



**From:** [REDACTED] (SANTE)  
**Sent:** vendredi 22 janvier 2021 18:26  
**To:** [REDACTED] (SANTE); [REDACTED]  
(SANTE); [REDACTED] (SANTE); [REDACTED]  
(SANTE)  
**Cc:** [REDACTED] (SANTE)  
**Subject:** Stakeholder/EMA /EC meeting in the margin of IWG.

Dear All,

I participated this morning in a meeting organised by EMA in the margin of the IWG with stakeholders from the pharma industry, notably :  
EFPIA (Coordination), AESGP, Animalhealth Europe, APIC, AME: Affordable Medicines Europe, ECA/EQPA, EIPG, GIRP, ISPE, Medicines for Europe, PDA, VE.  
Representatives from EMA, the human NCA of Ireland (HPRA) and the Veterinary NCA of France (ANSES) were also participating.

After an update on the latest activities of the IWG and on the EMA GMP/GDP -IWG Working plan 2021, the stakeholders raised questions issues on the following subjects :

- GMP for sterile medicinal products (Annex 1);
- Chapter 4 / Annex 11: Documentation / Computerised System Validation (CSV);
- GDP & GMP for Veterinary medicines (EU-GMP Annex 4, 5);
- Progress of MRA's;
- Other priorities including activities in e.g., VICH and PIC/S.
- Inspection and Audit Management in a changing environment
  - QP responsibilities including remote certification;
  - GMP/GDP-Certificates;
- EU/UK Relationship: Inspections

The following questions need to be followed up :

The industry observed an non harmonised interpretation of QP responsibilities between different MS and a different interpretation of the requirements to become a QP. This could be solved by a Q&A .

The industry stressed the urgent need to include the batch testing recognition in the UK agreement and to make it evolve to cover more products.

The waiver for EU re-testing is a waste of time and resources and is consuming products. In addition it is environment unfriendly. This should be a priority before the end of 2021 as there is already an unilateral EU batch release testing recognition of UK until end of 2022.

The stakeholders were very keen to help to accelerate the collaboration with US on the recognition of Vaccine and blood product inspections.

Regarding the EU UK agreement it would be urgent to remove the reference to the OECD guide as it doesn't make sense to ask GMP inspectors to take as reference a guide which is not on GMP but on unrelated sustainable manufacturing good practices. Reference to the EU GMP guidelines and Eudralex Volume 4 should be made instead.

The last question was on Section 3 of Commission Notice C(2020) 9264 and the checks of the unique identifier at export to UK and at import in NI or Cyprus ...

Are the two checks independent or should the records of the first check be sent with the products so that the importer in NI or Cyprus or other MS can have a prove that is-t was done ? It was considered that the checks are independent and under the responsibilities of the QP at the exporting MS and of the QP at the importing MS.

With kind regards

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