World Health Organization

WHO Submission for Regional Meetings prior to Mercury INC5

Index to Key Information from the World Health Organization

Prepared by WHO, 23 October 2012 as a resource for the Intergovernmental Negotiating Committee (INC) on the preparation of a legally binding treaty on mercury.

1. The present document provides an updated index to key information resources from the World Health Organization, relating to the draft text for a legally binding instrument on mercury. References to previous WHO submissions to the INC appear at the end of the document.

E. Products and Processes

Thermometers (for medical use) and Sphygmomanometers

2. *Replacement of mercury thermometers and sphygmomanometers in health care: Technical guidance,* WHO 2011.
   English: http://whqlibdoc.who.int/publications/2011/9789241548182_eng.pdf
   Spanish: http://whqlibdoc.who.int/publications/2011/9789243548180_spa.pdf

Pharmaceuticals: Thiomersal

3. In addition to the references provided in the following paragraphs, please refer to *Annex 1: Updated facts and figures on vaccines*, which contains a summary of key information, updated as of 23 October 2012.

4. A number of WHO advisory groups and committees on immunization address the issue of thiomersal in human vaccines. *Annex 2: WHO expert processes for thiomersal* summarizes the mandate of each group/committee, and provides an illustration of the functions of the bodies in relation to thiomersal. The relationship between each body, as well as the pathways for WHO recommendations, consultation and country decision-making is presented in the following figure.

5. WHO information on thiomersal presented to INC3: UNEP(DTIE)/Hg/INC.3/6. http://www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/INC3/3_6_health.pdf (available in other UN languages from the INC3 website http://www.unep.org/hazardoussubstances/Mercury/Negotiations/INC3/INC3MeetingDocuments/tabid/3487/language/en-US/Default.aspx).

6. *WHO informal Consultation to develop further guidance on vaccines for the UNEP-convened Intergovernmental Negotiating Committee Meeting 4*, WHO-HQ, 3-4 April 2012, and meeting of the *WHO Strategic Advisory Group of Experts (SAGE) on immunization,* April 2012.

   - Presentations are posted on the WHO website at http://www.who.int/immunization/sage/meetings/2012/april/presentations_background_d

ocs/en/index.html Navigate to "Session: Information on vaccines for an Intergovernmental Negotiating Committee on Mercury" for the presentations and background documents.

- Conclusions of the SAGE in English and French (see page 215): http://www.who.int/entity/wer/2012/wer8721.pdf

7. Meeting of the *WHO Global Advisory Committee on Vaccine Safety*, 7 June 2012, review of the safety of thiomersal. Report published in the WHO Weekly Epidemiological Record on 20 July 2012 http://www.who.int/wer/en/ Summary findings are presented in Annex 1 of the present submission.

Herbal/traditional/homeopathic medicines

8. *WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues,* 2007. http://apps.who.int/medicinedocs/en/m/abstract/Js14878e/

9. *WHO guidance on safety issues in the preparation of homeopathic medicines*, 2010 http://apps.who.int/medicinedocs/en/m/abstract/Js16769e/

Skin Lightening Products

10. *Mercury in Skin Lightening Products.* WHO Information Sheet, 2011.
Arabic http://www.who.int/entity/ipcs/assessment/public_health/mercury_flyer_ar.pdf Chinese http://www.who.int/entity/ipcs/assessment/public_health/mercury_flyer_cn.pdf English http://www.who.int/entity/ipcs/assessment/public_health/mercury_flyer.pdf French http://www.who.int/entity/ipcs/assessment/public_health/mercury_flyer_fr.pdf
Russian http://www.who.int/entity/ipcs/assessment/public_health/mercury_flyer_ru.pdf
Spanish http://www.who.int/entity/ipcs/assessment/public_health/mercury_flyer_sp.pdf

Dental Amalgam

11. *Future use of materials for dental restoration*, 2010. Report of meeting convened at WHO HQ, Geneva, Switzerland 16-17 November 2009. http://www.who.int/entity/oral_health/publications/dental_material_2011.pdf

G. Emissions and Releases

Indoor Burning of Coal for Residential Heating and Cooking

12. WHO global database of the percent of population per country using coal as the main cooking fuel (rural, urban and total) is available at: http://apps.who.int/ghodata/?vid=34100# (choose "exposure" option "solid cooking fuels (raw data)").

