supply. Information issue: WHO should promote vaccination plans coordination among countries. Chinese Taipei wants to share experiences with partners.

### NGOs

- International Pharmaceutical Federation (FIP)
- IntraHealth International Inc. (IntraHealth)
- Médecins Sans Frontières International (MSF)

- Medicus Mundi International International Organisation for Cooperation in Health Care (MMI)
- The Save the Children Fund (Save the Children)

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**Save the Children** Statement: supports renewed attention to vaccination, GAVI, comprehensive primary health care systems etc.

MSF: middle income countries GAVI ineligible - 30% of births

**MMI/PHM:** Thank you, Chair, for giving me the opportunity to address the distinguished members of the World Health Assembly on behalf of Medicus Mundi International and the People's Health Movement.

We endorse the resolution presented by Libya highlighting the urgent need for transparent pricing of vaccines and clearer documentation of price barriers, including regulatory and intellectual property barriers that undermine the introduction of priority vaccines. The resolution recognises the importance of competition to reduce prices and the need to support local manufacturing capacity in developing countries that can produce WHO-prequalified vaccines and make the vaccines affordable through generic competition. The entry of Indian generics into the market for Hepatitis B vaccines has brought the price down from \$23 to \$1.

We strongly supports the pooled regional procurement as reflected in the resolution which is the key for 24 middle income countries that have graduated from GAVI support this year.

We are concerned about the pressure on countries to introduce new vaccines in the absence of surveillance and information systems covering epidemiology, delivery, and evidence of safety and efficacy. The opportunity costs of introducing new vaccines need to be measured in terms of cost and health outcomes forgone.

We call upon WHO regional offices and country offices to provide the necessary support for fully informed decisions by countries on this issue, including guidance on the opportunity costs of expensive vaccines for low incidence conditions. This also requires that countries, which have not done so, proceed to establish and strengthen their National Immunisation Technical Advisory Groups as reflected in the Global Vaccination Action Plan.

We further urge WHO to give increased priority to the development of rigorous post-marketing surveillance systems including adverse events following immunisation.

**Greece:** Supports the GVAP and stresses importance of vaccination as most effective prevention tool, 2-3 million deaths prevented annually. According to WHO guidelines countries must promote adherence to vaccination guidelines. Vaccination cover of vulnerable groups and social groups that refuse vaccination due to anti-vaccination thinking.

Libya: accepts amendment made by Canada PP9:

point 7 line 1: to explore ways to secure funding

Latvia and EU asked for more time, we are very flexible for that - as we note that the draft was presented last week.

**Secretariat:** (Dr. Flavia): 3 years ago GVAP was approved in this very room - SAGE was agreed upon as regulatory body. Coverage is low and patchy. We have established a middle income country task force: affordability of new vaccines. Next year we will be able to come back I think with: pricing transparency, costing, surveillance, logistic capacity. As we work towards eliminating polio, we can also harness that effort for other diseases.

**Chair:** thank you dr, that completes discussion. We suspend discussion on resolution on doc <u>A68/A/CONF./4</u>, to let time to reach agreement. The item will be rescheduled in the program. People supposed to attend general committee meeting can now attend that meeting

### Suspend discussionpending informal discussions; resumed in Committee A on Friday 22 May

Chair: asks Libya to give short update

**Libya:** GVAP (16.4) commenced tuesday, with draft resolution by Libya with key measures towards making vaccination accessible. Total of 23 countries expressing support for draft resolution. Saouth Af, Brazil, Canada, Brazil have proposed ammendments. Latvia on behalf of EU asked for more time to study new resolution. Libya Thailand, Algeria held informal meeting with EU today - EU now says needs more time to share written inputs. Reminder, this resolution adresses unaffordable vaccines and inadequate supply. Since Tuesday Libya has received many requests for co-sponsorships. In light of these co-sponsorships, and 23 countries that gave their support, we request that decision be made as to next steps to accept resolution.

# Item suspended pending further discussion; resumed in Committee A on Sat 23 May Documents:

- · <u>A68/30</u>, Sect report
- · <u>A68/A/CONF./4 Rev.1</u> revised version of Libyan draft resolution
- <u>A68/A/CONF./4 Add.1</u> fin and admin

The draft has been discussed and updated through consultation, Lebanon iraq2 and kuwait bahrain have also cooperatted adopting this draft. Libya takes the floor to update on that draft.

