Vaccines and Biologicals

Certification of the Global Eradication of Poliomyelitis

Report of the seventh meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis

Geneva, 12 April 2002



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The Department of Vaccines and Biologicals thanks the donors whose unspecified financial support has made the production of this document possible.

This document was produced by the Expanded Programme on Immunization of the Department of Vaccines and Biologicals

Ordering code: WHO/V&B/02.13
Printed: October 2002

This document is available on the Internet at:

www.who.int/vaccines-documents/

Copies may be requested from:

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Abbreviations

AFP acute flaccid paralysis

AFR African Region

AMR Region of the Americas

AMRO WHO Regional Office of the Americas

ARCC African Regional Certification Commission

EPI Expanded Programme on Immunization

EMR Eastern Mediterranean Region

EMRCC Eastern Mediterranean Regional Certification Commission

EUR European Region

EURCC European Regional Certification Commission

GCC Global Commission for the Certification of the Eradication of

Poliomyelitis

ICCPE International Commission for the Certification of Poliomyelitis

Eradication from the Americas

ICCPES International Commission for the Certification of Poliomyelitis

Eradication in the South-East Asia Region

IPV inactivated polio vaccine

NCC National Certification Committee
PAHO Pan America Health Organization
RCC Regional Certification Commission

SEAR South-East Asia Region

TCG Technical Consultative Group on global polio eradication

cVDPV circulating vaccine-derived poliovirus

WHO World Health Organization

WPR Western Pacific Region

WPRCC Western Pacific Regional Certification Commission

1. Introduction

Sir Joseph Smith, the chairman of the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC, the "Commission"), convened the seventh meeting of the GCC on 12 April 2002, in Geneva, Switzerland.

Welcoming members of the GCC on behalf of Dr Gro Harlem Brundtland, Director-General of the World Health Organization (WHO), Dr Daniel Tarantola, Director, Department of Vaccines and Biologicals, expressed his confidence that the GCC would again provide help and guidance to facilitate the successful continuation of the global and regional process towards eventual certification of the interruption of wild poliovirus transmission.

GCC members attending were:

- African Region: Dr Rose Leke, Chair, African Regional Certification Commission (ARCC), Professor F. Nkrumah, Member, African Regional Certification Commission (ARCC);
- Region of the Americas: Dr Carlyle de Macedo, Member, Western Pacific Regional Certification Commission (WPRCC);
- Eastern Mediterranean Region: Dr Mohammed Suleiman Ali Jaffer, Chair, Eastern Mediterranean Regional Certification Commission (EMRCC), Dr A. Deria, Member, Eastern Mediterranean Regional Certification Commission (EMRCC);
- European Region: Sir J. Smith, Chair, European Regional Certification Commission (EURCC) and Chair, Global Certification Commission (GCC);
 Dr. S. G. Drozdov, Member, European Regional Certification Commission (EURCC);
- South-East Asia Region: Professor Natth, Chair, International Certification Commission for Poliomyelitis Eradication, South-East Asia Region (ICCPES);
- Western Pacific Region: Dr A. Adams, Chair, Western Pacific Regional Certification, Commission (WPRCC), Dr Wang Ke An.

All GCC members had attended the preceding seventh meeting of the Technical Consultative Group (TCG) on global polio eradication from 9 to 11 April 2002. Presentations and discussions at the TCG meeting had provided GCC members with a comprehensive global and regional overview of the current status of the eradication initiative, including detailed country-specific information about programme components relevant for certification, such as the quality of acute flaccid paralysis (AFP) surveillance, accuracy of AFP case classification, progress in laboratory containment of wild poliovirus and status of the programme of work towards the development of a post-certification immunization policy. The GCC concurs with all TCG recommendations related to the improvement of surveillance.

Based on the detailed technical briefing at the TCG meeting, the Commission focused its agenda on the following certification-specific objectives:

- receive and discuss updates on certification activities in each WHO region, with special emphasis on the European and African regions;
- discuss the increasing importance of laboratory containment activities, especially the emerging need for validating containment, and to align certification and containment efforts more closely;
- consider the possible implications of new information on circulating vaccinederived polioviruses for the certification process; and
- discuss issues related to GCC membership.

