Unit SANCO/D/3, BREY
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BY POST AND EMAIL TO SANCO-PHARMACEUTICALS@EC.EUROPA.EU

MHRA comments on the European Commission's concept paper on the requirements for manufacturing of active substances of medicinal products for human use

Please find enclosed the United Kingdom's response to the concept paper "Implementing Act on the requirements for the assessment of the regulatory framework applicable to the manufacturing of active substances of medicinal products for human use".

In this letter I would like to stress the main concerns that the UK has regarding the Implementing Act:

- exporting countries may be unwilling to participate in the scheme as it increases their regulatory burden;
- the EU authorities need, urgently, to engage much more extensively with third country regulators to inform them about the changes in the legislation and to ensure that countries will issue the written confirmations that will need to accompany active substances from July 2013 onwards;
- an increase in the need to conduct EU inspections of specific manufacturing sites cannot be accommodated in the resource available;
- we are extremely concerned that the additional burden placed on the industry may make European companies consider moving finished product manufacture offshore to reduce those burdens - this is because the requirements apply to the import of active substances only and not finished products;
- if the conditions for import cannot be satisfied it could potentially lead to a shortage of medicines.

There is very little time before implementation to engage with exporting countries: we would urge that the Commission does this as quickly as possible to discover how the main exporters (especially China and India) intend to take action to secure supply routes. It would be helpful to have, at the earliest possible opportunity, a meeting of the Standing Committee that will need to agree the approach to implementation to discuss how these provisions can be implemented in ways that avoid the unintended adverse impact we have flagged above.

Yours sincerely,

Jonathan Mogford
Director, Policy Division

Medicines and Healthcare products Regulatory Agency (MHRA)
151 Buckingham Palace Road London SW1W 9SZ UK
T 020 3080 6000 www.mhra.gov.uk