From: Jonathan Griffith [JGriffith@Naturalmedicine.ie]
Sent: lundi 12 septembre 2011 16:31
To: SANCO GMP
Subject: Commission Guidelines on Good Distribution Practice of medicinal products for Human Use - Consultation Process

Dear DG Sanco,

Our company is a licenced pharamceutical wholesaler based in the Republic of Ireland. We wish to submit the following observations on the recently issued consultation document relating to the EU pharmaceutical wholesaling guidelines.

Receipt of Goods

5.15 Whereas we recognise that the distribution of medicinal products may include many players and that there is a need in the current climate to establish specific measures to control the entry of falsified medicines into the market, we wish to observe that the distribution process does not always include many players and that in the case of simple transactions between the manufacturer and a directly appointed distributor, the possibility of falsified products entering the market is negligible. For example: a manufacturer produces products either directly for the Irish market with an Irish PA number, or in common packaging for the UK and Irish market with both UK and Irish PA numbers; the product is supplied directly to the wholesaler from the manufacturer; the wholesaler and manufacturer have mutually vetted their procedures and are satisfied that identification of the Irish PA number on each batch of product is adequate demonstration that the product is valid for the irish market, including that the batch has been released for the Irish market. We consider that the need for the manufacturer to issue and the wholesaler to supply a control report for each batch of product would not add additional security to the transaction, but would impose a significant additional administrative burden. We believe that, while the current text does allow for the possibility of 'an equivalent system' the wording is such as to imply that the system should be batch specific. We suggest that in cases such as that described above, where there is no intermediary, the GDP standards already established between manufacturer and wholesaler should be recognised as sufficient in themselves and should not require an additional requirement to certify batch release.

Complaints

6.1 This paragraph distinguishes between complaints relating to the quality of a medicinal product and complaints relating to distribution. It does not identify the third category of complaint which we deal with - Adverse Reactions. As Pharmacovigilence is not addressed anywhere else in the guidelines, we consider it important to at least identify here, as a third type of complaint, the requirement on wholesalers to accurately record Adverse Events and pass them on to the Regulatory Authorities and/or the Manufacturer as appropriate, should be included here.

Returned Medicinal Products

6.9.2 In our experience the specification of five days as the maximum period within which it is permitted to return distributed product to stock is unrealistic. We specialise in the distriubtion of traditional herbal and homoeopathic medicines with a typical shelf life of 2 years or more; we offer a 24 hour nationwide delivery service to clients, many of whom only order once a week or once a month. Our current terms require notification of an error in delivery within 3 days and the return of goods within one delivery cycle, which could be as much as 30days. In so far as the Responsible Person has to individually evaluate and sign off each return of medicinal products, we consider that our current system provides adequate control for these classes of medicinal products.

End of Submission.

Sincerely,

Jonathan Griffith
(Director: Natural Medicine Company Limited)