2. Region of the Americas

The GCC notes that progress is being made with respect to several March 2001 GCC decisions related to the Region of the Americas (AMR). Surveillance quality overall seems to have been maintained during 2001 compared to 2000; however, both AFP rates and stool collection completeness still show considerable variation by country, and within large countries (e.g. Brazil). Haiti – where the last known cVDPV case had onset of paralysis in July 2001 – did not to reach certification-standard AFP surveillance quality in 2001.

During its 2001 meeting, the GCC had urged all WHO regions to assure that, prior to global certification, updated country level data be examined and verified by an independent regional mechanism, preferably regional commissions for the certification of polio eradication (RCCs). The GCC had recommended that regions should consider maintaining regional and national certification bodies beyond regional certification; both the Western Pacific and European Region are following this recommendation. Neither the Regional Certification Commission nor country-level national certification committees (NCCs) were maintained in the Americas following regional certification in 1994. While the WHO Regional Office for the Americas (AMRO) Secretariat reported on plans to identify and appoint an independent group for verifying regional certification status, such a body has not yet been identified and designated.

Laboratory containment of wild poliovirus had not yet been introduced as a requirement for regional certification of the Americas in 1994. The GCC had requested (March 2001) that a regional plan of action for laboratory containment, based on the global containment plan, be prepared for the Americas, and notes that efforts to implement containment have begun in the Region. The AMRO Secretariat plans to form country-level containment committees and to appoint national containment coordinators in AMR countries; these activities are in an early phase.

Establishment of national containment groups provides an opportunity to have a body at the national level that could also perform duties similar to a National Certification Committee, which were disbanded in AMRO after certification. Therefore, the AMRO Secretariat considers to use these national groups working on laboratory containment, to assess and verify national polio-free status, and relay this information to the regional level, though consideration needs to be given to potential conflict of interest and whether or not these groups will have the relevant expertise to fulfil the certification role. National containment groups are implementing bodies typically composed of members from the laboratory/biosafety community and may not have relevant epidemiological and clinical expertise to re-evaluate the country's polio free status.

- 1. The quality of AFP surveillance in several countries of the Americas (i.e. Haiti, Brazil) is of concern and efforts are needed to assist countries to reach and maintain satisfactory AFP surveillance performance.
- 2. The GCC continues to be concerned about the limited progress in re-establishing independent regional capacity to verify the maintenance of polio-free status before global certification and reiterates the need to establish such a body.
- 3. The GCC concurs with the AMRO plan to establish national committees for laboratory containment and to expand the committee's terms of reference, and if necessary membership, to also perform a function similar to national certification committees. However, the exact terms of reference of these groups, in particular their capacity to deal with certification issues and mode of interaction with the regional level, need to be clarified once an independent regional body to verify polio-free status has been formed.
- 4. The GCC requests the AMRO Secretariat to provide a detailed progress report on the above issues at the next GCC meeting planned for early 2003.

3. European and Western Pacific Regions

European Region (EUR). The European Region is likely to become the third WHO region to be certified as free of indigenous wild poliovirus transmission during the second half of 2002. The 51 EUR Member States had submitted final update documentation on their polio-free status to the RCC/EUR. At its most recent meeting in March 2002 in Copenhagen, the RCC reviewed all available evidence on polio-free status, including the final written country reports, presentations from 16 countries, and a comprehensive data analysis of each of the European Region's six epidemiological zones. The RCC focused on several main issues:

- the evidence for the absence of transmission of indigenous wild poliovirus, including the interval since wild poliovirus was last identified in the country;
- the capacity of the country to identify re-established transmission of wild virus following an importation, and to effectively respond to importations to prevent indigenous transmission;
- progress in laboratory containment, and
- the capacity of countries to sustain polio-free status after certification.

In addition to AFP and virological surveillance data, polio immunization coverage rates, and reported polio cases by year, the RCC also took account of a range of supplementary evidence, including national morbidity and mortality data, and also the status of the national health care system. The RCC requested NCCs to endorse a statement of their rationale for concluding that no transmission of indigenous wild poliovirus had occurred in their countries for the past three years. Following their March 2002 review, the RCC concluded that:

- indigenous wild poliovirus transmission had not been detected in the European Region for more than three years,
- satisfactory progress had been made in laboratory containment,
- spread of wild poliovirus following an importation into polio-free areas of the Region would quickly be detected and responded to, and that
- EUR countries were likely to be able to sustain polio-free status following regional certification.

