EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Single market, implementation and legislation for consumer goods
Pharmaceuticals : regulatory framework and market authorisations

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Note to the Members of the GMP Inspectors group

Subject: Interpretation of Articles 51 (1) b of Directive 2001/83/EC and 55 (1) b of Directive 2001/82/EC

Dear colleagues,

Based on an actual case stemming from the Veterinary Mutual Recognition Facilitation Group, the Commission wants again to outline the interpretation of Articles 51 (1) b of Directive 2001/83/EC and 55 (1) b of Directive 2001/82/EC.

During a variation procedure for a veterinary vaccine, it became obvious that the responsible pharmaceutical company didn't re-test any batches imported from USA. The company stressed that this would be completely in line with Community legislation and argued that they would have several bilateral agreements with Member States Supervisory Authorities allowing doing so. Those "bilateral agreements" would be considered as "appropriate arrangements" in the sense of Community legislation. Therefore the company did not see any need for re-testing of batches imported from manufacturing sites in USA before batch release into EU/EEA on a routine basis.

The Commission explicitly objected this interpretation. Articles 51 (1) b and 55 (1) b clearly oblige the responsible qualified person to carry out a complete re-testing of imported batches in EU/EEA. Any quality control test being performed in USA or in any other 3rd country does not release the qualified person from the responsibility to ensure that "in the case of medicinal/veterinary medicinal products coming from third countries, each production batch imported has undergone in the Member State a full qualitative analysis and a quantitative analysis of at least the active substances". Additionally "other tests or checks necessary to ensure the quality of medicinal/veterinary medicinal products in accordance with the requirements of the market authorisation" have to be carried out.

Facilitation has already been introduced in point 6.1.3 of Annex 16 of the EU GMP Guide on Certification by a qualified person and batch release. Member States have agreed to the possibility that "importation and testing need not necessarily be performed in the same Member State", but it still has to be done in EU/EEA.

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Only if a Mutual Recognition Agreement (MRA) between EU and a 3rd country is operational, a qualified person can accept tests being carried out in the respective 3rd country. We do not have an operational MRA with USA on the GMP sector. Therefore Articles 51 (1) b and 55 (1) b are applicable for all medicinal/veterinary medicinal products or immunologicals being imported from USA, regardless whether they have been authorised through a central, mutual recognition or national authorisation procedure and irrespective of the company involved.

Consequently there is no room for individual agreements between a single Member State and a company which would completely contradict Community legislation and all operational Mutual Recognition Agreements. Therefore we consider the batch release of an imported medicinal/veterinary medicinal product from USA or any other 3rd country without re-testing as a serious failure of a qualified person's legal obligations. According to Article 52 of Directive 2001/83/EC and Article 56 of Directive 2001/82/EC we would expect Member States' Supervisory Authorities to launch appropriate administrative measures towards such a qualified person and to withdraw the product concerned from the market (Article 117 (1) d of Directive 2001/83/Ec and Article 84 (1) e of Directive 2001/82/EC).

To avoid any further misinterpretation by companies we urgently ask Member States Supervisory Authorities to act according to Community legislation and not to tolerate any exceptions from the principle of re-testing.

Yours sincerely,

signed
Philippe Brunet
Head of unit