From: Thomassen Per Thomas [mailto:Per-Thomas.Thomassen@hod.dep.no]
Sent: Monday, March 24, 2014 10:02 AM
To: SANCO PHARMACEUTICALS D5
Cc: Karine Havsås; Audun Hågå; Berg Jan
Subject: SV: External study on the availability of medicinal products for human use

Dear Mr/Ms,

Please find enclosed the answer from Norway on the two questions:

Question 1:

The report addresses, among other factors, the relationship between Good Manufacturing Practise (GMP) incompliance and issues related to shortage. Case study 2 explores and exemplifies this in more detail by depicting a common scenario where sudden shortage often comes as a result of a GMP inspection with a negative outcome. In such cases, release of batches to the market is often delayed until the GMP issues have been resolved. Sometimes batches released to the market are also withdrawn.

The report could be incorrectly interpreted in such way that the cause of shortage is directly related to the inspections performed by authorities and not to the actual GMP deficiencies revealed during these inspections. Bearing in mind the interest of the patient, it should be emphasised that neither the GMP rules nor the inspections are a part of the problem.

Instead, the core problem is that the Marketing Authorisation Holders (MAH) in many cases do not fulfil their duties as laid down in Directive 2001/83/EC when it comes to ensure that the manufacturing sites are GMP compliant so that non-compliance is not just coincidently revealed during inspections by authorities. As an example, ensuring GMP at active substance manufacturing sites is the sole responsibility of MAHs as laid down in Article 8.3. The report could preferably elaborate on the actual underlying issues that cause shortages following inspections.

The report also mentions the trend towards more complex global supply chains and reliance on fewer manufacturing sites, often outside the EEA. This often adds to shortage problems caused by GMP issues.

The above mentioned points are further supported by the document “Drug Shortage Issue, Solutions Highlighted” published by the PDA. The PDA report points out that a lack of incentives for the industry results in problems with medicinal product quality, which in turn leads to supply disruption and shortage. It can be concluded from the document that more focus on enforcing quality (*e.g.* by ensuring GMP compliance) will lead to an improved access of medication in the long run.

In light of the discussions in the report, especially the case study 2 and the conclusion, an additional point of recommendation could be added in order to address shortage issues more or less directly related to GMP incompliance:

- Further clarify and enforce the responsibilities of Marketing Authorisation Holders in terms of ensuring GMP compliance.

Question 2:

The possibility provided by Article 126a of directive 2001/83 is so far not used by Norway.

Best regards,

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