13. WHO contributes to the *Global Alliance for Clean Cookstoves*. http://cleancookstoves.org/overview/what-is-a-clean-cookstove/

14. *Health in the Green Economy: Household Energy Sector in Developing Countries.* WHO, 2011.
English http://www.who.int/entity/hia/brochure_hhe.pdf

Spanish http://www.who.int/entity/hia/hgebrief_hh_sp.pdf

15. WHO is in the process of establishing *WHO guidelines for household fuel combustion,* anticipated release date 2013. Guidelines on indoor burning of coal are expected.

J. Awareness-raising, research and monitoring, and communication of information

WHO Health Guidelines on air, drinking-water and dietary intake

16. *WHO Air Quality Guidelines* (2005), for inorganic mercury (inhalation). TWA 1ug/m3 annual average http://www.euro.who.int/__data/assets/pdf_file/0005/74732/E71922.pdf

17. *WHO Guidelines for Drinking-Water Quality,* 4th Edition (2011) for inorganic mercury 0.006mg/L http://www.who.int/entity/water_sanitation_health/publications/2011/9789241548151_ch08.pdf

18. *WHO Guidelines for dietary intake of methyl mercury and inorganic mercury* (update 2010). FAO/WHO Joint Expert Committee on Food Additives and Contaminants, Provisional Tolerable Weekly Intake for methyl mercury (maternal intake to protect the foetus) is 1.6 ug/kg bw, applicable to dietary exposure from fish and shellfish. Provisional Tolerable Weekly Intake for inorganic mercury is 4 ug/kg bw, applicable to dietary exposure to total mercury from foods other than fish and shellfish. http://www.who.int/ipcs/assessment/public_health/mercury_recent/en/index.html

WHO Protocol for human biomonitoring

19. Current status of WHO work: WHO is coordinating the development of standardized protocols for human biomonitoring surveys for mercury, and planning pilot testing in volunteer countries, under the mandate of the Parma Declaration commitments to reduce early life exposure to environmental pollutants. See the most recent meeting report (April 2012) in English and Russian: http://www.euro.who.int/en/what-we-do/data-and-evidence/environment-and-health-information-system-enhis/publications/2012/biomonitoring-based-indicators-of-exposure-to-chemical-pollutants.-meeting-report .

20. Previous submissions on this subject to the INC:
    - *Report on indicators to evaluate and track the health impacts of mercury and identify vulnerable populations.* UNEP(DTIE)/Hg/INC.2/5, prepared by the World Health Organization, 2010. Available in all UN languages. http://www.unep.org/hazardoussubstances/Mercury/Negotiations/INC2/INC2MeetingDocuments/tabid/3484/language/en-US/Default.aspx
    - *Report on information on harmonized systems for measuring mercury body burden.* UNEP(DTIE)/Hg/INC.2/6. Prepared by the World Health Organization, 2010. Available in all UN languages. http://www.unep.org/hazardoussubstances/Mercury/Negotiations/INC2/INC2MeetingDocuments/tabid/3484/language/en-US/Default.aspx

Health promotion (20bis)

21. Information about WHO functions and work programme relevant to Article 20bis are presented in an Annex to the UNEP Secretariat's paper (prepared for INC5) on 20bis.

Inventories of use

22. WHO maintains a global database of the percent of population using coal as the main cooking fuel (rural, urban and total) per country. See WHO Global Health Observatory: http://apps.who.int/ghodata/?vid=34100# (choose "exposure" option "solid cooking fuels (raw data)").

Harmonized methodologies for estimating health impacts

23. *Mercury: Assessing the environmental burden of disease at national and local levels.* Environmental Burden of Disease Series, No. 16. WHO, 2008. http://whqlibdoc.who.int/publications/2008/9789241596572_eng.pdf

24. *Guidance for identifying populations at risk from mercury exposure,* (UNEP/WHO, 2008) English: http://www.who.int/entity/foodsafety/publications/chem/mercury/en/index.html Executive summary available as UNEP(DTIE)/Hg/INC.2/19 in all UN languages on INC2 website.

