MEMORANDUM

To: Strategic Advisory Group of Experts on Immunization

From: Co-chairs Decade of Vaccines Collaboration Dr. Ciro de Quadros, Sabin Vaccine Institute and Prof. Pedro Alonso, Barcelona Institute for Global Health

Date: 8 February 2011

Re: Decade of Vaccines Collaboration progress update for 16 February Extraordinary SAGE meeting

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SAGE's guidance is critical to the Decade of Vaccines Collaboration (DoVC) process. We are grateful to be given the opportunity to share the revised draft of the Global Vaccine Action Plan (GVAP) for SAGE's comments and feedback, which will be used to shape and strengthen the document to be submitted to the World Health Organization for the Sixty-fifth World Health Assembly in May 2012.

The GVAP has been developed through a global consultation process and with the support of eight working groups on (i) Research & Development, (ii) Delivery, (iii) Global Access, (iv) Public & Political Support, (v) Costing & Funding, (vi) Health & Economic Benefits, (vii) Indicators, and (viii) Communications. This memo aims to provide SAGE with a brief update on the key themes highlighted through the ongoing consultation process, as well as the progress made by the DoVC since SAGE last discussed the DoVC on 8 November 2011.

DoVC progress since November

The DoVC consultation process was officially launched with the discussion of Draft 0 GVAP at the SAGE meeting on 8 November 2011. Since then, the DoVC has held approximately 20 consultations in Asia, Africa, Europe, Middle East, and Western Pacific regions as well as an online consultation. A regional consultation for the Americas is planned for 27-28 February. We have briefed all World Health Organization (WHO) Member States and country missions based in New York city in addition to receiving input from experts and different stakeholders from all world regions. We estimated that input from over 90 countries and 220 organisations has been received by the DoVC as part of the consultation process to develop the GVAP. The consultation process was designed to ensure that meaningful input could be solicited from all key stakeholder groups: governments and elected officials, health professionals, academia, manufacturers, global agencies, development partners, civil society, media and the private sector.

During the last SAGE meeting, SAGE members emphasized the particular importance of engaging countries and civil society organizations (CSOs) as part of the consultation process. Particular attention was therefore given to these two groups.

In parallel with the consultation process, DoVC working groups have provided technical inputs for the development of the GVAP, reviewed drafts and responded to feedback received during consultations. In particular, the Costing & Funding and Health & Economic Benefits working groups met regularly during Q3 2011-Q1 2012 to quantify potential costs and benefits for the DoV. The Indicators working group convened for their first meeting on 2-3 February. The progress of these working groups is summarized below.

Finally, on 20 January, the WHO Executive Board members reviewed and positively commented on the GVAP summary (http://apps.who.int/gb/ebwha/pdf_files/EB130/B130_21-en.pdf). Approximately 20 countries provided comments. There were also interventions from representatives of civil society, namely Save the Children and the GAVI Civil Society Constituency, who spoke on behalf of over 200 non-governmental organizations who praised the process to engage CSOs in the on-going consultation process led by the DoVC Secretariat (http://www.savethechildren.org.uk/blogs/2012/01/shaping-the-immunisation-plan-for-the-coming-decade-at-the-who-executive-board).

Key themes that emerged from the consultations

During the consultations there was great enthusiasm and engagement, as well as affirmation that the DoVC is a timely and welcome effort. Appendix A of this memo provides a summary of consultations undertaken between the last SAGE meeting and the upcoming 16 February SAGE meeting. Similar themes emerged from the different consultations, albeit with nuances according to each stakeholder group. The DoVC has incorporated, where possible, the themes that emerged into the revised draft GVAP submitted for this meeting. These include:

Country ownership: The GVAP needs to be meaningful to countries. Recommended actions and indicators should be relevant at country level and enable countries to reduce their reliance on external support. Country ownership means ownership by all stakeholders within a country (e.g., CSOs, academia, private sector and other national partners), not just governments.