The RCC/EUR specifically noted that the results of surveillance and immunization response activities conducted in Georgia following the wild poliovirus importation identified during the fourth quarter of 2001 had not yet been fully documented. The RCC expects, however, that Georgia will submit satisfactory evidence to prove that the imported virus had not re-established transmission, and that this evidence will be available in time to allow regional certification to occur in the third quarter of 2002.

The RCC/EUR proposes to follow the practice adopted in the Western Pacific Region of meeting annually after regional certification in order to monitor NCC's reports on their evidence for continued freedom from wild virus transmission, and their further progress in laboratory containment.

Western Pacific Region (WPR). Following certification of the absence of indigenous wild poliovirus in October 2000, the RCC/WPR conducted (in October 2001) the first meeting of an RCC following regional polio-free certification. The RCC/WPR noted the high quality of continued cooperation of countries and NCCs, which continue to function and work effectively in all WPR countries to assure that polio-free status post-regional certification is sustained. Most countries were able to report on continued high-quality surveillance, immunization and laboratory containment activities. The RCC/WPR endorsed several specific recommendations made by the regional technical advisory group on immunization and polio eradication (TAG) towards maintaining high-quality surveillance, following polio-free certification, and specifically on stool specimen transport.

In view of the emergence of a circulating vaccine-derived poliovirus (cVDPV) in the Philippines in 2001, the WPR RCC requested that the potential implications of VDPV circulation for polio-free certification be addressed at the global level.

The GCC notes that, while further progress towards containment occurred in the Western Pacific Region, Australia, China, Japan, Malaysia and the Philippines have not yet completed phase 1 containment activities (national inventory of laboratories holding infectious or potentially infectious material).

- 1. The GCC recognized that activities at country and regional level towards regional certification of the absence of indigenous wild poliovirus transmission in the European Region have been of sufficiently high quality to allow regional certification to occur later this year. The GCC requests, however, that the RCC closely scrutinize final country data from Georgia in their June meeting to assure that the documented importation did not result in re-established indigenous transmission.
- 2. The GCC commends countries of the Western Pacific Region for their successful efforts to sustain and document polio-free status following regional polio-free certification, and urges all WPR countries that have not yet completed phase 1 laboratory containment activities to reach this important milestone by the end of 2002.

4. Eastern Mediterranean and South-East Asia Regions

Both the Eastern Mediterranean and South-East Asia regions (EMR and SEAR respectively) are still engaged in interrupting transmission in two of the three global "high intensity transmission areas" – the Pakistan/Afghanistan epidemiological block and northern India, as well as in three countries with low intensity transmission, most notably Egypt. The GCC appreciates that international technical advisory groups at global (TCG) and country level (country TAGs) are now regularly reviewing progress and making specific recommendations to accelerate progress towards interrupting transmission, including the strengthening of surveillance.

Certification activities have progressed as planned in both EMR and SEAR, where AFP surveillance quality in 2001 had reached levels commensurate with certification. In most countries this was achieved at both the national and first subnational levels. Designated and functioning National Certification Committees and expert groups for case classification in all countries provide the necessary structure on which formal certification activities can be conducted.

Eastern Mediterranean Region (EMR). Five of the remaining 10 endemic countries are in EMR; however, there is good overall progress towards interrupting transmission in the Region. Increasingly reliable surveillance documents that only few foci of "low intensity transmission" remain in Sudan (South Sudan) and Somalia (Mogadishu area), despite ongoing conflict and complex emergency situations in both countries. Continued improvements of strategy implementation in the Afghanistan/Pakistan epidemiological block further reduced the extent of transmission in these countries during 2001. Events in Afghanistan following the 11 September terrorist attack did not have a significant negative impact on eradication activities in Afghanistan, though it has compromised surveillance quality in some key areas. The situation in Egypt, where the extent of virus transmission was severely underestimated until recently, will require urgent improvements in the quality of surveillance and supplementary immunization.