References to the World Health Organization

25. The draft text mentions the World Health Organization. Information on the functions of WHO, its membership (194 Member States), as well as other governance matters, can be found on the WHO website at: http://www.who.int/governance/en/index.html as well as in an Annex to the UNEP Secretariat's paper (prepared for INC5) addressing Article 20bis.

Previous WHO submissions to the INC

26. WHO submission for INC1: http://www.unep.org/hazardoussubstances/LinkClick.aspx?fileticket=2blN4eJhVDI%3d&tabid=4325&language=en-US

27. WHO submission for INC3: UNEP(DTIE)/Hg/INC.3/INF/4 - Information submitted by the World Health Organization, at: http://www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/INC3/3_INF4_WHO_information_.doc

28. WHO submission for INC4: http://www.unep.org/hazardoussubstances/Portals/9/Mercury/Documents/INC4/Submissions%20from%20IGOs/WHO%20Submission%20to%20INC4%2019%20June%202012.pdf

World Health Organization

Annex 1

Updated facts and figures on vaccines and the global mercury treaty
23 October 2012

Q. Are there new data on the human health impact of thiomersal in vaccines?

A. Yes; an independent scientific advisory body convened by WHO, the Global Advisory Committee on Vaccine Safety (GACVS), reviewed the latest data on 7 June 2012. The report of the meeting was published in the WHO Weekly Epidemiological Record on 20 July 2012. The Committee concluded that numerous well-designed epidemiological studies conducted in many countries have failed to find a causal relationship between prenatal, neonatal, or postnatal exposures to thiomersal in vaccines and a host of neuropsychological outcomes, including autism. The small number of studies which had suggested an association had significant flaws in their design and underlying assumptions, thus invalidating their conclusions. Other studies conducted since 2008, including analysis of mercury in blood and hair, provided confirmation that the half - life of thiomersal (ethyl mercury) was much shorter than that of methyl mercury.

Q. Are there new data from animal models on thiomersal?

A. Yes, new animal studies in mice, rats and non-human primates have evaluated thiomersal exposure and possible adverse behavioural, histopathological or neurochemical outcomes. On review, studies which claimed associations were found to either be using doses or dosing intervals that were not relevant to the human situation or making claims that were not confirmed. Of note, new mathematical models are now available to further evaluate the kinetic and toxicological differences between ethyl and methyl mercury.

Q. What is the WHO position on the safety of thiomersal taking into account these new data?

A. WHO remains of the opinion that there is no scientifically-sound evidence to show that there is a possible health hazard associated with the amounts of thiomersal currently used in human vaccines. Vaccine safety is a primary concern for WHO and GACVS serves as its independent expert group. WHO will continue to provide rigorous, scientifically valid, evaluation of new data on safety that emerges in the future.

Q. Can thiomersal be replaced with alternative preservatives?

A. WHO convened an expert scientific meeting on 3 and 4 April 2012 and examined this question in depth. Evidence was presented that current alternative preservatives (products other than thiomersal that are used in a small number of vaccines) interact in unpredictable ways with existing vaccines. At this point, there is consensus that no ideal alternative preservatives will be available for the near- or mid-term. The limited data available showed alternative preservatives, such as 2-phenoxy ethanol, to have variable anti-microbial effectiveness, which differs from vaccine to vaccine, and to have different compatibilities with different vaccine components such as antigens and excipients.

Q. Is there a research and development pipeline of alternative preservatives?

A. Experts at the 3-4 April meeting advised that, while important, development of new preservatives will be an unpredictable, cost-intensive, time consuming, trial and error, case-by case process. There are, for example, significant technical barriers such as no anti-microbial

effectiveness standards and assays that predict field performance. However research on alternatives is being encouraged by WHO to support the broad objectives of the mercury treaty (to reduce human releases of mercury) and not because of any health threat from thiomersal. As absence of thiomersal would seriously interrupt the manufacture of particular vaccines such as pertussis (whooping cough) and seasonal and pandemic influenza vaccines, research should be conducted on alternatives to the use of thiomersal in the manufacturing process. The research investment should also consider immunization programme changes such as new technologies for maintaining sterility when withdrawing doses from a multiple dose vial, new requirements for vaccine handling, logistics and waste disposal.