Community engagement: While ownership at country level is of paramount importance, so is community-level engagement. Consultation participants emphasized that DoV actions must be undertaken with communities and not imposed on them.

CSOs engagement and capacity building: There is an opportunity to strengthen the role of CSOs in vaccines and immunization. CSOs are well positioned to support the implementation of many of the actions recommended in the GVAP if investments are made to build and strengthen CSOs capacity.

Vaccine hesitancy: Health care workers and other immunization champions feel unprepared to address misguided criticism of vaccines and immunization. Research is needed to understand the factors that contribute to vaccine hesitancy and training is needed to enable programme managers and champions to proactively address these factors. The impact and use of social media needs to be understood in this context.

Vaccines as part of comprehensive disease prevention and control: A concerted effort should be made during the DoV to shift from monitoring coverage to monitoring the disease impact of immunization. Immunization plans should be part of the broader national health sector plans. Country-specific immunization targets should be set within the context of national health priorities and morbidity and mortality reduction goals. Country commitment to immunization as a priority should under no circumstances come at the expense of other health programmes.

Coordination rather than integration: Previous GVAP drafts called for the integration of immunization with health systems. Consultation participants expressed concern that integration implied a merger of immunization programmes with other health programmes, which could compromise efficiency and effectiveness of EPI. Further discussions clarified that in many cases, immunization should continue to operate as it has done so-far, but coordination of immunization with other health services (and other immunization programmes in the case of campaigns) should take place at all levels of a country's programmes.

Identifying the "game changers": A question that has come up repeatedly during the consultation process is "what will be different about this decade"? An attempt was made to identify one "game changer" action for each outcome in the GVAP. This attempt revealed that no one action is a silver bullet. Success will rely on multiple stakeholders collectively taking action to deliver on the DoV vision – some of these actions are already happening but additional actions are likely to be needed. For existing actions, there is a need to maintain and intensify progress. For new actions, there is a need to more fully define how to implement these actions and who will be responsible for the task.

Accountability framework: Consultation participants agreed that the establishment of a robust accountability framework for the DoV could be game changing. DoVC progress towards defining an accountability framework is summarized below.

Stakeholder responsibilities: Consultation participants affirmed the high-level stakeholder responsibilities articulated in the GVAP draft (see GVAP Appendix 2). They clarified that the primary responsibility is held by individuals and communities, governments and health professionals, as the recipients and providers of immunization. Other stakeholders also have an important role in achieving the GVAP outcomes and need to coordinate with those mentioned above.

Making the GVAP operational: Consultation participants consistently noted that the GVAP is a very high-level document that will be submitted for endorsement by the WHA in May 2012. They also noted that the process to translate the GVAP into country programmes needs to be clarified. The Delivery working group is taking the lead on this issue. However, the DoV Collaboration would welcome inputs and suggestions from SAGE members on how to do this. The DoV Collaboration body of knowledge will be available on the DoV website.

What happens after the DoVC sunsets: The positioning of the DoVC as a "time-limited" effort produced mixed reactions. While it was commended that DoVC is not creating additional structures, concerns were raised by consultation participants on how to maintain momentum. They affirmed that now is an opportune time for an effort like the DoVC. But they are anxious to understand who will be responsible

for implementing the GVAP after the DoVC sunsets. Further work is needed to define the accountability framework for the DoV, which will include the definition of a structure and process for monitoring progress during the decade and holding stakeholders accountable.

Accountability framework (Section 7 of the GVAP)

As mentioned above, there is near universal agreement that a strong accountability framework has the potential to be a "game changer" for vaccines and immunization. There is also consensus that this framework should build on existing accountability measures where appropriate (this was a specific request of the DoVC Leadership Council). The latest GVAP draft explains that the DoV accountability framework will have three elements: 1) stakeholder commitments to implement the actions recommended in the GVAP, 2) indicators for DoV goals, outcomes and actions, and 3) a structure and process for monitoring progress. The comprehensive accountability framework will not be included in the GVAP. The GVAP only includes high level stakeholder roles and responsibilities and indicators for DoV goals and outcomes. The full development and implementation of the accountability framework will take place after the May 2012 WHA.

