AESGP

Association Européenne des Spécialités Pharmaceutiques Grand Public
Association of the European Self-Medication Industry
Europäischer Verband der Arzneimittel-Hersteller

AESGP comments on the Template for the Qualified Person's Declaration concerning GMP compliance of Investigational Medicinal Products manufactured in non-EU countries

AESGP represents the manufacturers of non-prescription medicines of either chemical or herbal origin at European level. Through its wide national and associate membership, it represents many small and medium-sized as well as multinational companies.

AESGP generally welcomes the intent of having a single EU-wide template for the provision of QP declarations. This will address the current situation with various requirements in different Member States and, as intended, pave the way for the new Clinical Trial Regulation with its single submission. We however have the following comments on the template:

- We would prefer the template not to have the EudraCT number. This would facilitate the creation of Product/Site declarations which can then be used in multiple submissions, which would reduce bureaucracy during late stage development when a number of studies (which will each have a different EudraCT number) are utilising the same products.
  However, in the event that the decision is that the declaration must be for a given EudraCT number, it should be possible to cover all the products used in that trial with a single declaration. An amended Part A format such as given below would readily facilitate this:

Product name	**Third country site(s) (Name and address of site)**	**Activities performed at this site (Manufacturing, packaging, labelling and/or testing)**

- We would like to request that greater clarity be provided, either on the form or via an associated guidance document, regarding the scope of activities that are intended to be covered by this declaration. Based on the wording, we believe that it is only those activities pertaining to secondary product manufacture, packaging, labelling and/or testing that are intended to be covered and that active pharmaceutical ingredient and bulk biopharmaceutical active are out of scope. Also, if a site has manufacturing, packaging & labelling and analytical testing and there are separate audits for each of these activities, we expect that the date of the last audit of the site is to be given, not the date of last audit of each activity.

- It should be clarified that 'third countries' are those outside the EEA (not just outside EU).

- Is there really a need to separate out (i) and (ii) of Part B? The form could be simplified to a single table capturing audits, as under (ii) with the 'Third party' header being replaced by 'Auditing party', which might include the signing QP personally.

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We believe it should be acceptable that a QP may use, as a basis for their declaration, audits conducted by Quality Assurance personnel who are based on the manufacturing site if they are satisfied that they are appropriately trained, knowledgeable in EU GMP and suitably independent of the areas audited.

- We appreciate the acknowledgement of particular situations (e.g. remote audits) reflected by the insertion of point iii), and the willingness to accept those particular situations when properly justified.

- What would be the implementation timeframe of such declaration? A transition period may be necessary to ensure smooth implementation.

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