Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

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Issues of substance and process for the period before the next Review Conference, with a view to reaching consensus on an intersessional process

Confidence building measure G - Declaration of vaccine production facilities: potential for missed reporting of relevant facilities

Submitted by Netherlands, Switzerland and the United Kingdom of Great Britain and Northern Ireland

I. Background

1. Confidence Building Measure "G" (CBM G) requires States Parties to declare information on vaccine production facilities. The current wording stipulates that:

'… each State party will declare all facilities, both governmental and non-governmental, within its territory or under its jurisdiction or control anywhere, producing vaccines licensed by the State party for the protection of humans.'

and the CBM guide clarifies this further:

'On this form you should list all vaccine production facilities in your country, which produce vaccines that are licensed by your government for use for the protection of humans, regardless of whether they are owned or run by the government or privately.'

Thus CBM G covers only vaccines produced on the territory of a State Party, or under its control, which are licensed by that State Party. However, pharmaceutical companies are increasingly outsourcing vaccine production processes in whole or in part to contract manufacturers. It is possible that such contractors could be located in a different country and hence that the vaccine(s) produced in their facilities might be licensed exclusively by the authority of another sovereign state. Hence, given the wording of CBM G, in such cases neither the State Party on whose territory the production facility is located nor the State Party which licenses the vaccine may feel obliged to declare facilities that fall into this category. Clearly then, there is the potential that CBM G may fail to capture all relevant facilities producing vaccines licensed for the protection of humans.

2. This potential gap has been raised previously, for example, in discussion of proposals to amend the CBMs in the lead up to the Seventh Review Conference.[1] However no amendments to CBM G were included in the revised reporting forms adopted by States Parties in 2011. Subsequently, this issue was raised by Switzerland[2] during the Intersessional Programme biennial item in 2012/13 on how to enable fuller participation in the CBMs, but no further action ensued.

II. Case Study

3. In summer 2016, the Swiss delegation drew to the attention of the UK delegation a press release about the licensing of a new cholera vaccine by the US Food and Drug Administration (FDA), which stated that the product, Vaxchora, was manufactured by PaxVax Bermuda Ltd., a UK registered company.[3] Since this example may have fallen into the category described in paragraph 1, the UK delegation undertook to investigate further and, if appropriate, to consider making a declaration in the UK CBM submission for the sake of transparency even if the vaccine was not licensed by the UK authority.

4. However, research through open-source documents, such those available on the FDA website approved products page for Vaxchora and press releases related to the licensing of the vaccine, indicated that no manufacturing processes were carried out in Bermuda. The UK Foreign and Commonwealth Office (FCO) also contacted the Ministry of Health in Bermuda, who confirmed that PaxVax was a registered company, but was not licensed to conduct any manufacturing on the island. Hence, since there was no production of the Vaxchora vaccine on UK territory, it would not be appropriate to make a declaration on Form G of the UK CBM submission. It transpired that the manufacture of the bulk drug substance for Vaxchora was contracted out by PaxVax Bermuda Ltd. to a company in the Netherlands, SynCo Bio Partners B.V. This company had supported PaxVax during the clinical development programme including manufacture and supply of bulk drug for clinical trials, process validation, FDA pre-approval inspection for product registration and manufacture of pre-commercial supply. Following the FDA approval of the vaccine in June 2016, SynCo Bio Partners B.V. would continue to support PaxVax by manufacturing the commercial VaxChora vaccine.

5. Following discovery of the information on the manufacture of the bulk drug substance, the UK FCO passed it onto the Netherlands Ministry of Foreign Affairs. Since this vaccine is licensed by a US Government authority but will be manufactured in the Netherlands, under the current wording of CBM G it would seem that the Netherlands would not obliged to declare the facility. Besides, this specific vaccine had only achieved licensing approval in June 2016, so it would not have been expected to be included in previous CBM submissions. Nonetheless, this is clearly an example where the reporting of a production facility relevant to the BTWC could be missed. However, under the Netherlands policy of transparency, the CBM submission for 2016, dated 31 March 2017 and posted on the publicly accessible area of the BTWC website, included the SynCo Bio Partners B.V facility in its CBM G declaration. The information provided made it clear that the company manufactured bulk drug products, which were delivered to clients for final release to clinic or market or for further processing, and did not hold the market authorisation for the products manufactured on site. In its capacity as supplier, SynCo Bio Partners BV operates according to Dutch national regulation, which states that the entities responsible for final product release should hold the proper market authorisations.

[1] The Governments of Switzerland, Norway and Germany together with the Geneva Forum in collaboration with the BIOS Centre of the London School of Economics organised three workshops in 2009 and 2010 to discuss the way forward for preparing the CBM discussion for the Seventh Review Conference. These and subsequent discussion on an e-platform led to submission of the Working Paper 'Review and update of the Confidence-Building Measures' by Germany, Norway and Switzerland (BWC/CONF.VII/WP.9).

[2] 'Confidence-Building Measures: enabling fuller participation' Submitted by Switzerland (BWC/MSP/2013/MX/WP.13)

[3] Bermuda is a British Overseas Territory.

III. Recommendations

6. Although the potential reporting gap described in this Working Paper has been raised previously, it was not addressed in the last revision of the CBMs at the Seventh Review Conference. Thus any future consideration of amendments to the content of the CBMs in light of scientific and technological developments, including trends in production processes, should take account of this issue.

7. In the absence of any current effort to revise CBMs, we would encourage other States Parties to collaborate on the identification of relevant vaccine production facilities that may be missed under the current CBM G wording, and to adopt a similar policy of transparency to that taken in this case. That is, to follow the approach of declaring all known facilities that produce vaccines for the protection of humans on their territory or under their control, whether licensed by their own Government authority or by that of another state.