**Libya:** following my statement yesterday; yesterdady had mtg with EU, Thai, Nigeria; EU provided written comments; constructive;

PP6 Line 1 replace killer with vaccine preventable

PP9 line 1 add , inter alia,

pP17: new para: sources of vaccines, effective and sustaina ble vaccine production etc

PP18 new para: concerned about scepticism...Concerned that scepticism against vaccination is continuing to grow in society despite the proven efficacy and safety of modern vaccines, and that many children do not receive life-saving vaccines as a result of insufficient information to parents or health care workers or even of active anti-vaccination propaganda,

OP1 footnote 'where approp etc

OP1 2 Line 1 add as aand where appropr for pooling vaccine as appropriate

OP 1 line 3 providing to provide, where avail timely vaccine price data with the goal of improving affordability

OP1(5) line 1-2 delete norms and add the availability of comparable; ...to create mech to incr avail of comp data gov funding strategy public healht benefit

OP1(7) new para improve purchasing uninterupted and safe supply and avail

OP1(8) str imn advocacy and strn information to the public

OO2(2) replace explore ways to mob funding to fully .... support low and mid income ...

OP2(5) line 3 and 4 various deletions and edits: now reads: to str WHO prequal and provide....

OP2(6) line 1 delete 'IP barriers'that can enable....

OP2 call upon MS re tech su

OP2(8) new para continue to support MS ... str knowledge and skills of health care professiona;

OP2(9) new para report back through EB annual report

This agenda item started on Tuesday with 23 countries expressing support; corresponds to GVAP report on vaccine affordability and supply; we are requesting decision on next steps to adopting the resolution

Chair: thanks Libya

**Saudi Arabia**: I want to confirm our co sponsorship of this resolution and we support the amendments.

**Canada**: Thanks; appreciate the efforts of Libya; wish to see better progress to be made; Canada supports immunisation; remains concerned about the way the resolution was presented to the Assembly; full discussion in Jan would have been approp to discuss then; instead it appeared on the first day of this Assembly; support transfer to EB137 (seek Sect advice) also ask about the implications of this for the PB16-17?

**Tunisia**: Thank you chair, we are convinced that immunization is one of the most effective public health interventions, absolutely vital; we ensure 95% coverage; difficult to maintain bec of prices

we are middle income country so we don't get full benefit; we have contributed to efforts composing this paper, price transparency and access to middle income countries for adequate supplies of vaccinations

**Pakistan**: strongly believes in eff immunisation; hampered by resource constraints; supports the resolution; confirms sponsorship

Indonesia: Mr. Chairman We would like to convey our support to the draft resolution entitled Global Vaccine Action Plan as orally amended by the delegation of Libya. The current draft will directly contribute to our common endeavor in enhancing global immunization program. Our delegation shares the view that immunization is one of the most effective interventions in public health and access to immunization as a key step towards access to health and universal health coverage.

In order to make sure that the resolution is going to be fully implemented, we are of the view that we need to consider properly several follow up mechanism that will be derived from the draft resotluion, including the proper mechanism connected to the issue of pooling vaccie procurement. I thank you Thank you Chair.

**Ethiopia**: draft was discussed this morning by Afro and it was agreed to support draft resolution in acc with GVAP

India: India strongly supports the draft resolution, thank you

Iran: add our name as cosponsor

**Congo**: thank you chairman, some african states like us because of the difficult situation of our economic indicators had benefited from GAVY but not anymore, some vaccines are expensive and depends on changing oil prices, we would like to support this resolution specially the transparency and affordability of the vaccines, it is essential to ensure that member states are aware of the importance of affordable vaccines as it's very important to a country like us

In relation to Op2(1,2 3,4) it's unreasonable to postpone adoption of this resolution as it would affect providing us with vaccines, as we are no more eligible for GAVY so we fully support of immediate adoption of the resolution.

**Sudan**: Global immunization...(to be retrieved from the video)......, sudan declares support and cosponsoring and alignment with co sponsoring

**Brazil**: congrat Libya; imm a key priority for Brazil; totally understand the Resolution; esp for dev countries; brings to the table guaranteed access to vaccines so must approve at this Assembly

**Libya**: while it maybe not the usual route of adoption of the resolution, the resolution can be accepted till the first day of the meeting.

we submitted the resolution week prior to commencement of the Assembly, we received feedback from concerned countries, all comments have been incorporated, the Assembly as sovereign body has the right to submit changes.