Q. Are there new data on the possibility to switch, globally, to single-dose preservative free vaccine presentations?

A. Yes, the WHO meeting on 3-4 April 2012, plus the WHO Immunization Practices Advisory Committee meeting on 18 April 2012, heard from experts that this option would have would have a significant impact on vaccine costs as well as on operational matters such as vaccine storage, delivery and waste management and would limit access. This research was based on a survey of manufacturers and modeling based on procurement patterns by UN agencies, as well as available data from selected countries. Development costs and time to shift to thiomersal-free vaccines are considered substantial, with the outcome of trials and future vaccine stability uncertain. The likely increase in cost to the countries buying vaccines varies. For vaccines that are procured by UN agencies, it is estimated that a preservative-free approach corresponds to an annual increase of $130 million which is 50% of the current cost of thiomersal-containing vaccines. The number of international vaccine shipments by airfreight will rise substantially, with a commensurate increase in carbon dioxide emissions. Volume implications for cold chain storage are significant, varying from 165% to 324% increases, with major impact on central and peripheral stores. Waste management implications are of the order of a tripling of impact with a shift to all single-dose vials, increasing vial waste from 2,350 m^3 (2011 UN agency procurement data) to between 3,850 m^3 and 7,600 m^3.

Q. What is the WHO position on global use of single dose preservative-free presentations?

A. A shift to global use of single dose preservative-free presentations would almost certainly lead to severe vaccine shortages due to the major impact on manufacturing, distribution, vaccine costs and environmental waste; and the greater workload for logistic and nursing staff. Overall there is considered to be a high risk of serious immunization program disruption, particularly in countries with fragile health systems. WHO continues to support use of multi-dose vials because it increases flexibility in handling and storage of vaccines.

Q. Is there an equity issue concerning thiomersal-free vaccines?

A. Yes; since thiomersal in vaccines is not a health threat and since thiomersal-containing vaccines are essential to allow all populations in all countries of the world to have access to these life-saving medicines at affordable prices then restricting access to thiomersal-containing vaccines would create inequity. This is because countries would need more resources (human, financial, infrastructure) to deliver their vaccines; the poorest and most disadvantaged populations would most likely miss out if countries could not scale-up their resources to cover their entire population. Access to safe vaccines, no matter where one lives, is of the utmost importance to WHO. Thiomersal-containing vaccines facilitate access. A commentary article from an academic ethics research group, making the points above, is in press and should be published prior to INC5.

Q. Is there new WHO guidance to countries?

A. Yes; policy implications for immunization programmes resulting from the mercury treaty negotiations were addressed by the WHO Strategic Advisory Group of Experts for Immunization on 12 April 2012, and were published in the WHO Weekly Epidemiological Record on 25 May (http://www.who.int/wer/2012/wer8721.pdf).

Based on multiple expert reviews, WHO concluded that there would be a clear risk (if reformulation with alternative preservatives or with no preservatives is required) that some products would become unavailable – particularly the current low cost vaccines. There would be a high risk of serious disruption to routine immunization programmes and mass immunization campaigns if currently thiomersal-preserved vaccines are not available. The consequences would be a negative health impact, due to the predictable and sizable increase in mortality through lack of access to vaccines, for very limited environmental impact.

WHO reaffirms that thiomersal-containing vaccines are very safe. They are essential and currently irreplaceable components of immunization programmes, especially in developing countries, and removal of these products would disproportionately jeopardize the health and lives of the most disadvantaged children worldwide.

Whilst WHO supports global moves to minimize mercury releases to the environment, it is essential that access to thiomersal-containing vaccines is not restricted under this global initiative. Due to the unpredictable nature of research, efforts must not create artificial timelines to transition to non-thiomersal containing products. WHO will continue to monitor the development of alternative presentations. If non-thiomersal based alternatives are developed that are globally viable and cost-effective, then the WHO position will be re-visited.

Q: Will veterinary vaccines be affected if pharmaceutical products are included within the scope of the treaty?

