RAG Risk Assessment Group

PRIMARY RISK ASSESSMENT

Polio incident GSK

Date of the signal	Date of the RA	Signal provider	Experts consultation	Method
08/08/2018	10/08/2018	GSK	**Permanent experts:** Valeska Laisnez (AZG), Carole Schirvel (AViQ), Romain Mahieu (COCOM-GGC), Mireille Tomas (DG), Daniel Reynders (FOD) **Specific experts :** Didier Breyer (SBB, Sciensano), Geneviève Waeterloos (Quality Vaccines and Blood Products, Sciensano), Marc Van Ranst (NRC polio, KUL)	**Email consultation**
Date of update	**Closing date**			
27/08/2018				

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Signal	On the 8th of August, AViQ was informed by an anonymous call about a polio incident that occurred at GSK, Rixensart. Incident (see more detailed report in annex): in the night of 9th to the 10th of July, a tube disconnected from a tank linked to the chromatography tower in building 39.3, room 319, leading to a spillage of around 20L bulk containing wild type 2 poliovirus under purification process (= before inactivation), on the chromatography tower and the floor. The virus concentration in the tank was 10 E^{7-10} log/ml. Biosafety procedure for pathogens was applied with cleaning (Actril), decontamination and closure of the zone (inter-campaign period meaning declassified room without any manufacturing activity). On the 17th of July, routine inter-campaign swabbing was carried out in the zone, with additional swabbing on the site of the leak and the zone was accessed again without biosafety protection. On 3 August, the quality department reported that the swab from the chromatography tower potentially contained poliovirus, based on a qualitative test (cytopathogenic effect in cell culture). A confirmation test based on ELISA was negative. Results from a PCR are pending (final results expected on 22/08). Between 17/07 and 03/08, 45 people (35 GSK employees and 10 external people) entered the zone. Five of them were in contact with the leakage zone: two persons working in the IPV Manufacturing Product Unit who were vaccinated (of which the employee who performed the swabbing) and three persons from the UK, working for MA Control, who did the maintenance (and have returned to the UK). The employees were wearing gloves, but no mask. According to the medical evaluation by GSK, the two employees were fully immunized (defined as at least 3 doses IPV or OPV or 4 doses if IPV and OPV were combined). Specific information on the schedule used for the two persons has not been provided by GSK. The three exposed workers from MA Control returned to the UK, were informed and are thought to be vaccinated with OPV (the vaccine used in the UK until 2004) but their vaccination status could not be documented. Two of them received a IPV booster on the 6th of August, with blood sampling for serology. For the third person, the information given is not clear (recommendation to get an IPV booster or actual vaccination provided ?). Update 27/08/2018

			Both the confirmatory ELISA and the PCR tests on the sample from 08/08 were negatives.
Description		**Score**	**Description / arguments**
1	Cause known?	Yes	Poliovirus is well known. Healthy carriers can shed the virus in the stools and in the saliva, even after complete vaccination.
2	Unexpected/unusual	No/yes	Accidental exposure to wild poliovirus in a laboratory is not unexpected, but is unusual. This is the third (reported) incidence at GSK since 2014.
3	Severity	Very low	The five people exposed are not considered at risk of developing the disease.
4	Dissemination (Low/Medium/High)	Very low	Infection following exposure is more likely in IPV than in OPV vaccinated persons and shedding by infected IPV vaccinated persons is on average of higher load and longer duration (average 20 vs 9 days) than for OPV vaccinated persons. Detailed information on the vaccination schedule has not been given by GSK.
5	Risk of (inter)national spread	Very Low	Very low in Belgian population thanks to high vaccine coverage (98,2% polio 3, national average in 2016). Three exposed workers returned to the UK, where the vaccination coverage for polio is lower (93.4% polio 3 and 86.2% booster at 5 years in 2016-17). They are thought to be vaccinated with OPV but their vaccination status could not be documented.
Preparedness and response			
6	Preparedness		An emergency scenario of polio spillage is present at GSK and was updated with guidelines for management and care of an exposed staff member after the previous incident in 2017. According to the most recent National Plan of Action to Sustain Polio-Free Status (update April 2018), each Polio Essential Facility (PEF) has an internal protocol (that fulfils all GAPIII requirements), including external communication procedures to the competent authorities.
7	Specific control measures (surveillance, control, communication)		Actions taken by GSK (see more detailed description in annex): - Urgent biosecurity procedure on 10/07 morning. - Closure of the unit from 10/07 to 17/07 (end of

			production) and from 03/08 onwards. - New environmental sampling in the room on 06/08. Results will be available within three weeks. -Information of FAGG-AFMPS, the Biosafety and Biotechnology Unit of Sciensano, and Daniel Reynders (National Focal Point) on 08/08. - Evaluation of the risk for the 45 people exposed : very low risk because no risk of aerosol and the people wore gloves. Vaccination status was checked for five people who were in contact with the equipment where the positive swab was taken. The UK employees received an IPV booster. - Evaluation of the risk for the environment : no risk.
Public health impact			
A	Public health impact in Belgium (Low/Medium/high)	Very low	Risk in Belgium considered very low because of high vaccination coverage.
B	Recommendations (surveillance, control, communication)		- Any incident involving exposure of employees to poliovirus and containment rupture should be reported immediately to - the FPS Health in its role as the National Focal Point and designated National Authority of Containment (Daniel Reynders); - the services Biosafety and Biotechnology and Quality of Vaccines and Blood Products of Sciensano; - the regional authorities; - the FAGG-AFMPS. - In case of an incident, laboratory testing (environment) should be carried out by the National Reference Centre for poliovirus.
	Actions		AViQ: Request information on the sensibility/specificity of the ELISA test performed at GSK. GSK + AViQ: Follow-up of the people exposed. If the positive result of the first test is confirmed (and after an incubation period of 2 weeks after the exposure=18 August at the latest), three consecutive stool samples should be taken with an interval of 24h for the 5 people exposed, to exclude virus excretion. → 27/08: no need for further follow-up and stool sampling. NFP: Information of WHO by National Focal Point, especially because of the late communication of the incident by GSK.

			NFP: Notification to the UK through a selective EWRS message. RMG: Organize shortly a debriefing/lessons learned meeting with GSK + FAGG/AFMPS + President Polio committee + Cabinet.

REFERENCES

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