**USA:** US a major supporter of global vaccine programs · Weve made enormous investments in this area · Some valuable elements of this resolution , incuding on promoting reporting of publicly available vaccine prices · We circulated edits late last night, have not received comments back, but would be happy to read these out if needed; · We're not prepared to support at this time · We echo the comments of Canada about the process – · Certainly does not violate the rules, but · there is a significant discussion taking place on best practices of the governing bodies, and note that the correct procedure would have been to have submitted this resolution ahead of the January EB · if it even could have been ciru We would support canada's call to move this item to the EB later this week

**Jordan**: we realize the importance of providing affordable quality vaccines for the low and mid income countries, the EMRO region is going through crisis and lack of vaccines would cause added problems to the crisis.

**DR Congo**: for DRC vaccinating all our children a priority; imm a h9i9gh impact strategy; supports the adoption of this resolution as proposed by Libya

<u>Lebanon</u>: Lebanon would like to reiterate its support and co-sponsorship for this resolution in view of its tremendous impact on raising immunization coverage through raising affordability and accessibility and hence the availability of vaccines to everyone especially in developing countries and those not eligible for GAVI.

**Latvia**: thanks to Libya for taking into acc the comments made by MS; regarding OP1(3) there is 'where possible' but Libya changed it to 'where available' but we want to change it back because in some cases prices are available to government but bec of legal reasons not possible to publish them

**Bolivia:** we thank libya for the resolution fully support, OP2 asking the GD to continue......(video)

**China**: thank Libya this res has comprehensively introduced the main issues from GVAP; has proposed feasible action plan; we support and hope taht the Assembly can adopt this resolution

**Thailand**: Thank you chair, we would like to thank libya for leadership and coordination, co sponsorship and support for the resolution and amendments, lastly

OP2(6) like to request to bring back after barriers, "including regulation and intellectual property", ....

Timor Leste: strongly and fully supports the resolution

**Zimbabwe**: aligns with statement with ethiopia, we noted consent of number of many african countries getting out of GAVY support so we support the resolution.

we are concerned of affordability of new vaccines, there is a need to address the gap between accessibility of the vaccines between high and low income countries.

<u>Maldives</u>: Thank you Chair, Maldives would like to thank Libya for the proposed resolution. Maldives believes that immunization is key to preventing serious communicable diseases and we have managed to maintain a high immunization coverage in the Maldives. However a number of challenges still remain in terms of ensuring timely access to affordable supply of vaccines and reaching vulnerable groups. In this regard, we would like to support the proposed resolution by Libya with amendments proposed by Thailand and would like to urge member states to adopt this resolution during this assembly. Thank you for your attention.

**Ecuador:** thank you chair, good morning, from the beginning we have strongly supported the report and we are grateful for libya, this is type of effort we need, we accept the most recent version but after hearing thailand this morning we would like to adopt the resolution including thailand amendments and adding "possible" instead of "available" and inclusion of intellectual property

**Myanmar**: thanks; thanks to Libya for its leadership; aware of issue of access to affordable vaccines; strongly support Lib draft resolution

<u>Ghana:</u> Ghana supports the current resolution by Libya on the above subject and wishes to congratulation the WHO Secretariat for putting together the document. Immunization is no doubt one of the most cost effective interventions in reducing morbidity and mortality especially in children. Ghana has made remarkable progress in immunization. Coverage for various antigens is high. New vaccines have been introduced into our routine immunization programme.

Since 2003, no child has died from measles and measles cases are rarely seen in the country. Since November 2008, no case of wild polio has been confirmed. All the above achievements are due to Global efforts to eradicate and eliminate vaccine preventable diseases.

Ghana is one of the GAVI eligible countries but has now attained a lower middle income country status and is among the countries to be graduated from GAVI support, starting 2015. This graduation definitely has its pros and cons. We find the graduation to be too soon since the initial date for Ghana to be graduated was 2030 and so the country has not put in place any plan for the graduation. We also feel that the timing is not good considering the current economic situation of the country and this could affect the remarkable gains made in immunization.