To date, the RCC/EMR has received and favourably reviewed preliminary national reports from 15 of 23 countries, with preliminary reports pending from 8 countries (including Pakistan). The RCC/EMR has prepared a special abbreviated format for annual update reports from NCCs to the RCC; this format was used for annual update reports submitted from eight countries of which three (Oman, Saudi Arabia and Tunisia) included a preliminary report on laboratory containment. In March 2002, a meeting was conducted to update and brief chairs of EMR national certification committees and national expert review groups on the current status of polio eradication, focusing on issues relevant for certification, surveillance and accuracy of AFP case classification.

South-East Asia Region (SEAR). India is the only remaining endemic country in the Region. With certification-quality AFP surveillance during 2001 in all other SEAR countries, transmission is likely to be interrupted in these areas, most notably in Bangladesh (last wild virus in mid-2000).

Even though the total number of cases reported from India did not decrease between 2000 and 2001, there was a marked reduction in both the geographic extent of transmission (50% reduction in the number of endemic districts) and the biodiversity of circulating virus lineages (from 8 to 3). Only parts of the northern Indian states of Uttar Pradesh and Bihar were endemic in 2001.

Of particular relevance for certification, the timeliness and accuracy of AFP case classification through the Indian national expert review committee has met international standards. Through appropriate application of the virological case classification and specifically the polio-compatible concept, the India programme identifies and collects additional information on polio-compatible cases within three months of paralysis onset. High-quality clinical follow-up data is collected for virtually all cases with inadequate specimens. As India moves toward a wild-virus free status, the practice of thorough follow-up and scrutiny of polio-compatible cases will lead to more accurate final case classification and allow increased confidence in having interrupted wild virus transmission in all parts of the country.

The RCC/SEAR has met most recently in March 2002 and reviewed preliminary national reports from eight countries and update reports from two (Sri Lanka and Thailand) of 10 countries in the Region. NCCs in all SEAR countries have now collected basic data on polio activities, largely based on the draft format proposed by WHO. However, there is still more work needed to ensure the completeness of the required data and to further develop the database of essential national documentation. The SEAR/RCC noted that the highest priority must currently be afforded to achieving the objective of eradicating all foci of wild poliovirus transmission in India. This priority far outweighed all other activities related to polio eradication and its certification in SEAR. The SEAR/RCC will meet again in September 2003.

- The GCC concurs with recent recommendations made by the global TCG and country TAGs that accelerated efforts towards interrupting wild poliovirus transmission in the remaining endemic countries of EMR and in India should receive the highest priority.
- 2. The GCC encourages both RCCs and the WHO Secretariat to increasingly coordinate certification activities between EMR and SEAR, through cross-attendance at meetings and the ongoing informal exchange of information.

5. African Region

Compared to other WHO regions, eradication and certification activities commenced most recently in the African Region (AFR). However, significant progress towards interrupting wild virus transmission and establishing reliable surveillance is being made in the remaining endemic countries of the Region, notably in the Democratic Republic of Congo, Ethiopia, Nigeria, and in large parts of West Africa. The GCC specifically commends the continued high level of political support for polio eradication in a number of African countries.

However, the implementation of eradication strategies, particularly high-quality AFP surveillance and accurate AFP case classification, and the certification process, face a number of specific challenges in AFR.

The GCC noted the AFR/RCCs substantial concern about:

- the challenges to interrupting transmission in Nigeria;
- continued low performance of routine immunization systems;
- weak cross-border coordination, especially of supplementary immunization activities;
- the need to urgently improve surveillance in several countries of the southern block (i.e. Madagascar, Mozambique, South Africa); and
- recent evidence suggesting that an important focus of ongoing virus transmission may have been missed in Western Africa (Mauritania and surrounding countries) through suboptimal surveillance and response.

Since the March 2001 meeting of the GCC, national certification committees and national expert committees (NECs) for case classification have been appointed in 41 of 46 AFR countries. At three intercountry meetings attended by members of the AFR/RCC, NCC and NEC chairs of 37 of 41 countries were oriented to polio eradication and the process of RCC review of country documentation. The meeting was held with assistance from WHO/HQ, WHO/EUR and WHO/WPR.