A: Yes, during the April 3-4 2012 consultation held by WHO, data were presented to show the importance of thiomersal-containing vaccines to veterinary public health. The World Organization for Animal Health (OIE) must ensure that its 178 Member States have access to affordable vaccines of good quality in order to effectively combat animal diseases of importance. The OIE informed WHO that it therefore shares the concerns of WHO on the possible negative impact on the availability of vaccines if an addition layer of regulation under the mercury treaty were introduced.

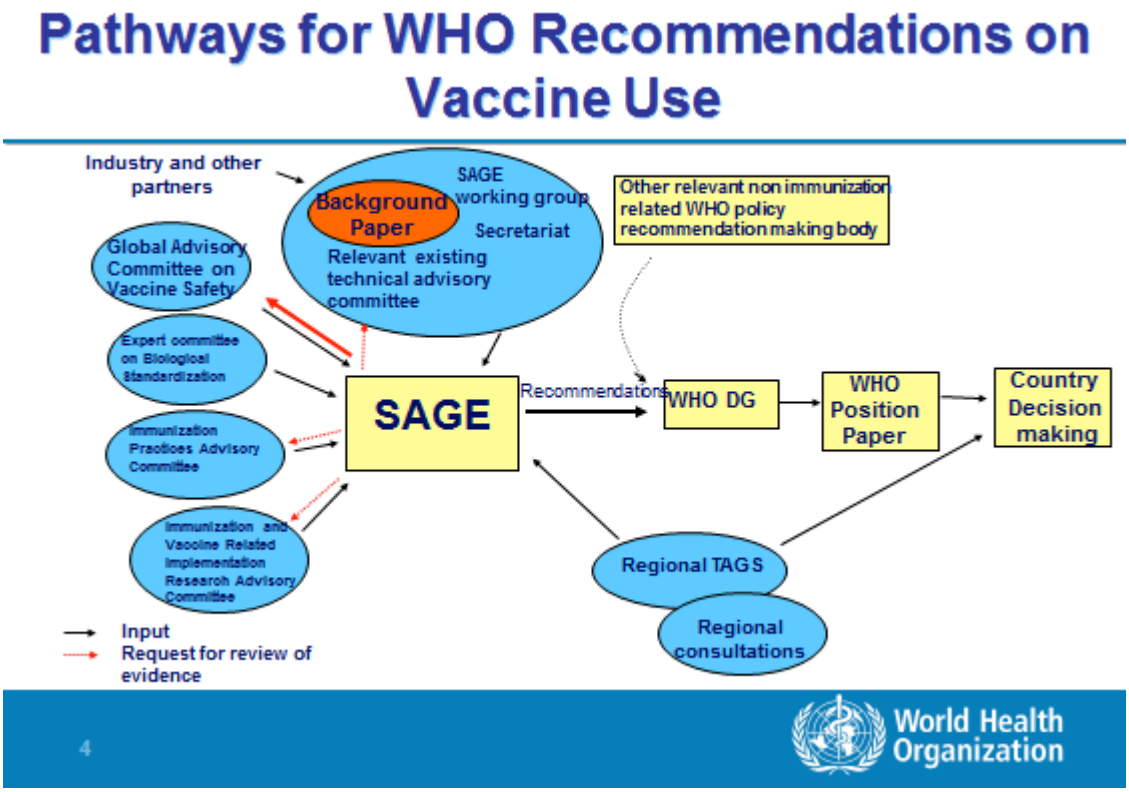
Q: Is there a need for policy coherence from Member States concerning thiomersal?

A: Yes; Pharmaceuticals are already highly regulated (by health regulators) and inconsistency at the international level as well as increased regulatory burden should be avoided. *Annex 2: WHO expert processes for thiomersal* summarizes the process for WHO recommendations, consultation and country decision-making on this issue.

Annex 2

WHO Expert Processes for Thiomersal

1. A number of WHO advisory groups and committees on immunization address the issue of thiomersal in human vaccines. The present annex summarizes the mandate of each group/committee, and provides an illustration of the functions of the bodies in relation to thiomersal. The relationship between each body, as well as the pathways for WHO recommendations, consultation and country decision-making is presented in the following figure.



Strategic Advisory Group of Experts

2. The Strategic Advisory Group of Experts (SAGE) on Immunization was established in 1999 by the Director-General of the World Health Organization. SAGE is the principal advisory group to WHO for vaccines and immunization. It is charged with advising WHO on overall global policies and strategies, ranging from vaccines and technology, research and development, to delivery of immunization and its linkages with other health interventions. SAGE is concerned not just with childhood vaccines and immunization, but all vaccine-preventable diseases.

3. SAGE members represent a broad range of disciplines encompassing many aspects of immunization and vaccines, for example epidemiology, public health, vaccinology, paediatrics, internal medicine, infectious diseases, immunology, drug regulation, program management, immunization delivery, healthcare administration, health economics and

vaccine safety. The membership also reflects a spectrum of professional affiliation and geographical and diversity balance.

4. In making its recommendations, SAGE takes into consideration issues such as disease epidemiology, clinical characteristics, vaccine and immunization characteristics, economic considerations, health systems opportunities and the existence of, and interaction with, other existing intervention and control strategies.

5. The SAGE will specifically advise the WHO Director-General on the:

    i. Adequacy of progress towards the achievement of the goals of the Decade of Vaccines (DoV) Collaboration and Global Vaccine Action Plan (GVAP);
    ii. Major issues and challenges to be addressed with respect to achieving the goals of the DoV and GVAP;
    iii. Immunization programme response to current public health priorities;
    iv. Major general policies, goals and targets including those related to vaccine research and development;
    v. Adequacy of WHO's strategic plan and priority activities to achieve the DoV and GVAP goals consistent with its mandate and considering the comparative advantages and the respective roles of partner organizations;
    vi. Cross-departmental activities and initiatives related to vaccine and immunization technologies and strategies and linkages with other health interventions;
    vii. Engagement of WHO in partnerships that will enhance achievement of global immunization goals.

6. The Committee has no executive or regulatory function. Its role solely is to provide advice and recommendations to the Director-General of WHO, and includes providing advice and recommendations on urgent matters as needed.

7. The recommendations/conclusions of SAGE meetings shall be published, with the prior approval of WHO, in the Weekly Epidemiological Record and posted on the WHO web site within two months of each SAGE meeting. In addition, these recommendations and conclusions will be translated into all WHO-HQ official languages and posted on the WHO web site.

Global Advisory Committee on Vaccine Safety

8. The Global Advisory Committee on Vaccine Safety (GACVS) provides independent, authoritative, scientific advice to WHO on vaccine safety issues of global or regional concern with the potential to affect in the short or long term national immunization programmes. This includes providing advice on urgent matters as needed.

9. More specifically, the GACVS:

    i. Rigorously reviews the latest knowledge, in all fields ranging from basic sciences to epidemiology, concerning any aspect of vaccine safety of global or regional interest, in close collaboration with all parties involved, including experts from national governments, academia, and industry;
    ii. Determines causal relationships between vaccines and/or their components and adverse events attributed to them;

iii. Creates, where necessary, ad hoc task forces with a mandate to commission, monitor and evaluate appropriate methodological and empirical research on any purported association between specific vaccines/vaccine components and adverse event(s); and

iv. Provides scientific recommendations which are intended to assist WHO, the WHO's Strategic Advisory Group of Experts (SAGE) for vaccines and immunization, national governments and international organizations in formulating policies regarding vaccine safety issues, with particular attention to those problems which affect developing countries.

Expert Committee on Biological Standardization

10. The WHO Expert Committee on Biological Standardization (ECBS) is commissioned by WHO to establish detailed recommendations and guidelines for the manufacturing, licensing, and control of blood products, cell regulators, vaccines and related in vitro diagnostic tests. Members of the Expert Committee are scientists from national control agencies, academia, research institutes, public health bodies and the pharmaceutical industry acting as individual experts and not as representatives of their respective organizations or employers. The decisions and recommendations of the Committee are based entirely on scientific principles and considerations of public health.

11. The Expert Committee on Biological Standardization meets on an annual basis (since 1947) and is responsible for the establishment of the WHO International Biological Reference Preparations and for the adoption of WHO Recommendations and Guidelines. The Expert Committee directly reports to the Executive Board, which is the executive arm of the World Health Assembly.

12. The outcomes of meetings of the ECBS as well as documents adopted by the Committee are published on the WHO web site (http://www.who.int/biologicals/en/) and in Technical Report Series (TRS). These publications provide updated information on the establishment, discontinuation and replacement of the WHO International Biological Reference Preparations as well on the adoption of Guidelines and Recommendations.

Immunization Practices Advisory Committee

13. The Immunization Practices Advisory Committee (IPAC), established in 2010, supports and advises the Director of the Department of Immunization, Vaccines and Biologicals (IVB), with the review and/or formulation of immunization practices, operational standards, tools and technologies to strengthen and improve the delivery of immunization programmes at the country level in order to realize the Global Immunization Vision and Strategies (GIVS) goals. GIVS plays a key role in supporting countries to achieve the Millennium Development Goals (MDGs), thereby contributing to the reduction of child mortality, improvements in maternal health and achievement of disease control goals.

14. The expertise of IPAC members represents a broad range of disciplines including but not limited to epidemiology, health information systems and evidence, health policy, immunization programme management and evaluation, immunization delivery, infectious diseases, international public health, maternal and child health, mechanical engineering paediatrics, and tropical medicine. The membership also reflects a spectrum of professional affiliation and geographical and diversity balance.

15. IPAC has no executive, regulatory or decision-making function. The role of IPAC is to provide advice and recommendations to the Director: IVB, on three main interconnected areas:

i. *Innovation and Strategy:*
- Operationalizing policy recommendations made by SAGE and other WHO advisory committees into recommended practices to enable their effective implementation in countries;
- Developing and reviewing immunization delivery strategies, including strategies for integration and strengthening of immunization programmes within the broader health systems context;
- Identifying opportunities for integration of new vaccine delivery with other disease control interventions;
- Monitoring and evaluating strategies, including through data collection, analysis and use.

ii. *Operations:*
- Managing immunization programmes, including planning, monitoring and supervising;
- Planning for the introduction of new or revised immunization schedules;
- Managing human resources, including through capacity building and training;
- Managing vaccine supply system operations, including those related to cold chain, equipment and transport;
- Developing information systems for improved immunization delivery, logistics etc.
- Ensuring financial sustainability, including through identification of measures to increase cost-effectiveness.

iii. *Tools and Technologies:*
- Identifying and implementing innovative technologies, tools and systems to strengthen immunization programmes;
- In collaboration with other advisory bodies, improving vaccine packaging and presentation in relation to the programmatic suitability of vaccines for use in the public sector;
- Reviewing vaccine supply system assessment tools;
- Designing tools to support immunization planning, financing, monitoring and evaluation.

An illustration of the functions of the WHO expert bodies in relation to thiomersal

16. The renewed interest about the use of thiomersal in vaccines and the WHO expert considerations that followed provides a comprehensive picture of the functions and interactions of the WHO expert bodies. All four bodies provided their specific contributions to the WHO submission for INC4. WHO additionally organized an informal consultation on 3-4 April 2012 that reviewed aspects related to thiomersal safety and efficacy, as well as options for replacing thiomersal including currently available alternative preservatives and impact on vaccine access and pricing. Based on that intelligence each expert body reflected

on the implications that a ban on thiomersal could have on vaccination activities that relate to their respective mandates.

17. SAGE highlighted implications related to vaccine access in the parts of the world that are the most affected by vaccine preventable diseases. The Committee also advised on priorities related to advocacy, communication and intersectoral dialogue on the issue. GACVS summarized the findings from the safety reviews conducted between 2002 and 2008 and reflected on the most recently available information related to possible health effects of thiomersal in vaccines. GACVS also provided advice on current gaps in knowledge and clarified its expectations with respect to scientific standards required from studies on the topic. ECBS summarized the reviews it had conducted since 1999 with respect to the toxicity of related substances and guidelines issued in 2003 on regulatory expectations related to the elimination, reduction or replacement of thiomersal in vaccines. ECBS noted the need for the continued availability of vaccines in multi-dose vials that provide safe and effective prevention of serious diseases worldwide. IPAC made a series of recommendations that relate to the programmatic implications of thiomersal use, the current benefits of thiomersal, communication needs, and opportunities presented with respect to vaccine formulation, presentation and logistics.