*Mr.* Chairman, middle income countries as well as developing countries that are not eligible for GAVI support including graduating countries like Ghana will need affordable vaccines in order to eradicate, eliminate and control vaccine preventable diseases globally. In view of the above, Ghana supports the current resolution by Libya on Global Vaccine Action Plan for information on

vaccine manufacturers and prices of vaccines to be made available for member countries to enable them plan, access and sustain the gains. Thank you

**Togo**: supports draft by Libya bec diff of supply and fin access to vaccines; new vaccines for L&MICs; would like to see it adopted immediately; and listed as co-sponsor

**Niger**: Thank you chairman, we just like the other want to allign ourselves and list of speakers supporting libya, we had the benefit of GAVI (.....) we support the draft resolution and ask for adoption

**Botswana**: aligns with statement from Ethiopia on behalf of Afro; we buy vaccines without ass of Gavi and not easy; looking at draft OP1(3) don't know whether the vaccine price one country has negotiated with one company; or is it the country where the vaccine is manufactured; needs to be clarified; if it is the price negotiated by countries it will not be standard

**Eritrea**: Thank you chairman, we are fully aware of immunizations as important key for public health, we support the draft resolution

**Japan:** can support draft res as proposed and revised; however we cannot agree on proposal from Thailand "including reg and IP barriers"

**Australia:** Implementaion of action plan is vital for global health, this resolution will help access to developing country, despite the concern raised by USA and Canada the amount effort and good will made through the creating of this resolution we would Like to see that adopted this meeting; we would like to see it adopted and ask Libya to engage with those who have outstanding comments with a view to adopting

Oman: thanks; why vaccines matter and we support adoption of this resolution

**PNG**: reviewing our compr health plan and aligning with GVaP into rubella conjugate. rubella, HPV, so we strongly support adoption as proposed by Libya; please lets work on the amendments and adopt at this assembly

**Mali**: Thank you chair, we thank libya for draft resolution and we support it, we benefits from GAVI support in regards new vaccine, we are in favor for affordable and accessible vaccines.

<u>Gabon</u>: support draft as proposed; commends Libya for the consultations; also concerned with the possibility that this resolution be not adopted by this resolution; fully support adopt during this assembly

Le Gabon reprend la parole pour soutenir le projet de résolution de la Lybie et le félicite pour ses consultations en vue de trouver un consensus pour faire adopter cette résolution. Le Gabon s'inquiète cependant de la possibilité que cette résolution ne soit pas adoptée pendant la présente assemblée. Le Gabon finance entièrement sa vaccination car nous ne sommes pas éligibles à l'Alliance GAVI. Malgré plus d'un million de dollars dépensé chaque année pour la vaccination, nous avons du mal à atteindre les objectifs du Plan d'action mondial pour les vaccins. C'est pourquoi nous demandons instamment à l'assemblée d'adopter cette résolution.

**Afghanistan**: Thank you, we strongly believe in the importance of immmunization in reducing child and maternal mortality, we fully support the draft resolution.

**Benin**: Thank you, bearing in mind the importance of vaccines in reducing maternal and infant mortality we support the draft resolution made by libya and wishes this resolution will be adopted.

**Venezuela**: supports draft as amended by Lib; stress price reviews so we can afford vaccination; we have put in place a production plant to improve affordability; wish to be a co-sponsor;

**Azerbaijan**: colleague the action plan in communicable diseases has been procllaimed by the WHO; progressively generalise access to vaccines at all leevels from glo to loca

**Argentina**: reiterate social and helath value and importance of imm; unacceptable to interrupt imm plans underway; in our region; [could technicians check microphones] bec of inad supply and unaffordable; negotiating with suppliers; imm vitally impt for PH; urges other delegations to support and we support the amendment proposed by Thailand regarding intellectual property

**Morocco:** our gratitudes go to libya for work undertaken, same time financing shouldn't be lagging, life expectancies is one of the positive outcomes, national plans on providing vaccines, we support the draft resolution made by libya.

<u>Chile:</u> in conformity with the comments of the GVAP we support this res and support the amendment from Thailand and urge adoption at this assembly

En concordancia con los comentarios en relación a la Plan de Acción Mundial sobre Vacunas. Chile apoya el proyecto de resolución presentado por Libia y solicita se incluya la enmienda presentada por Tailandia , enfatizando la importancia de que esta resolución se apruebe en esta Asamblea. Gracias

**Algeria**: Thank you chair, we support the draft resolution by libya, giving importance of vaccines we are supporting adoption of the resolution through this assembly

**South Africa**: joins Afro group in supporting this res; there maybe some amendments which can be considered as suggested by Australia but does not need to go to EB; we have introduced Rota virus ands concerned about measles and HPV vaccines as we role it out for ages 9+; prevention is the cornerstone of public health and we want to see this adopted in this assembly

<u>Namibia:</u> Namibia, like the overwhelming majority who spoke before us, support the Draft Resolution by Lybia. We believe in Prevention as a best Strategy rather than Cure. We will however like to stress the importance of : Uninterrupted manufacturing and supply Chain as well as Access and transparent Pricing Structures especially for lower and middle income countries. Lastly, like Australia, we believe the imperative for adopting this Resolution as demonstrated by so many cannot be waived by minority objectives. We therefore believe the issues raised by Canada and U.S. can be addressed without halting the adoption of the resolution.

