Department of Health

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28 MAR 2017

Dear Christina,

Thank you for your letter of 28 February to Jeremy Hunt on behalf of the All Party Parliamentary Group on Vegetarianism and Veganism about medication for vegans and vegetarians.

I appreciate the concerns raised and note your suggestions. Thank you for bringing them to my attention.

As you know, the current requirements for medicines labelling are set out in European and national legislation and separate guidance is available concerning the inclusion of information in relation to inactive constituents of medicines which may pose a safety risk in their own right. This guidance requires any medicine that contains an excipient of known effect to clearly display it on the packaging and a warning explaining this be included in the accompanying patient information leaflet. A listing of all the ingredients of the medicine will be contained within the patient information leaflet (PIL).

Unlike food legislation, there is no mechanism for the inclusion within the labelling of a medicine for any information on whether or not the product is suitable for vegetarians or vegans. This issue has been raised in Europe on a number of occasions previously without success, as medicines labelling may become too complex where different interest groups may have particular labelling requirements. Patients who wish to identify such products will need to rely on the information that can be provided directly by their pharmacist.

The Medicines and Healthcare products Regulatory Agency (MHRA) has published the summary of products characteristics (the information for the healthcare professional) and the PILs for all medicines on their web portal in line with a recent legal obligation. These documents, which include details of all the ingredients in

individual medicines on the UK market, are available on the Government website at www.gov.uk by searching for 'find PILs and SPCs for different medicines'.

On the issue of animal-free alternatives, at present medicines containing animal-derived ingredients are licenced by MHRA. Licensing of medicines is currently based on public health considerations. If ingredients are safe and their inclusion justified then generally they can be used. Although there are many medicines that are free from animal-derived materials, there are also cases where no animal-free treatment options exist.

Many active substances are made synthetically from chemicals, but some can only be derived from animal sources. For instance, in certain situations, Heparin is the most appropriate treatment option for anticoagulation during pregnancy.

In addition, capsule shells are most often made from animal gelatine. The use of alternative options or technologies, for example the use of hypromellose or hydroxypropylmethylcellulose (HMPC) capsules by the pharmaceutical industry, has been very limited so far. MHRA data reveal approximately 4,000 licences for gelatine capsules on the UK market and approximately 100 licences for HMPC capsules. Difficulties with HMPC capsules can include reduced release rates of the medicine from the capsule when taken, brittleness causing difficulties during large scale manufacturing and potential leakage issues for patients. For medicines already in gelatine capsules, expensive reformulation exercises and clinical studies may be required in order to switch to HMPC capsules. At the moment, for medicines where capsules are the only option, it is likely that there would be no animal-free alternatives available.

Animal-derived materials may be used in the manufacture of medicines. Modern biological drugs are often complex proteins made by recombinant DNA technologies using cell cultures, some of which require animal proteins in the culture media to support growth of the cells. Only purification processes that preserve the activity of the complex biological active substances can be used. Although these products are highly purified during the manufacturing process, the possibility of trace amounts of these animal materials being present cannot be excluded.

For new medicines coming to market there is an increasing tendency to avoid animal-derived ingredients. As technology advances, we expect that more non animal-derived materials will become available. However, for some medicines, the avoidance of animal-derived components is currently not possible.

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Regarding your suggestions on the labelling of medicines after the UK leaves the EU, until exit negotiations are concluded, the UK remains a full member of the EU and all the rights and obligations of EU membership remain in force. During these negotiations, the Government will work to ensure the best possible outcomes for UK citizens. However, it would be wrong to set out unilateral positions in advance of the negotiating process.

I hope this reply is helpful.

JAMES O'SHAUGHNESSY