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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Confidence Building Measures (CBM) submissions in terms of quantity and quality

Confidence Building Measure G - Declaration of Vaccine Production Facilities: identifying additional relevant facilities

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

I. Background

1. At the 2017 Meeting of States Parties, the Netherlands, Switzerland and the United Kingdom submitted a Working Paper that highlighted a potential reporting gap in the declaration of vaccine production facilities under Confidence Building Measure "G" (CBM G).[1] The current CBM text and the clarification provided in the CBM Guide stipulate that CBM G covers only vaccines produced on the territory of a State Party, or under its control, which are licensed by that State Party for use for the protection of humans. However, with the increasing trend of outsourcing vaccine production processes to contract manufacturers, it is possible that such contractors could be located in a different country; hence the vaccine(s) produced in their facilities might be licensed for use in humans exclusively by the marketing authority of another state or region. Also, multinational companies may have their manufacturing operations in a different country from the holders of the marketing authorisations. In such cases it is possible that neither the State Party on whose territory the production facility is located nor the State Party that grants or holds marketing authorisation may feel obliged to declare facilities that fall into this category. Also, it may transpire that the information gathering processes undertaken did not detect such facilities.

2. The 2017 Working Paper described a case study in which a collaborative effort between Switzerland, the Netherlands and the UK resulted in the identification and subsequent reporting of an additional facility located in the Netherlands. The facility had recently undertaken manufacture of a bulk drug substance for a cholera vaccine that had just received marketing authorisation from the United States Food and Drug Administration (FDA). Since the bulk substances were delivered to clients for final release to clinic or market or for further processing, and the facility did not hold the market authorisation for the products manufactured on site, strict interpretation of CBM G would imply that the

[1] BWC/MSP/2017/WP.6 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.

Netherlands was not required to report this facility. However, under the Netherlands policy of transparency, its subsequent CBM submissions have included this newly-relevant vaccine production facility.

3. The paper concluded by encouraging 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. Subsequently, in 2018 the Swedish delegation drew to the attention of the UK delegation a facility located in the UK that seemed to fall into this category. On its website, Valneva indicates that it maintains a commercial manufacturing operation in Livingston, Scotland for the production of a Japanese encephalitis vaccine. The UK undertook to investigate further and, if appropriate, to include this and any other relevant facilities identified in its subsequent CBM G submissions.

II. UK approaches to identify facilities for declaration in CBM G submissions

4. When gathering information for the UK CBM submission on relevant vaccine production facilities, officials routinely contacted the Medicines and Healthcare products Regulatory Agency (MHRA), which is the UK authority that licenses medicines and healthcare products for marketing in the UK. Previously, requests for confirmation of the relevant facilities were based on the wording in the CBM G description and in the CBM Guide and thus focussed on vaccines produced on UK territory and granted marketing authority in the UK. Investigations into the Valneva site in Scotland indicated that the facility manufactures Japanese encephalitis vaccine under a Manufacturing Authorisation granted by MHRA, while the marketing authorisation holder, located in another country, is Valneva Austria GmbH. Hence this is another example where the reporting of a production facility relevant to the BTWC could be missed by narrow application of the current CBM G wording.

5. Subsequently, the request to the MHRA was amended to include information on UK vaccine production facilities that hold UK manufacturing authorisation, as well as those granted marketing authorisation by MHRA. In addition to Valneva, a further relevant facility was identified. At its biomanufacturing facility in Glasgow, Scotland, Merck BioReliance® Services produces the active viral ingredient for an Adenovirus vaccine on behalf of a US-based pharmaceutical company, for use in the United States. The site is licensed and operates under a Manufacturing Authorisation granted by the MHRA. The product is sent to the client as a frozen liquid formulation, for further processing and tabletting. The US-based pharmaceutical company holds marketing authorisation from the FDA for use of the vaccine in the United States.

6. Consequently, in the spirit of transparency, the UK CBM G declaration for 2018, submitted on 3 April 2019 via the newly launched eCBM facility and available publicly on the BTWC website, included the Valneva and Merck BioReliance® Services facilities in Scotland. The information provided made it clear that both facilities held the appropriate manufacturing authorisations to produce the relevant vaccine products, but did not hold the marketing authorisations for the products manufactured on site. Both the licensing authorities and the holders of the marketing authorisation were specified in each case. Information was also given on other work undertaken in the facilities, including the production of materials for clinical trials of candidate vaccines. Since products in the clinical trial process are not yet licensed for use for the protection of humans, there would seem to be no requirement under the current CBM G wording to include information on their production. However, such information usefully provides increased transparency of the wider range of activities taking place in declared facilities, and can 'broaden scientific and technical knowledge as agreed in Article X'[2] on potential vaccines that may be available in future for use in the protection of humans.

[2] As specified in the CBM G description.

III. Recommendations

7. We encourage States Parties to continue 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 the reported cases. 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 or region. In this context, when requesting information on vaccine production facilities from national licensing authorities, it would be useful to specify that both manufacturing and marketing authorisations are relevant.

8. Although the potential reporting gap described 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.