To date, DoVC's efforts to define the DoV accountability framework have focused on the identification of indicators. A long list of potential indicators of progress towards the achievement of DoV goals and outcomes was generated through the consultation process. The Indicators working group then convened to review this list and recommended a sub-set for inclusion in the GVAP based on four criteria: relevance to outcome, relevance to countries, ease of measurement and objectivity. Recommendations are summarized in Appendix B of this memo. Some of the indicators initially recommended by the working group were subsequently modified in consultation with them and endorsed by the Steering Committee co-chairs.

Cost, Funding and Health and Economic Benefit Estimates (Section 6 of the GVAP)

The Costing & Funding working group comprised of experts from multiple global health institutions is working to develop estimates of the cost of procuring and delivering existing and expected new vaccines during this decade (as defined for 2011-2020) to 94 low and lower-middle income countries. The Health & Economic Benefits working group is working to estimate the potential health and economic benefits associated with these procurement and delivery costs. During the 16 February meeting, the methodology for these exercises will be presented for discussion by SAGE. The methodology is summarized in Appendices 3 and 4 of the GVAP.

These groups will refine their estimates based on feedback provided by SAGE. The final numbers resulting from this exercise will be presented at the WHO missions brief in early March.

Appendix A: DoVC consultation events

8 November 2011: SAGE consultations, Geneva, Switzerland.
8 November: Grand Challenges consultation, Delhi, India.
17 November2011: Vaccine Symposium consultation, Delhi, India.
29-30 November 2011: R&D Working Group meeting, Washington DC, US.
1 December 2011: Biotechnology Industry Organization (BIO) consultation, San Francisco, US.
6 December: DoVC Leadership Council meeting.
8 December 2011: Southern Africa Consultation. Windhoek, Namibia.
9 December 2011: Center for Strategic and International Studies (CSIS) Conference, Washington DC, US.
9 December 2011: DoVC Cross Working Group meeting, Washington DC, US.
15 December 2011: Civil Society Organizations virtual meeting.
19 December 2011: International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) virtual meeting.
10-11 January 2012: Civil Society Organizations (from various regions) consultation. Louvain, Belgium.
11 January 2012: Civil Society Organizations virtual meeting.
16 January – 1 February 2012: Online consultation
17 January 2012: US CSOs consultation. Washington DC, US.
19 January 2012: UNICEF and DoVC missions brief, New York, US.
20 January 2012: WHO Executive Board Meeting, Geneva, Switzerland.
24 January 2012: PDP virtual meeting consultation.
25-26 January 2012: Middle East, Europe and Northern Africa Consultation, Rabat, Morocco.
2 February 2012: Delivery Working Group virtual meeting.
9 February 2012: Civil Society Organizations virtual meeting.
15 February 2012: DoVC Sterring Committee, Geneva, Switzerland.
16 February 2012: SAGE Extraordinary Meeting, Geneva, Switzerland.

Upcoming events:

27-28 March 2012: Americas consultation, Mexico City, Mexico.
First week of March 2012: WHO mission brief (to be confirmed), Geneva, Switzerland.

Appendix B: Indicators recommended by the Indicators working group

Overview

A meeting of the Indicators Working Group for the Decade of Vaccines Collaboration (DoVC) was held on 2 - 3 February, 2012 in Geneva. Participants included: David Brown (UNICEF), Anthony Burton (WHO), John Grove (BMGF), Chung-Won Lee (US CDC), Dragoslav Popovic (UNICEF) , and Daniel Thornton (GAVI Alliance). From the Secretariat, Magdalena Robert, Altaf Lal, Laurie Werner, Emily Serazin, and Rebecca Anastos-Wallen were present.