Progress in certification in the African Region has been more difficult than anticipated. Challenges include:

- several countries (Algeria, Equatorial Guinea, Mauritania and Sierra Leone) have not yet nominated NCCs and a NEC;
- in more than half of the 37 countries where the NCC chairs had participated in regional orientation meetings, other NCC members have not yet been briefed in turn;

- other difficulties to make designated committees fully functional, such as insufficient support for NCCs locally (inadequate administrative support, problems in making meeting per diems available);
- limited administrative and technical staff support at AFRO to conduct the required multicountry meetings.

The RCC/AFR is concerned that the importance of certification is not yet fully acknowledged by a number of countries, negatively affecting implementation of the certification process.

- 1. The GCC requests WHO to urgently strengthen the managerial and administrative support necessary for efficient implementation of the certification process in member states of the African Region.
- 2. Recognizing the large number of recently endemic countries in the Region, certification activities in Africa should continue to be the first priority for receiving technical support from WHO staff with certification experience (e.g. PAHO, WPRO, WHO/HQ).
- 3. The RCC/AFR should request AFRO to assure that, by the end of 2002, NCCs are designated and made functional in all countries, with completion of the orientation of all NCC chairs and members.
- 4. The GCC is concerned about the lack of progress towards revitalizing AFP surveillance in Madagascar and other countries of southern Africa, and fully endorses the global TCG's recommendations in this regard.

6. Laboratory containment

The GCC notes that progress is being made in all regions towards laboratory containment, particularly in the European and Western Pacific regions. As part of the pre-certification phase of containment, more than 80 000 laboratories worldwide (in all regions except AFR) are now listed in national registers of bio-medical laboratories to be surveyed, and more than 50% of these laboratories have already responded to the survey. To date, 450 laboratories worldwide have been identified as having wild poliovirus infectious material. Guidelines for containment in inactived polio vaccine (IPV) production facilities have been drafted, and will be published during the first half of 2002.

RCCs reported progress in many countries towards closer aligning and coordinating certification and containment activities at the national level. However, progress in several regions (AMR) was not as fast as had been expected (see regional sections above). The GCC is concerned that, although regional and national certification groups are now expected to coordinate certification and containment efforts more closely, the actual reporting requirements on containment are not clear.

The GCC appreciates that the second edition of the global action plan for laboratory containment will better define several key issues relevant for effective laboratory containment, and therefore for certification, most notably:

- the biosafety requirements for wild poliovirus infectious and potentially infectious materials, depending on risk assessments,
- the need for containment of vaccine-derived polioviruses, and
- better definition of storage conditions.

The second draft of the global plan also highlights the fact that specific recommendations on containment for the post-certification era can only be made following decisions on post-certification policy.

The GCC encourages the ongoing efforts to develop methods to confirm and validate laboratory containment achievements and notes that consideration is given to form technical groups to facilitate national validation efforts.

- 1. The updated version of the global plan for laboratory containment of wild polioviruses should be finalized, published and made available to the GCC and RCCs as soon as possible.
- 2. The GCC urges the Secretariat to review containment documentation needs at national and regional level, and to continue efforts to develop methods for national authorities to validate reported containment achievements. The GCC requests the Secretariat to report on the proposed validation methods, including the development of relevant guidelines, during the next GCC meeting.
- 3. Regional certification commissions, in consultation with WHO regional secretariats, should consider the potential value of RCC subcommittees on laboratory containment to work more closely with biosafety oversight groups active in large countries and at the regional level.

7. The GCC mandate and circulating vaccine-derived poliovirus (cVPDV)

Noting the additional information and data on cVDPV presented during the April 2002 meeting of the global TCG, the GCC acknowledges that further progress was made in understanding cVDPV and the possible implications of cVDPV for the global eradication effort. The global polio laboratory network has agreed on standard nomenclature to categorize VDPVs and has established special screening methods to improve the sensitivity of existing laboratory surveillance to assure the timely detection and characterization of VDPV. Of note, all cVDPVs found to date showed recombinations with non-polio enteroviruses in the non-structural region of the virus, a possible marker to facilitate the detection of cVDPV.

The GCC further notes progress in other research to better define the epidemiology and duration of shedding of Sabin viruses following immunization campaigns. In addition to ongoing research studies in Cuba, the programme has begun to analyse data derived from AFP surveillance to study patterns of Sabin virus isolation in relation to supplemental immunization activities (SIAs). Preliminary results using data from India suggest that Sabin virus is not shed for more than four weeks following campaigns. Final results of this work will become available within a year.

