EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

PHARM 645

PHARMACEUTICAL COMMITTEE
26 March 2014

Subject: **GMP Guide**

Agenda item 2g

The GMP/GDP Inspectors Working Group representing Member States' GMP/GDP experts has forwarded to the European Commission a proposal to revise "Chapter 6: Quality Control" of the EU GMP Guide.

Changes have been made to include a new section on technical transfer of testing methods and other items such as Out Of Specification results.

Prior to publishing the guideline, we would like to consult the Pharmaceutical Committee to allow its members to raise objections, if any. We plan to publish the aforementioned document if no objections are raised by 26 March 2014 to sanco-pharmaceuticals-d6@ec.europa.eu.

The Veterinary Pharmaceutical Committee is consulted by written procedure.

Furthermore, the European Medicines Agency has brought to our attention that in "Chapter 2: Personnel", paragraph 2.5 the references to other paragraphs in Chapter 2 need to be corrected. The correction is supported by the GMD/GDP Inspectors Working Group. A slightly updated version of Chapter 2 is presented prior to its publication.

Annexes:
- Draft Chapter 6: Quality Control.
- Revised Chapter 2: Personnel.

Action to be taken:
For information.
Any comments in writing by 26 March 2014.