AWTORITÀ DWAR L-MEDIĊINI

Circular Number: MA 02/13

To all Qualified Persons and Licence Holders
Of licensed Manufacturers

19th June 2013

RE: New requirements for importation of Active Pharmaceutical Ingredients (APIs)

Dear Stakeholder,

As you are already aware the provisions of the new article 46b in Directive 2001/83/EC, introduced through amendments brought about by the Falsified Medicines Directive (Directive 2011/62/EU) and transposed into national legislation via regulation 17 of subsidiary legislation 458.42 (Good Manufacturing Practice in Respect of Medicinal Products, Active Substances and Investigational Medicinal Products for Human Use Regulations), would come into force as from coming 2nd July.

According to this legislation Active Pharmaceutical Ingredients (APIs), also referred to as Active Substances, can be imported and used by finished dosage form manufacturers only if the country from where they are manufactured is either listed with the EU Commission as having in place rules and enforcement procedures for APIs at least equivalent to those in the EU (Current listed countries can be viewed on the EU Commission website using the link: http://ec.europa.eu/health/human-use/quality/index_en.htm), or otherwise if they are accompanied with a written confirmation issued by the health authorities of the exporting country, which written confirmation should be based on the template as published in Part III of EudraLex, Volume 4.

However the legislation also provides for when the above two options are not in place and there is no alternative, the API can be imported if the API manufacturer has a valid EU GMP certificate. In such a case if this provision, sometimes referred to also as the waiver, is intended to be used the finished dosage form manufacturer should inform the competent authority where he is established that he will be using this waiver, as the competent authority then has an obligation to inform the EU Commission of this.

Therefore if after 2nd July you are going to import APIs from countries listed by the EU Commission or the API consignments will be accompanied with a written confirmation, no further action is required from your end, except in the latter's case keeping a copy of such written confirmation as proof of this. However if you intend to use the waiver, i.e. import the API with the availability of a valid EU GMP certificate, kindly send us a letter (can be sent as hardcopy but preferably via email on the inspectorate general mailbox:inspectorate.adm@gov.mt) informing us which APIs will be imported together with name and address of their manufacturer and a copy of the valid EU GMP certificate used as the basis for this waiver. Kindly inform us ideally before placing the order but definitely before the API reaches your end, ideally at least 10 days before, as we have to inform the Commission in advance. There is no need to inform us for each and every consignment but only for

the first time you intend to use this waiver based on the availability of the EU GMP certificate and again when you want to stop this waiver (e.g. when a written confirmation will then be made available). In order to facilitate your work during this transition period, unless informed to the contrary, there is no need to wait for an approval from our end before proceeding with the importation, always however keeping in mind that the ultimate responsibility for the APIs you are using rests with you to ensure that they are of the right standard and are in line with the legislation.

The above is meant as a short guidance on the implementation of these new requirements, but please do not hesitate to contact us if you need to clarify anything else in connection with the above. As further means of information on this aspect you can also access the Question and Answer document published by the EU Commission on its website using the below link:
http://ec.europa.eu/health/files/gmp/2013_04_12_qa_en.pdf

Regards,

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Medicines Authority