**Bangladesh:** Mr. Chair, Bangladesh delegation likes to mention that we are consistently maintaining high coverage of routine immunization. Bangladesh already achieved MDG4, and this high immunization coverage worked as one of the most important factors for this achievement.

Bangladesh has a high population and therefore has also a high child population. We want to make sure that high coverage of immunization is sustained and further improved in the remaining period of MDGs and in era of SDGs. Therefore, we strongly support the resolution and also strongly recommend to endorse this resolution in this 68th World Health Assembly.

Regarding the ammendment of Thailand, we express common views of other Member States of the South East Asia Region. We believe that accommodating the Thailand's ammendment should not be looked as a problem; because it calls for simply reporting. This reporting is important because we should know what are the factors that are creating barriers of maintaining high coverage of immunization in Member States. To simplify the text of the ammendment, we propose that the text of OP2 subparagraph6 can be rephrased as: "to report upon technical, IP and legal barriers that may undermine robust conpetition that can enable price reductionsfor the new vaccines" Thank you chair.

<u>Cameroon</u>: we are in position with african states concerning this draft resolution, we thank libya, we will not be in GAVI list in 2 years that's why we support the draft resolution in it's current form and we would be really sorry if the draft wasn't adopted.

Le Cameroun est solidaire de la déclaration faite au nom de la Région Afrique. A ce titre, le Cameroun félicite la Lybie pour l'initiative. En effet, le Cameroun voit avec inquiétude la perspective de sa sortie de la liste des pays bénéficiant de l'appui de GAVI pour l'acquisition des vaccins, et pour cause, la charge énorme et subite qui serait difficilement supportable. En conséquence, le Cameroun soutien fermement le projet de résolution dans sa version actualisée par la Lybie. Merci Monsieur le Président.

<u>Switzerland</u>: the impl of GVAP on Imm is of extreme relevance; Switz would like to see greater cov by imm in our country; have conducted a new campaign; we ass ourselves with the position of the US; this res was developed outside the formal structures; would have been better to be developed inside this house; concerned about the proposal by Thailand; support delegation of Japan; on the other hand we ass ourselves with Australia in terms of the need to work in parallel and ach a consensus on this resolution

Monsieur le Président, La mise en œuvre du Plan d'action mondial pour les vaccins est d'une grande importance, également pour la Suisse qui a pris des mesures pour augmenter la couverture nationale de vaccinations, notamment pour la rougeole. La Suisse souhaite associer sa voix à la délégation des Etats-Unis. Nous regrettons que le projet de résolution ait été tablé in extremis au début de cette Assemblée. Afin de garantir la qualité de nos travaux et des documents adoptés, il eut été préférable de disposer de ce projet à l'avance. Au vu des nombreuses interventions et des diverses suggestions d'amendements sur ce projet de résolution, la délégation suisse n'a plus de vue d'ensemble de ces différentes propositions. Concernant l'OP 2, point 6, la Suisse s'oppose à la proposition du distingué délégué de la Thaïlande et appuie la déclaration faite par le distingué délégué du Japon. Au vu du large soutien donné à ce projet de résolution sur le Plan d'action mondial pour les vaccins, la Suisse estime, tout comme l'Australie, qu'il est important que cette résolution soit adoptée lors de cette Assemblé. Afin de trouver un consensus, ma délégation suggère au Président d'interrompre les discussions sur ce point afin qu'un consensus soit trouvé dans le cadre de discussions informelles, voire d'un groupe de rédaction. Je vous remercie Monsieur le Président.

**Brazil:** SOrry to take the floor again, we fully support that amendments we totally agree with procedures, it is important that we must discuss and adopt the resolution.