The meeting objectives were: 1) recommend indicators to track progress against the Decade of Vaccines goals and 2) recommend indicators to track Global Vaccine Action Plan (GVAP) progress.

Indicators recommended for inclusion in the GVAP

Recommended indicators to track progress against the **DoV Goals**:

- Number of vaccine preventable deaths
- Number of future deaths averted
- Under 5 mortality
- Indicator measuring morbidity - TBD
- Progress towards established eradication and elimination goals
- % of target population immunized with 3 does of DTP containing vaccine
- % of target population immunized with other WHO recommended vaccines

The group noted that, with respect to the number of vaccine preventable deaths, the indicator will in part capture progress in R&D and so this number may increase as improvements in available vaccines are made. The group also noted that, even though it will be a modeled and not a measured number, the number of future deaths averted was important to include as an indicator of success. The "Under 5 mortality" indicator is relevant to childhood immunization and not the entire life-course, but it is important to include as an indicator of the overall strength of health systems. It was recognized that the inclusion of an indicator on morbidity is important. There was consensus that current measures of morbidity are insufficient and a research agenda is needed to define how morbidity due to vaccine preventable diseases should be tracked. Finally, with respect to the coverage metrics, two indicators were selected: 1) coverage with 3 doses of DTP containing vaccine was selected to allow for historical comparisons and continuity given its status as the standard metric for coverage; 2) coverage with other WHO recommended vaccines was included to reflect the need to move beyond simply tracking coverage with DTP to capture a wider set of vaccines that are relevant across the life-course.

Recommended indicators for **Outcome 1: All countries commit to immunization as a priority**:

- Presence of up to date legislation that includes establishment of a national immunization plan for effective delivery of vaccines

- Presence of independent technical advisory group that meets defined criteria[1]
- Number of WHO recommended vaccines in national immunization schedule
- *% of target population immunized with 3 does of DTP containing vaccine*
- *% of target population immunized with other WHO recommended vaccines*
- *% of routine immunization costs financed through government budgets*
- *% of immunization financing gap (as projected in cMYP) met by donors*
- *For GAVI-countries: % of co-financing requirements met and % of supported vaccines that continue to be funded post-graduation*

Note: the indicators in italics above were replicated from the Goals and Outcome 5. It is valuable to replicate them here given that they are also important indicators of country commitment.

Recommended indicators for **Outcome 2: Individuals and communities understand and demand immunization as both their right and responsibility**:

- Indicator(s) capturing knowledge, attitudes, beliefs, and practices on immunization - TBD
- Indicator based on analysis of media coverage on immunization (immunization week and rest of year) – TBD

The group debated at length what existing indicators could be used, but concluded that there is no existing indicator to measure progress against this outcome. After much consideration, they recommended the indicators above. To develop an indicator capturing knowledge, attitudes, beliefs, and practices on immunization, a new research agenda is needed. Data will likely need to be collected via survey and sources may differ by country; existing surveys (DHS, MICS, and KAP) could be leveraged or, if needed, new surveys could be developed. Although no global indicator currently exists on media coverage, the group selected the indicator because it should be possible to define in the near term and as such can serve as a short-term proxy for the first indicator. To develop this indicator existing expertise in the field of media will need to be leveraged.

Recommended indicators for **Outcome 3: The benefits of immunization are equitably extended to all people**:

- % of districts (or lowest possible administrative level) with less than 90% coverage with 3 doses of DTP containing vaccine against baseline
- % progress against baseline for coverage with 3 doses of DTP containing vaccine by dominant pattern(s) of deprivation for country (as defined by countries)
- % of children protected at birth against tetanus (PAB) at district level (or lowest possible administrative level)

The group sought to balance the need to track progress against the many dimensions of equity with the challenges of data collection and the reality of country circumstances. It was decided that for each

[1] Availability of formal written terms of reference; Legislative or administrative basis establishing the committee; Core membership with at least 5 main expertise areas represented among members; Committee meets at least once a year; Agenda and expectations from the committee together with background materials distributed at least a week ahead of meetings; Declaration of interests by committee members.