Prospective screening and retrospective analysis of more than 3400 SABIN isolates from AFP cases reported since 1999 from all WHO regions is consistent with the assumption that the circulation of neurovirulent VDPV is a very rare event. Despite the considerable increase in surveillance sensitivity, cVPDV has not been found again since the detection of cVDPV in 3 children in the Philippines between March and September 2001. Sensitive AFP surveillance in Haiti, the Dominican Republic and the Philippines indicates that cVPDV transmission in all three countries was interrupted through well-implemented supplementary immunization campaigns with oral polio vaccine (OPV).

The GCC, during its 2001 meeting, reaffirmed that the objective of its activities, as outlined in the report of the first meeting of the GCC in May 1995, is to certify the global interruption of the transmission of wild polioviruses. An additional prerequisite for global certification – the need to complete the laboratory containment process – was added in 1997. The GCC had noted in 2001 that the full benefits of eradication will only be realized in the absence of cVDPV, and that the potential implications of cVDPV for the certification process must remain under review. The GCC had urged WHO to continue its research on cVDPV, taking account of the need for methods to verify the absence of VDPV.

- 1. The GCC reaffirms its 2001 decision to encourage WHO to continue its work to understand cVDPV, to improve surveillance sensitivity for cVDPV, and to create a mechanism to verify cVDPV absence after the certification of wild poliovirus eradication.
- 2. While acknowledging the need to verify the absence of cVDPV once the eradication of wild poliovirus has been certified globally, the GCC re-emphasizes that the main objective of its work remains the certification, when and if appropriate, of the interruption of wild poliovirus transmission globally.
- 3. In view of currently available data on cVDPV and the probable rarity of cVDPV emergence, the GCC considers it premature to discuss an expansion of its own mandate to also include verification of the absence of cVDPV following certification of wild poliovirus eradication. This verification task may well be accomplished through another mechanism and by another group.

8. GCC membership and operating procedures

The GCC noted the importance of the independence of all experts serving on WHO technical advisory groups and oversight bodies. The GCC has previously discussed the issue of potential conflicts of interest among its members and in one of its 2001 decisions, stressed the need for independence of certification bodies at global and regional level. Specifically, GCC and RCC members should remain separate from the implementation of polio eradication activities, but can participate in activities such as country visits to review the status of polio eradication and to promote certification activities.

The GCC noted that the overlap of membership between regional and global commissions (all RCC chairmen are also GCC members) had proved very useful for its work. The only potential conflict of interest that may arise from this cross-membership would be in relation to the certification of a region. However, several GCC members also serve on other polio eradication-related technical advisory groups at global, regional and national level, with direct influence on programmatic activities. These groups include the global TCG, WHO's global steering committee on polio research, as well as regional and national TAGs, with differing terms of reference.

Cross-membership of GCC (or RCC) members on technical consultative Groups (global or regional level) or technical advisory groups (TAGs) may be perceived as incompatible with the strict assessment function of a certification group. Although TCGs and TAGs are not actually implementing the programme, both exert a direct influence on programme implementation as their advice and guidance is directly translated into programmatic action.

The GCC also noted that the Commission has not been able to work with the full number of members (13) originally designated by the Director-General of WHO, as two members had been unable to attend meetings for several years. At the same time, the GCC believes it could benefit from enhanced expertise for some technical areas of the GCC's work (i.e. laboratory containment, emergence of cVDPV). The group discussed the value of appointing additional members with expertise in enterovirology, molecular biology and biosafety in particular.

In discussing the issue of reporting needs from RCCs to the GCC, the Commission noted that such reporting requirements had not yet been standardized, for either certified regions or those yet to be certified. RCCs are also requesting more detailed guidelines on the reporting of progress in laboratory containment, in particular from country level (NCCs or containment task forces).

