Re: Public Consultation
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 (SANCO/D3/(2011)ddg1.d3.1438409

Dear Sirs,

The Bogin is the Association of the Dutch Generic Medicines Industry. On behalf of the Bogin members we would like to bring to your attention the following points with respect to the above mentioned regulation on API (active product ingredients)

We support the direction of the Directive 2011/62/EU with rules for importation of active substances in order that the supervision of compliance to standards of GMP for API is equivalent for all medicinal products within the European community, regardless of where the API is manufactured. The practical aspects of introduction however also have to be taken into account. Certainly it is important that the supply of medicines to patients will not be negatively influenced by the introduction of these rules. The Bogin is worried that strict introduction of the rules in July 2013 might result in shortages of many products. At this moment it is unclear what will happen for the importation of API from countries not on the EU list of equivalent countries. It is uncertain whether the so called third countries will be able or willing to supply the requested written confirmation and more importantly to meet EU expectations as defined in the Directive.

A great number of products has an API coming from the so called third countries. If the required documentation will not be available in time this will cause production problems that will result in medicines shortages. Finding an alternative source is not easy and if one is available it will in most cases both have consequences in need for changes in the regulatory dossier, needing quite some time to amend the dossier, as well as having consequences in the cost factor of the API. This cannot be the goal of the introduction of this Directive. The products are already on the market in the EU and the Bogin is of the opinion that the MAH legal responsibilities to regularly audit each and every manufacturer for API GMP compliance remain unchanged, a transitional waiver should be given to those APIs coming from third countries that cannot supply the requested documents in time yet can establish a history of good compliance with GMP.
From the viewpoint of the Bogin the waiver 2 principle should be applied in those circumstances in order to guarantee a continuous supply of those products to patients in the market, implying a need for more EU inspections . In case it becomes clear that from the third country the required documentation will not be available in a reasonable time, an adequate period of time should be given to allow a transfer to another source of API and regulatory procedures should be expedited.

So we urge you to be pragmatic in the introduction of this Directive in the interest of the patient.

Yours sincerely,

Drs. P.F. (Frank) Bongers

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