country a standard indicator tracking geographic equity (the first indicator) would be used in conjunction with one or more indicators focused on specific areas of inequity selected by the country from a list. This list will be defined according to the patterns of deprivation that are prevalent in that country (for example, disparities based on gender, ethnicity, income, etc.). This indicator was selected to reflect the need for country-specific approaches to measuring improvements in equity. Data collection is likely to be every few years by survey. The final indicator on protection at birth from tetanus is a variation on the original indicator proposed by the working group (coverage with 2+ doses of tetanus during last pregnancy). The DoVC co-chairs recommended using PAB instead of coverage as they felt it was a more accurate reflection of equity (in an immunization system with very high coverage rates, pregnant women may not be immunized during pregnancy because they are already protected). This indicator was selected as a measure of equity across the life-course.

Recommended indicators for **Outcome 4: Strong immunization systems that are an integral part of a well functioning health system:**

- Planning cycles or targets of immunization plans are aligned with national health plans
- Indicator for missed opportunities in immunization - TBD
- DTP1 – DTP3, DTP1 - measles dropout rate
- # of Stock-outs of any vaccine or syringes at the national and district level
- % of mothers and babies who received postnatal care visit within two days of childbirth
- % births attended by skilled health personnel (alternative HR indicators under discussion)
- Number of independent data reviews conducted in the last 24 months

The first two indicators above (alignment of planning cycles and missed opportunities) were selected as measures of coordination of immunization with the broader health system and were added by the DoVC co-chairs to the list recommended by the working group. The co-chairs recognized that a specific indicator to capture missed opportunities between immunization and other health interventions is needed, but that work will be required to define this more specifically. The DTP1 to measles dropout rate was selected because it covers a longer time horizon than the DTP1 to DTP3 dropout rate and so is a better indicator of health system strength and follow-up. However, because the DTP1 to measles dropout rate could theoretically result in a negative figure, the DTP1 to DTP3 dropout rate was added to balance this weakness. The indicators on postnatal care and % of births attended do not specifically relate to immunization systems, but were included as measures of health system strength. The indicator on "number of independent data reviews" was added to address concerns around data quality.

Recommended indicators for **Outcome 5: Immunization programmes have sustainable access to long-term funding and quality supply**:

- % of routine immunization costs financed through government budgets
- % of immunization financing gap (as projected in cMYP) met by development partners
- For GAVI-countries: % of co-financing requirements met and % of supported vaccines that continue to be funded post-graduation
- Number of suppliers for each vaccine type (a. WHO prequalified, b. others)

From a funding perspective, the indicators above were designed to capture country commitment, development partner commitment, and the unique circumstance of current GAVI countries. It should be

noted that there was significant debate among the members of the working group as to the need for an indicator specific to GAVI countries. The last indicator was added to capture the need for affordable, quality supply.

Recommended indicators for **Outcome 6: Country, regional, and global R&D efforts maximise the benefits of immunization**:

- Licensure and launch of vaccine or vaccines against one or more major diseases not currently vaccine preventable, such as dengue, hookworm, leishmaniasis, malaria, and improved TB
- Proof of concept for a vaccine that shows 75% efficacy for AIDS, TB, or malaria
- Licensure & launch of a new version of an existing vaccine with improved posology, presentation and thermo stability
- New WHO standards for a research based regulatory agenda

Data quality considerations

The group also had extensive discussion around the question of data quality and availability. It was noted that in order to monitor progress effectively against the DoV's goals and outcomes, higher quality, more reliable data than that which exists today is needed. To achieve this, investments in data collection and monitoring and evaluation capabilities at the country, regional, and global levels will be needed. Where necessary, these investments should be accompanied by data quality audits and assessments. To track progress with respect to improving data quality, an indicator on "Number of independent data reviews conducted in the last 24 months" was added to Outcome 4.