- 1. The WHO Secretariat should review for the GCC the cross-appointments of GCC members in polio eradication technical oversight bodies to identify potential conflicts of interest. The Secretariat should develop a matrix listing names, structure, roles and objectives of all relevant polio eradication committees and groups to facilitate future GCC deliberations on this issue. Any new GCC members should not be members of technical oversight groups.
- Dual membership in a regional and the global certification commission does not constitute a conflict of interest, provided that GCC members from a particular region abstain from voting on issues related to polio-free certification of their own region.
- 3. Recognizing that only 10 of the original GCC members are currently fully active in the work of the Commission, the GCC reiterated the importance of ensuring a full complement of at least 13 active members representing all WHO regions. The GCC concurred that the Commission should continue to have two representatives from each WHO region (ideally including the RCC chairperson), with the origin of the 13th member at the discretion of the Director-General of WHO. Given that some members may not be able to fully carry out their duties, the GCC Chair should use a set of "attendance rules" to discuss future participation with any member who should miss three consecutive meetings.
- 4. In appointing new members, the GCC requests that the Director-General of WHO give consideration to the geographic knowledge and/or specific technical expertise of a candidate for GCC membership. Areas of expertise to consider are virology (especially enterovirology), molecular biology and biosafety. Also, as much as possible, the gender balance of the Commission should be addressed. GCC members are able to provide names of potential candidate GCC members for the consideration of DG/WHO.
- 5. The GCC further recognizes the need to summarize, in a single document, the GCC Terms of Reference, membership issues, role of the WHO Secretariat, and operating principles (including relationship to RCCs), with a special focus on standardizing annual reporting requirements from RCCs to the GCC before and after regional certification. It is suggested that this document be compiled by the Secretariat, then reviewed and updated by the Commission as a standing agenda item at future meetings. The updated document could then serve as an Annex to all future reports of the Commission, superseding any previous documents.
- 6. Annual GCC meetings should be convened as dedicated 2-day meetings, potentially at WHO regional offices, to provide appropriate support to regional and national certification efforts. The next meeting of the GCC should be conducted in early 2003 in the African Region. GCC members should also continue to have the opportunity to follow the deliberations of the global TCG on polio eradication.

Annex 1: Agenda

| 08:45-09:00 | Opening | |
|-------------|---|------------------|
| | Administrative remarks | |
| 09:00-10:30 | Status of 2001 GCC decisions and issues arising from the WHO meeting of certification focal points (Dec 2001) | WHO/HQ |
| | Discussion points: | |
| | GCC mandate with respect to VDPVs | |
| | GCC cross-membership in technical oversight bodies | |
| | • Selection of new GCC members | |
| 10:30-11:00 | Coffee break | |
| 11:00-12:30 | RCC reports – EUR, SEAR, EMR, WPR and AMR | RCC Chairpersons |
| 12:30-14:00 | Lunch | |
| 14:00-14:30 | RCC report: AFR, with special focus on the certification process in the WHO Region for Africa | RCC Chairperson |
| 14:30-15:30 | Issues arising from the seventh TCG meeting | GCC Members |
| | Discussion points: | |
| | • GCC capacity to validate laboratory containment | |
| | Proposed GCC and RCC activities through mid-2003 | |
| 15:30-16:00 | Coffee break | |
| 16:00-17:00 | Finalization of decisions of the seventh GCC meeting | GCC Chairperson |
| 17:00 | Closing | |

Annex 2: List of participants

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The Department of Vaccines and Biologicals was established by the World Health Organization in 1998 to operate within the Cluster of Health Technologies and Pharmaceuticals. The Department's major goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases.

Five groups implement its strategy, which starts with the establishment and maintenance of norms and standards, focusing on major vaccine and technology issues, and ends with implementation and guidance for immunization services. The work of the groups is outlined below.

The Quality Assurance and Safety of Biologicals team team ensures the quality and safety of vaccines and other biological medicines through the development and establishment of global norms and standards.

The *Initiative for Vaccine Research* and its three teams involved in viral, bacterial and parasitic

diseases coordinate and facilitate research and development of new vaccines and immunization-related technologies.

The Vaccine Assessment and Monitoring team assesses strategies and activities for reducing morbidity and mortality caused by vaccine-preventable diseases.

The Access to Technologies team endeavours to reduce financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies.

The Expanded Programme on Immunization develops policies and strategies for maximizing the use of vaccines of public health importance and their delivery. It supports the WHO regions and countries in acquiring the skills, competence and infrastructure needed for implementing these policies and strategies and for achieving disease control and/or elimination and eradication objectives.

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