U.S. FOOD & DRUG ADMINISTRATION

June 10, 2019

Dr. J.A.A.M. (Ronnie) van Diemen-Steenvoorde
Inspector General
Health and Youth Care Inspectorate
Ministry of Health, Welfare and Sport
Stadsplateau 1
3521 AZ Utrecht, Netherlands

Dear Dr. Diemen-Steenvoorde:

The purpose of this letter is to inform you that U.S. FDA has completed the assessment of the Ministry of Health, Welfare and Sport, Healthcare Inspectorate (IGJ), foreseen under Article 6 of the *Sectoral Annex for Pharmaceutical Good Manufacturing Practices* (GMPs) last amended on March 1, 2017.

The assessment has been conducted according to the provisions of Appendix 4, Section II, Paragraph A, of the Sectoral Annex.

Based on the outcome of the above mentioned assessment, our technical conclusion is that IGJ has the capability, capacity and procedures to carry out GMP surveillance inspections that meet FDA requirements for the product scope defined in Appendix 3 to the Sectoral Annex. This conclusion does not apply to vaccines for human use, plasma derived pharmaceuticals, investigational and veterinary products. In accordance with Article 7 of the Sectoral Annex, the Joint Sectoral Committee will be notified of the determination.

To obtain the most benefit from a capability determination, FDA calculated a specific date for each capable inspectorate that precedes the formal recognition date as much as possible. FDA will begin to use reports of inspections from each European Union (EU) member state (MS) human drug inspectorate that are completed on or after this date, referred to as the ***MRA Reference date***. To determine this ***MRA Reference date,*** FDA considered:

- Completion of EU's Joint Audit Programme audit with all corrective actions appropriately addressed;
- FDA's review and determination that the EU's conflict of interest provisions provide the same level of impartiality as FDA; and
- Completion of any corrective actions/preventive actions identified by FDA.

Based upon these considerations, the ***MRA Reference date*** for IGJ is December 10, 2018.

Although our intent, consistent with the Sectoral Annex, is to rely on the factual findings in official GMPs documents from capable inspectorates, there may be circumstances when FDA will conduct its own inspection in your territory.

U.S. Food & Drug Administration
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The following are reasons for which an inspection may be conducted in a capable country (some may not be applicable to your inspectorate):

- The products of interest are outside the scope of the *Sectoral Annex* or are subject to Article 20 (e.g., vaccines, etc.)
- The capability assessment was unable to confirm inspection competency in a specified product area or manufacturing type (e.g., sterile filling)
- The inspection is product-specific (e.g., preapproval or FDA's application specific post-approval inspection)
- The inspectional information provided is outside the date range for which FDA recognizes inspection reports or otherwise identifies a need for FDA to inspect
- The regulatory authority is unable to conduct the inspections within the specified timeframe
- Other exceptional circumstance (e.g., FDA-directed inspections)

In addition, Article 8 of the Sectoral Annex expressly allows for EU and FDA to conduct their own inspections, if necessary.

We especially like to express our gratitude to IGJ, the European Medicines Agency, and the European Commission for their efforts and cooperation that have made this work possible.

Sincerely,

Mark Abdoo
Associate Commissioner for Global Policy and Strategy

cc: Director-General Xavier Prats Monné, Director-General, Directorate-General for Health and Food Safety, European Commission
Dr. Andrzej Rys, Director of Health Systems for Medical Products and Innovation, Directorate-General for Health and Food Safety, European Commission
Ms. Anna-Eva Ampélas, Head of Unit, Directorate-General for Health and Food Safety, European Commission
Professor Guido Rasi, Executive Director, European Medicines Agency