



First Face-to-Face Meeting Between the  
Global Certification Commission - Containment Working Group (GCC-CWG)  
and National Authorities for Containment (NAC)

27 October 2017

Geneva, Switzerland

Note for the Record

## Table of Contents

List of abbreviations .....	3
Introduction .....	4
Meeting objectives and expected outcomes .....	4
Meeting process and outcomes .....	4
Country presentations .....	4
China, Sweden .....	5
India, Canada, Netherlands .....	6
Japan, USA, Republic of Korea .....	7
Indonesia, Belgium .....	8
France .....	9
Conclusions .....	10
Recommendations .....	10
Annexes .....	11
Annex 1: Agenda .....	11
Annex 2: List of Participants .....	12

## LIST OF ABBREVIATIONS

CAG	Containment Advisory Group
CC	Certificate of Containment
CCS	Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment
CP	Certificate of participation
ECBS	Expert Committee on Biological Standardization
GAPIII	WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use otherwise known as the WHO Global Action Plan for Poliovirus Containment (3 <sup>rd</sup> edition; 2014)
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
GPEI	Global Polio Eradication Initiative
ICC	Interim certificate of containment
IHR	International Health Regulations
IPV	Inactivated polio vaccine
NAC	National authority for containment
OPV	Oral polio vaccine
bOPV	Bivalent oral polio vaccine containing type 1 and type 3
mOPV2	Monovalent oral polio vaccine type 2
nOPV	Novel oral polio vaccine type 2
PEF	Poliovirus-essential facility
PIM	Potentially Infectious Materials, Poliovirus
PV	Poliovirus
RCC	Regional Commission for the Certification of the Eradication of Poliomyelitis
SAGE	Strategic Advisory Group of Experts on Immunization
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus
WPV1	Wild poliovirus type 1
WPV2	Wild poliovirus type 2
WPV3	Wild poliovirus type 3

## INTRODUCTION

This meeting was organized by WHO GCC-CWG Secretariat and led by the Chair of the GCC-CWG. It was the first time that a “Face-to-Face” opportunity was provided for National Authorities for Containment (NAC) to meet one another and to meet members of the GCC-CWG.

Some of the countries hosting PEFs, have designated their NACs and others are still under consideration by their host governments’. The meeting agenda and list of participants are included in Annex 1 and 2.

The countries represented during this meeting were: Belgium (NAC designated); Canada (NAC designated); China (NAC under nomination process); France (NAC designated); India (NAC designated); Indonesia (NAC designated); Japan (NAC under consideration); Korea (NAC under consideration); Netherlands (NAC under consideration); Sweden (NAC designated). Representatives from Denmark, Iran, the Russia Federation and Viet Nam were unable to attend.

## MEETING OBJECTIVES AND EXPECTED OUTCOMES

The meeting was structured in three parts:

1. Brainstorming opportunity to identify the challenges met, needs and ways to address them
2. Timelines and ways to initiate and accelerate the containment certification process.
3. Future trainings opportunities and criteria for selection of participants.

## MEETING PROCESS AND OUTCOMES

Several presentations covering different subjects were presented and discussed with the audience.

Key discussion points were:

1. National regulatory authority (NRA) usually work in line with national regulatory requirements that could be different from the GAPIII requirements (international), and challenges for the industry to meet the containment requirements.
2. Request for additional training to enhance their national capacities and GAPIII auditing skills.
3. A request was made to WHO to share the containment breach reports that have occurred in the countries which have vaccine production capacity.
4. GCC-CWG to provide details to NACs on the set of the documents required to be included with the CP application-ASAP.

WHO Secretariat provided some clarification on:

1. The role of the NAC on the CP application, prior to sharing the CP application with GCC-CWG
2. Additional information on the certification process and standardisation of the review process among the reviewers is planned.
3. The channel of communication between NAC and GCC-CWG was presented and discussed and will be piloted with the first CP application.
4. WHO is considering developing an international auditing capacity that could serve some countries
5. Relationship and role differences between Containment Advisory Group (CAG)/GCC/CWG
6. Advocacy required to continue reducing number of PEFs

Country delegations were invited to present their current specific situation with their relevant priorities.

#### CHINA

- NAC not yet nominated, under discussion (1 or 2)
- Existing legal policies (Regulation on biosafety management); the notification of Poliovirus wild type 2 is mandatory;
- Current discussion on the nature of NAC China,
- China supports submission applications from 8 PEF that perform critical functions
- Recommendations
  - Advocacy support to get a NAC nominated

#### SWEDEN

- NAC was appointed in February 2017 with different member' profiles, country currently has one PEF which is a vaccine producer;
- PEF pre-audit planned in early Q1/2018, it will be supported by two national GAPIII trained auditors in NAC that will help in other phases.
- Challenges: logistics required around audits; international lack of experience in GAPIII auditing
- Containment engineering is not represented in the NAC group and global availability is an additional challenge
- Recommendations
  - Request of additional training opportunity from WHO.
  - Auditing expertise capacity needed to be discussed between NAC and WHO for the pre-PEF audit.

## INDIA

- NAC appointed in July 16 and revised in October 2017 based on existing national law and regulations.
- Currently 4-5 potential PEFs: 1WPV Polio Lab; 1 Sabin vaccine Lab; 3 sIPV vaccine manufacturers.
- Trained against GAPIII but lack of auditing capacity skills (Lead Auditors).
- The National Polio Task Force is supporting the NAC with advocacy to decrease number of PEFs
- NAC requested some clarity to GCC-CWG on how to address the issue of CP application per site, or facility when several sites.
- Recommendations
  - GCC-CWG will discuss with the Secretariat generating guidance on how to apply when different sites for the same company is identified;
  - GCC CWG to consider communication with India NAC prior to submission of the CP application

## CANADA

- NAC appointed in 2015, certified auditors team (21) nationally trained for 18 months; this programme was initiated in 1994. In the current legal system, there is no authority to stop an institution from applying to be a PEF. Persuasion efforts from NAC enabled a decrease from 23 to 4 PEFs.
- Legislation changes require long time and GCC timelines recommendations are very appreciated will help to align Government legislation when possible with GAPIII Containment requirements.
- Two pre-audit assessments are planned for two PEFs in 2018
- Existing challenge in clarity on the “critical “national functions and “crucial” research
- Recommendations
  - Opportunity to get additional GAPIII trainings
  - Invitation from GCC-CWG to share inputs in relation to provide definition of “critical” function
  - GCC requested to provide clarity in defining “critical “national functions and “crucial” research

## THE NETHERLANDS

- NAC not yet designated, planned for Q1 2018
- Challenge in lack of existing legislation, lack of trained auditors, budgetary constraints due to change of Government and priorities; however, the details of NAC constitution are agreed. Will be housed within the Healthcare Inspectorate.
- Potential 7-9 PEF under consideration.
- Future NAC will be challenged by the lack of legislation enabling limitations of PEF application and no possibility of charging PEF for the certification process (audit).

## JAPAN

- NAC was nominated in 2015, although current existing legislation does not include Polio, to enable GAPIII implementation.
- Potential 5 PEF under consideration (4 IPV production sites and 1 laboratory/research); they were reduced from 9 initially through persuasion.
- NAC trained by WHO on GAPIII auditing
- NAC audit manual under preparation, and audits should be implemented in the upcoming fiscal year.
- Current regulations challenge the full GAPIII implementation.

## USA (presentation was made by Polio Containment Coordinator, CDC)

- NAC not yet nominated but a group is identified and acting in this role
- Presentation on the structure of CDC and link with future NAC under the Director's office.
- Two pre-audits (under analysis) were conducted by acting NAC.
- No current legal framework to enforce GAPIII compliance, or refuse PEF application, however a lot of identified issues are currently being addressed.
- Collaboration on PEF auditing between Canada and USA is under discussion.

## REPUBLIC OF KOREA

- The NAC is not yet nominated; the process is ongoing.
- Existence of two national organisations related to the bio containment issues which are under consideration for NAC nomination (MFDS or KCDC).
- No existing national regulation related to GAPIII;
- Lack of awareness of GAPIII.
- One potential PEF to be considered (manufacturer).
- Recommendations:
  - Nomination of NAC
  - Advocate for legislation changes required to issue certificates.

## INDONESIA

- NAC nominated (I-NAC) in February 2017, it is composed of 14 members with intersectoral participation (- e.g. Defence), and 8 trained auditors.
- A ministerial decree was issued for NAC TORs.
- Challenges to understanding GAPIII requirements in terms of NAC responsibilities and national capacity availability.
- Some auditors were trained against GAPIII.
- Two PEFs are under consideration and will be designated (manufacturer, laboratory)
- NAC is currently reviewing CP application for the manufacturer prior GCC-CWG submission; planned in upcoming days.
- Recommendations:
  - Challenge to define the safeguards in the context of archipelago country with 250 million people (IPV immunization in the PEF area or whole country?)
  - Pre-audit to be considered for this PEF, date under discussion.
  - WHO is considering presenting to the upcoming CAG the IPV coverage challenge met in some countries.

## BELGIUM

- NAC nominated in September 2017 within Ministry of Health (MOH);
- Currently there are potentially 4-7 PEF under consideration.
- Lack of bio-risk management capacity in MOH but exists in other federal structures that will support MOH, internal collaboration/coordination ongoing.
- To address lack of legislation to enforce GAPIII implementation, a Royal decree, to support containment function, still under final discussion.
- OPV stockpile in country for temporary function (GAPIII compliance necessary?)
- Number of PEFs is still under consideration, certification process not yet initiated
- Potential changes to national law are under consideration anticipating potential GAPIII changes.
- Recommendations
  - Initiate PEF nominations.
  - Forward to CAG question for how to handle temporary OPV stockpile and their GAPIII compliance.

## FRANCE

- NAC nominated in 2017
- New Position note provided by France few days ago: Existing national containment action plan with a designated NAC, re affirming the government commitment to support global polio containment efforts.
- Country is currently considering a total of four PEFs (2 manufacturers, 2 laboratories);
- National efforts to decrease initial number of 29 labs identified to have type 2 virus to only 4 (unneeded material destroyed), no additional national authorisation will be provided to any facility to retain type 2.
- Classification of poliovirus type 2 will be upgraded from level 2 to level 3.
- Important challenges identified between national regulation and GAPIII requirements limiting its implementation in short timeframe, information provided to WHO with ongoing discussion.
- Recommendations:
  - More discussion required between NAC and WHO

## CONCLUSION

Productive interactive discussions among the different participants allowed the GCC-CWG to directly interact with some NAC and country delegations involved in the national containment efforts. Clarification was provided to participants and allowed alignment of understanding. Discussions enabled the sharing of experiences and have initiated some direct connections among countries for future collaboration.

## RECOMMENDATIONS

- WHO Secretariat will support GCC-CWG in reviewing and harmonizing documentation (CP application form) and specifying detailed documents required in advance of the official CP application.
- NAC should specify type of training requirements needed to strengthen their certification capacity and communicate them to WHO Region/HQ.
- When a mock audit opportunity is planned, and external participants could be invited, NAC are encouraged to share this opportunity with others.
- Country requirements for GAPIII lead auditors from WHO (international pool should be made available)
- WHO Secretariat to specify the type of certificate status to be held at the time of the global certification of eradication (GCC recommendations).
- Countries are interested in obtaining some additional information on the certification process associated costs of audits, immunization coverage, etc
- WHO Secretariat has invited NAC to communicate technical question through a submission form for upcoming CAG meeting;

Annexes:

Annex 1: Agenda

Annex 2: List of Participants

## Annex 1: Agenda



# World Health Organization

Face to Face meeting between GCC-CWG  
and National Authorities for Containment  
27 October 2017, Geneva, Switzerland (WHO/HQ, M605)

## AGENDA

Facilitator: Nicoletta Previsani

Rapporteur: Liliane Boualam

Friday 27 October 2017		Chair Arlene King
08:30	Registration Opening and welcome remarks	Arlene King
SESSION 1: GAP III CCS implementation: global progress update and challenges		
09:00	Objective of the meeting and expected outcomes	Jackie Fournier-Caruana
09:15	Communication channel between NAC and GCC	Liliane Boualam
09:30	NACs feedback and discussion (15 minutes max per NAC)	All
10:30	<i>Coffee Break</i>	
11:00	NACs feedback and discussion (15 minutes max per NAC)	All
12:30	<i>Lunch</i>	
SESSION 2: Management of challenges		
13:30	Gaps and challenges: identification and management	Nicoletta Previsani
14:00	Brainstorming	All
15:30	<i>Coffee Break</i>	
16:00	Action plan to accelerate the CP applications	Arlene King
16:30	Wrap up meeting	Chair

## Annex 2: List of Participants



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National Authorities for Containment  
27 October 2017, Geneva, Switzerland  
WHO/HQ, M605

## List of Participants

## Global Certification Commission Containment Working Group (GCC-CWG)

1. Dr Arlene King  
Chair, GCC-CWG and RCC of the Region of Americas and Member, GCC  
Adjunct Professor, Dalla Lana School of Public Health,  
Division of Clinical Public Health and Institute of Health Policy, Management and  
Evaluation, University of Toronto, Canada

## National Authorities for Containment (NAC)

2. Ms Anna Kubina  
International Relations Attaché, Federal Public Service, Health, Food Chain Safety  
and Environment, Ministry of Social Affairs and Public Health, Belgium
3. Dr Mary Louise Graham  
NAC, Canada and Director, Office of Biosafety and Biocontainment Operations,  
Public Health Agency of Canada, Centre for Biosecurity, Ontario, Canada
4. Dr Bing Liang  
Deputy Division Director, National Health and Family Planning Commission of China,  
China
5. Dr Jaeho JUNG  
Deputy Director, Pharmacist, Biopharmaceutical Quality Management Division  
Ministry of Food and Drug Safety, Republic of Korea
6. Dr Jagadish Deshpande  
NAC India and Technical Coordinator, National Task Force on Poliovirus  
Containment, Indian Council of Medical Research, India
7. Dr Yasunori Ichimura  
NAC Japan and Director, Infectious Disease Information Surveillance Office,  
Ministry of Health, Labour and Welfare, Japan
8. Dr Pretty Multihartina,  
NAC Secretary Indonesia and Director, Biomedic and Basic Health Technology,  
Ministry of Health, Indonesia

9. Dr. Åsa Björndal  
Head of NAC, Sweden and Senior Expert Advisor, Institutional Biosafety Officer,  
Public Health Agency of Sweden, Sweden
10. Dr Jonas Löfling  
Member of NAC Sweden, Public Health Agency of Sweden, Sweden
11. Dr G. R. Robbin Westerhof  
NAC of the Netherlands (ad interim), Public Health Department, Ministry of Health,  
Welfare and Sports, Netherlands
12. Mrs Marie-Anne Mortelette  
Advisor (Health), Permanent Mission of France to the United Nations in Geneva and  
other international organizations in Switzerland, Switzerland

#### Technical Experts

13. Dr Paul Huntly,  
WHO Biorisk Management Expert, Riskren, Singapore

#### WHO Regional Offices

14. Dr Jacob Barnor, Technical Officer AF/RGO/ORD/PEP
15. Ms Ashley Burman, Containment Consultant EM/ACO/JOR
16. Ms Varja Grabovac, Scientist WP/RGO/DCD/EPI
17. Ms Maria Iakovenko, Consultant EU/RGO/DCE
18. Dr Gloria Rey-Benito, Advisor, Laboratory Network Management AM/PAHO
19. Dr Sigrun Roesel, Technical Officer SE/RGO/IVD/VPD

#### WHO Headquarters

20. Ms Liliane Boualam, Technical Officer HQ/DGO/POL/RPC/CNT
21. Dr Jacqueline Fournier-Caruana, Team Lead, a.i. HQ/DGO/POL/RPC/CNT
22. Ms Caroline Nakandi, Assistant (Team) HQ/DGO/POL/RPC/CNT
23. Dr Nicoletta Previsani, Technical Officer HQ/DGO/POL/RPC/CNT
24. Dr Harpal Singh, Technical Officer HQ/DGO/POL/RPC/CNT
25. Dr Roland Sutter, Coordinator HQ/DGO/POL/RPC

#### Partners

26. Dr Anna Llewellyn, CDC, Atlanta, USA