Developing Countries Vaccine Manufacturers Network

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Update on WHO Global Action Plan for containment of polioviruses (GAPIII/CCS)

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Containment:
"The other half of eradication"

PV containment. Where are we now?

- WPV2: declared eradicated in Sep 2015
- Global tOPV-bOPV switch: Apr 2016

- We are now in the ‘PV2 containment period’ (Phase II of GAPIII)

What does this mean?
PV containment. What does this mean?

- According to GAPIII, PV2 should by now be in containment
  - WPV2/VDPV2 since 1 Jan 2016
  - OPV2/Sabin2 since 1 Aug 2016

- GAPIII was first drafted in 2009, then endorsed by
  - SAGE in 2014
  - WHA in 2015

- Containment certification scheme endorsed by SAGE in October 2016
Phase II timelines

Phase I: Global readiness coordination
- 2014
- Inventory, Destruction, Preparation for containment
- Global readiness criteria met

Phase II: Poliovirus type 2 containment period
- 2015
- Destruction, Preparation for containment

- 2016
- OPV2 withdrawal
- Containment certification

- 2017
- Containment certification

- 2018
- IIa: WPV2 containment

- 2019
- IIb: OPV2/Sabin2 poliovirus containment
- 6 x Regional certification of WPV eradication

- 2020
- IIIb: Containment of all Sabin polioviruses
- bOPV cessation

- 2021
- IIIa: Final containment of all WPV
- Safe handling of new samples potentially containing PV material in non-essential laboratories

PV-essential facilities holding WPV
- 2014
- PV-essential facilities holding OPV/Sabin only (no WPV)
- PV-non-essential facilities
- Inventory, Destruction, Preparation for containment
- Destruction, Preparation for containment
- Destruction, Safe handling, No storage
- Adopt safe measures
Phase II: Where should we be now?

According to GAPIII:

- PEFs should have demonstrated implementation of GAPIII
- NACs should have certified PEFs against GAPIII

PEFs: Poliovirus-essential facilities
- Poliovirus vaccine production facilities
- Research facilities
- Repositories

NACs: National Authorities for Containment

Are we where we should be? If not, why not?
Phase II:
Why are we not where we should be?

- Containment implementation timelines short
- Lack of national regulatory framework to implement containment
- Lack of expertise to implement GAPIII
- National Authority for Containment (NAC) just being identified
- Lack of certification expertise
A containment certification scheme to ensure:

1. A robust, transparent and equitable mechanism is applied for containment certification across sectors and geographies

2. GAPIII is appropriately and timely implemented in all PV-essential facilities

3. Gradual implementation of GAPIII requirements
   1. Certificate of participation CP
   2. Interim certificate of containment ICC
   3. Certificate of containment CC
Containment Certification Scheme (CCS): Objectives

- Identify and define **roles and responsibilities for stakeholders (PEFs, NACs, GCC, WHO)** ensuring transparency and consistency of approach.

- Specify the mechanisms required for oversight at international and national levels to ensure **robust, transparent and equitable certification mechanisms** across sectors and geographies.

- Describe the relevant **oversight mechanism** to assure that GAPIII controls have been appropriately identified, implemented and monitored.

- Define adequate reporting and recording mechanisms to ensure confidence in the scheme and its ability to **provide the required level of assurance** to global eradication stakeholders.
WHO’s support for the implementation of Phase II

Support to stakeholders

- Containment Certification Scheme (CCS)
- Interim containment certification options available in preparation for full implementation of GAPIII requirements in Phase III (CP, ICC, CC)
- International oversight mechanism proposed to ensure globally harmonized containment certification procedures
- Regional GAPIII Implementation and certification trainings for NACs and PEFs
- Development of pool of GAPIII containment auditors to support countries' containment certification efforts
Next steps

- Publish CCS

- Promote CCS and engage countries in CCS implementation
  - Ensure dPEFs request 'Certificate of Participation' and engage in ICC/CC process
  - Ensure appropriate biorisk management in agreement with NAC and GCC
  - Allow to maintain stocks for a defined period without full GAPIII implementation
  - Minimize risk of interruption of IPV production and supply

- GAPIII Implementation and Certification Training for late-comers
  - 24-28 Oct, Bangkok

- GAPIII Training for Auditors: develop a pool of auditors to support NACs
  - 5 sessions planned Q 1/2, 2017

- Align TRS 926 Annex 2 with GAPIII
Conclusions

⚠️ Poliovirus containment is a major **global endeavour**, engaging and non-polio stakeholders

⚠️ **Only destruction** of polioviruses **eliminates** risk of release from facilities

⚠️ **Global oversight** of containment is necessary

⚠️ Countries and facilities are key to poliovirus containment
For any questions or suggestions on poliovirus containment, GAPIII and CCS

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Thank you