Croatia (the following statement is posted on the WHO website for the 11<sup>th</sup> meeting of Committee A on Sat 23; however we have no record of it being delivered): Thank you Mr Chair, distuinguished delegates Ø Based on the noble targets of the Global Vaccine Action Plan, the regional European Vaccine Action Plan is prepared and we wish to emphasize our full support to the both strategic documents. Ø All six goals of the European Vaccine Action Plan have our full support and Croatia is dedicated to continuous improvement in achieving all of these goals. The six goals of the European Vaccine Action Plan with Croatian achievements are the following: 1. sustaining polio-free status · Croatia is considered polio-free, as well as the entire WHO European region; 2. eliminating measles and rubella Measles and rubella are practically eliminated in Croatia, with sporadic imported cases; 3. controlling hepatitis B infection Croatia is a low prevalence country and following the introduction of hepatitis B vaccination into the national immunisation programme in 1999, the incidence of hepatitis B has been declining. especially in children, adolescents and young adults; 4. meeting regional vaccination coverage targets at all administrative levels throughout the Region . In the last decade, all counties have been achieving 95% vaccination coverage with childhood vaccines according to the programme; 5. making evidence-based decisions on introduction of new vaccines . The decision on introduction of new vaccines in Croatia is based on solid epidemiological data, 6. achieving financial sustainability of national immunization programmes - Financing of traditional Expanded programme of Immunisation (EPI) vaccines is sustainable, but the lack of funds is an impediment for introduction of new vaccines. Oover the last two years, due to problems with availability of certain vaccines on the market, Croatia, as well as a number of other countries, has experienced difficulties in timely procurement of vaccines for the Immunisation programme. Ø This shortage of vaccines has forced us to modify our National Immunisation programme. Ø In this respect, we see the continuous engagement of WHO in public communication strategies on the benefits of vaccination beneficial for Member States and would like to see WHO taking on a stronger role as mediator between the vaccine industry and national Immunisation programmes.

**DG**: thanks; this is a v imp subject; judging by no of intervnetions; have been listening very carefully; no intervention disagrees with imp of immn; good news; the range of interventions is

huge; many delegations support drdaft res and urge its imm adoption; also heard some countries who want more time; either move to EB or use the remaining hours from today onwards until countries can find consensus; given the importance and my suggestion is to follow advice of Australia, PNG and Switzerland; please get together and discuss; there are additional amendments; come together to discuss; propose we suspend the item and for those who need to consult please get together now;

Chair: there is a consensus supporting the DGs'rec so we move on

## Item suspended for further discussion; resumed in Committee A on Monday 25 May

### Documents:

- <u>A68/30</u> Sect report
- <u>A68/A/CONF./4 Rev.2</u> further revision of Libyan draft
- A68/A/CONF./4 Add.1 fin & admin

**Chair:** congratulates delegations for their informal discussions to advance the issue. Revision of draft resolution was prepared, this is contained in <u>A68/A/CONF./4 Rev.2</u>

**Libya**: Thank you for opportunity to update the floor. GVAP agenda item opened, through informal consultation helpful amendments incorporated into draft. More consultations held with EU thailand etc after thursday. On Saturday over 60 countries individually endorsed the resolution. A number of countries stressed importance of reaching an agreement. Information consultation: Algeria Argentina Australia, Canada EU, Latvia, Korea South Africa, Switzerland USA - convened in environment of good will and constructive discussion resulted. Thanks the 19 countries that requested co-sponsorship. With precious knowledge of SA, passion of Brazil, notes flexibility of MS to complete this work during WHA68. Is but one step towards more accessible and affordable vaccines. We should be proud to take a step in the right direction for our children.

Chair: adoption of resolution ready?? Brazil has the floor

**Brazil**: Gracias. we want to approve resolution and grateful to be part of this discussion and will to cosponsor resolution

**USA**: Thank you chair. Thanks all delegates that took part in discussion on sat afternoon. US had come in with concerns, driven in large part as this is such an important issue - we have made enormous investments in closing gaps in vaccine coverage. By no means were any rules violated, however we remind best practise which is to introduce resolutions in November-December before EB.

<u>Canada</u>: as we noted in our earlier intervention, Canada deeply appreciates the efforts of Libya in advancing our collective efforts. We are aligned with our fellow Members in wishing to see better progress be made.

Canada wishes to reiterate that our primary and only concern was that the resolution was distributed to the Members on the same morning it was introduced on this floor. We need to ensure that important public health issues are given appropriate time for all Member States to consider so that all of our concerns and needs are incorporated.

Canada is pleased that we were able to move this important item forward in this Assembly. We are strongly supportive of immunization as a key component of our development work. It is extremely important that this work continues to move forward and that we look for collective solutions. In that light, we are pleased to join consensus on the resolution and will continue to work collaboratively on this very important issue. Thank you

#### Resolution (WHA68.6) adopted; item closed