Independent Expert Committee Recommendation for AMC Pilot

Executive Summary

Following the G7's welcome of Minister Tremonti's report on AMCs, Ministers requested GAVI and the World Bank to convene experts and perform necessary analytical work to develop a proposal for a pilot AMC for their consideration at the Spring Meetings. To assess the key question of which of the six vaccines included in the Tremonti report would be most suitable for a pilot AMC, an independent Expert Committee was convened, chaired by Dr Ntaba, Minister of Health, Malawi, and comprising developing and industrial country experts in public health, epidemiology, industry economics, vaccine development and law (see annex 1). Based on an evaluation of all the data, the Expert Committee made the following recommendations:

1) Vaccines against all six candidate diseases (HIV/AIDS, human papilloma virus, malaria, pneumococcus, rotavirus and TB) are public health priorities. AMCs are an important tool in efforts to develop such vaccines and they should be put in place for all diseases once the AMC mechanism is well established.

2) Pneumococcal vaccines are the most suitable candidate for a demonstration/pilot AMC both because of their ability to demonstrate quickly that the AMC concept works and their potential impact on the health of the target populations.

3) A second demonstration AMC is recommended to test its impact on early-stage vaccines. Given the early and uncertain state of the science for HIV/AIDS vaccines, an AMC would have greater impact on this vaccine once the AMC concept had been successfully piloted and the candidate pipeline was more advanced. While both malaria and TB vaccines would be suitable candidates for a demonstration AMC, a malaria vaccine with 80% or greater efficacy against severe disease would be the best candidate for a demonstration AMC.

4) A number of additional factors are important to the success of an AMC pilot. These include mitigating demand risk and coordinating the AMC pull with direct push funding.

AMC for pneumo: The minimum size of an AMC for pneumococcal vaccines is estimated at $1.5 billion in nominal terms ($828 million in 2006 dollars). These resources would be disbursed as AMC payments over a period of around 9 years. Additional discussions with donors would be needed to determine the optimal structure for AMC payments. An AMC for pneumo would be expected to motivate suppliers to invest in production capacity to supply poorest countries, resurrect 'discontinued' vaccine development programs, and develop second generation technologies (e.g., protein vaccines) with increased focus on developing countries.

AMC for malaria: The minimum size of an AMC for malaria is estimated to be $2.3 billion ($955 million in 2006 dollars) which would also disburse over a period of around 9 years. Again, further discussions would be needed to decide payment size and structure. An AMC for malaria would be expected to motivate suppliers to increase investment in the development of 80% efficacious vaccines and in production capacity to supply poorest countries.

The full text of the Expert Committee's recommendations, which were agreed unanimously, follows below.

AMC Expert Committee Recommendations

All vaccines are highly desirable public health tools.

The EC evaluated the six vaccines proposed in Minister Tremonti's report, and recommends pneumococcal vaccines as the most suitable candidate for a demonstration AMC because of both its ability to rapidly demonstrate that the AMC concept works and because of its potential impact on the health of the target populations. A number of factors were taken into consideration in making this recommendation including:

- This demonstration AMC provides the ability to rapidly measure the effectiveness of the AMC concept in influencing industry behaviour and to establish effective AMC implementation mechanisms;
- The science and technology for an effective pneumococcal vaccine are well understood;
- There is a robust pipeline that includes several efficacious vaccines for the target countries. However there is a need to accelerate their development and production for use in these countries.
- Pneumococcal vaccines are likely to fit into the existing delivery systems and so can be cost-effectively introduced;
- There is a high disease burden and concern about growing antibiotic resistance.

In recommending pneumococcal vaccines for the initial demonstration AMC, the EC wanted to underscore the importance of accelerating the development, scale-up and reduction in manufacturing costs of new vaccines that will have increased public health impact in the target developing countries. The EC encourages the IAC to take this intent into consideration when determining the Target Product Profile for pneumococcal vaccines.

The EC recommends a second demonstration AMC to test the impact of the AMC on early stage vaccines. While vaccines against HIV/AIDS, malaria and TB are all critically important, the EC concluded that given the state of the science for HIV/AIDS vaccines, increased levels of push funding would be more appropriate than an AMC at this time. The EC is of the view that both malaria and TB vaccines would be suitable candidates for a demonstration AMC. However, on balance the EC found a malaria vaccine with 80% or greater efficacy against severe disease to be a more suitable candidate for this demonstration AMC for the following reasons:

- Given the high number of candidates in the pipeline, there is greater potential for the AMC to focus industry's attention and accelerate the development of the most promising ones.
- The development process will be more rapid because the length of trials to establish efficacy would be shorter as malaria is an acute disease with a more defined target population.
- Malaria makes the vicious circle of poverty and ill health in the poorest countries even

more acute.

- National demand for malaria vaccines in endemic countries is likely to be strong given the very high awareness of its human and economic impact.

In view of the dynamic nature of vaccine development and the need for recommendations from the EC to be based on up-to-date information, the EC is happy to reconvene if further recommendations for future AMCs are requested.

Enabling Recommendations

To maximize the impact of AMCs, the IAC recommends the following complementary actions:

Recognize the importance of the IAC and WHO pre-qualification processes being in harmony. The EC understands that ways to harmonize these two processes are already being explored. The EC recommends further exploration into how the knowledge and capacity of WHO might be leveraged to support the IAC process (e.g. defining product profile) and to ensure the timely pre-qualification of AMC-eligible vaccines.

Assure the availability of financial and human resources to strengthen the capacity of countries to ensure the sustained delivery of vaccines.

Explore mechanisms and dialogue with existing entities and donors to support governments to ensure adequate funding for the long-term, sustainable purchase of vaccines once the AMC is depleted.

Support governments to make timely decisions regarding the introduction of the AMC vaccine.

Improve the accuracy and timeliness of demand forecasts so as to reduce the demand risk faced by industry.

Monitor and evaluate the progress of demonstration AMC(s).

Finally, as recommended in the report from Minister Tremonti, the EC strongly endorses the continued need for complementary push funding, and recommends coordination between push and pull for efficiency and maximum impact of funding… "Such a pull mechanism is not an alternative, but is highly complementary to other public and philanthropic interventions in the health sector and, more generally, in development aid."

Annex 1 **AMC Independent Expert Committee**

To ensure an independent and evidence-based recommendation to the G8 Ministers on which vaccine(s) would be most suitable for the initial AMC pilot, the World Bank and GAVI convened an AMC Expert Committee. Based on suggestions from numerous bodies including governments, UN agencies, public-private partnerships and foundations, experts without conflicts of interest were identified in the areas of public health, epidemiology, industry economics, vaccine development and law. The Expert Committee was tasked with evaluating the six potential AMC vaccines identified in Minister Tremonti's AMC Report (HIV/AIDS, malaria, tuberculosis, rotavirus (diarrheal disease), pneumococcus (pneumonia and meningitis) and human papilloma virus (cervical cancer)) against agreed criteria. The Expert Committee made assessments about which vaccine(s) should be recommended as most suitable for the initial pilot. The Expert Committee was chaired by Minister Ntaba, the Minister of Health of Malawi. Over 60% of the experts came from developing countries. The full membership of the Expert Committee is included in Annex 2.

PARTICIPANT LIST

Chair:
Minister Ntaba, Minister of Health, Malawi ***(Chair, Expert Committee)***

Participants:

Adrian Towse, Office of Health Economics, UK

David Fleming, Director of Global Health Strategies, Bill & Melinda Gates Foundation

Dr. Barakamfitiye, former WHO AFRO Director of Communicable Disease Division and head of Sub-regional office for West Africa

Joy Phumaphi, Asst. DG Family and Community Health, WHO

Maryann Chawo, Ministry of Health, Malawi

Merceline Dahl-Regis, Chair of the GAVI Independent Review Committee, Bahamas

Michael Conway, McKinsey & Co.

Paul Henri Lambert, Chair of the Global Advisory Committee on Vaccine Safety

Professor Adenike Grange, President of International Pediatrics Association, Nigeria

Professor Anthony Mbewu, President of the South African Medical Research Council

Steve Hurst, Senior Advisor to BioVentures for Global Health

Supamit Chunsuttiwat, Senior Medical Officer, Department of Public Health Thailand