May 29 th 2012
Response of the Ministry of Health, Welfare and Sport, the Netherlands to the Public consultation: DRAFT TEMPLATE FOR THE WRITTEN CONFIRMATION FOR ACTIVE SUBSTANCES IMPORTED INTO THE EUROPEAN UNION FOR MEDICINAL PRODUCTS FOR HUMAN USE, SANCO/D6/(2012)ddg1.d6.517666

The Netherlands welcomes the use of the written confirmation. Enclosed you will find our comments.

- *1. Name and address of site:*

The Netherlands suggests adding the name of the company and location. Is it intended that each manufacturer fills out the form for each location/site and not for the entire company?

- Activity(ies)

Which activities should be distinguished?

- The responsible person

Does the responsible person need to have specific requirements?

- Additional information

To determine whether the information is up to date, and is regularly audited by the company, The Netherlands would like to add the following information to the form:

Based on an audit by ……..carried out on …… (Date).

- The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU;

What is the legal implication of the statement 'at least equivalent to those of the EU' for authorities in 3rd countries? What if there is no reference to EU laws for example?

If the main API export 3rd countries do not respond to this consultation, the Netherlands suggests the Commission to verify their opinion to this topic to identify the implications for the issuing regulatory authority.

- How will API's imported from 3rd countries will be distinguished by Customs?

  For example API's can be intended for veterinary use, or intended for research and laboratory purpose.