European Medicines Agency
Inspections

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EC-Canada Mutual Recognition Agreement

Sectoral Annex on Good Manufacturing Practices

Common Statement regarding the Scope of the MRA

Background

A new federal Natural Health Products Regulations governing natural health products (NHPs) in Canada came into effect 1 January 2004. As a result of these regulations certain products which were previously regulated as drugs (medicinal products) are now regulated as natural health products (e.g. vitamins, minerals, herbal remedies, homeopathic medicines and probiotics). Due to the new NHP regulations, drug establishment licenses previously held by natural health product companies are considered expired and have not been renewed since January 2006. In order to bring these products back within the scope of the MRA, Health Canada is preparing a regulatory amendment which would allow, on a voluntary basis, Canadian natural health product companies to hold an establishment licence, issued based on compliance with pharmaceutical Good Manufacturing Practices (GMP), in addition to the site licence required under the NHP Regulations. Further information is available at http://hc-sc.gc.ca/dhp-mps/prodnatur/index_e.html. Health Canada will update EC of any progress in this matter.

In the European legislation Directives 2001/83/EC and 2001/82/EC provide definitions of medicinal products including herbal medicinal products. As such, manufacturers of these products require a manufacturing authorisation and need to comply with EU GMP.

Interim Measures for Natural Health Products with respect to the MRA Agreement

Recognising that the Canadian regulations have their own set of GMP requirements for natural health products and do not require these products to be manufactured in a facility to a GMP level equal to those for drugs, many companies do ensure this level of manufacture.

With respect to the MRA agreement, products regulated in Canada as NHPs will be captured by this MRA, when they are manufactured to a GMP standard equal to those for pharmaceutical drugs. While not limited to the following, these will primarily include specific commercial products of herbal medicines, probiotics and vitamin/ minerals.

Upon request of a Canadian exporter, or a Regulatory Authority under the MRA, Health Canada will issue a Certificate of Compliance (GMP certificate) for facilities manufacturing, packaging/labelling, importing, distributing and/or testing NHPs in addition to drugs, which will clearly indicate, which NHPs are held to a drug GMP standard (including premises, equipment, personnel, sanitation, raw material testing, manufacturing control, quality control department, packaging material testing, finished product testing, records, samples and stability).

Should a facility manufacture, package/label, import, distribute and/or test NHPs only, Health Canada will perform a full inspection (of the sections stated above) and issue a Certificate of Compliance in support of the activities, listing all of the products to be exported to an MRA country. A Canadian drug establishment license will not be issued in these cases, as it is not required by Canadian Law.

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Health Canada considers good manufacturing practice requirements of the EU, as being equivalent to the GMP requirements outlined in the *Natural Health Products Regulations*. Therefore, Health Canada accepts valid GMP certificates issued by the Regulatory Authority within the EC – Canada MRA, as evidence of compliance to NHP GMPs. In addition, all products that are manufactured at these sites are considered to be acceptable and do not require further confirmatory finished product testing in Canada.

Health Canada is continuing to pursue its regulatory amendment which would allow Canadian NHP companies to hold an establishment license based on drug GMP compliance. Until such time as this legislative amendment is passed, the approach noted above will facilitate trade under the MRA.

Further information on the MRA Sectoral Annex can be found at:
http://www.emea.europa.eu/inspections/mra.html and http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate