From the Earl Howe
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Dear Jenny,

Thank you for your further letter of 12 January to Andrew Lansley about the withdrawal of human Mixtard 30 insulin. I am replying as the Minister responsible for medicines policy.

I would first of all like to reassure you that we are aware of the possible implications for patients of the discontinuation of Mixtard insulin, and can fully appreciate your concerns. As you may already know, the decision to discontinue this product was taken for commercial reasons. The company informed Departmental officials that sales of the product had been declining for the last six years, and that the discontinuation would allow the company to free up capacity and resources in order to invest in new and innovative products. Pharmaceutical companies constantly keep their product portfolios under review, and the Department of Health has no powers to force a company to continue marketing a product if it decides not to.

As far as Actraphane is concerned, this is the name given to a similar product to Mixtard, also marketed by NovoNordisk, which is subject to a separate marketing authorisation. It is sold in other countries, but it is neither routinely available nor routinely used in the UK. Products from the Actraphane range are currently marketed in Germany and Italy but not in the UK.

It might help if I explain that Actraphane has a central marketing authorisation. This is the same type of authorisation under which Mixtard was marketed, but they are considered to be separate authorisations, although they may be identical. Consequently, they are marketed separately. Actraphane has been authorised to be marketed in all EU member states but may only be available in selected

markets, as determined by the Marketing Authorisation Holder. This was also true of Mixtard.

Since Actraphane is authorised in the EU, it cannot be imported into the UK using the unlicensed import procedures, although if available outside the EU, the product could in principle be imported as an unlicensed product from a country that is not part of the EU centrally authorised licensing process.

The appropriate procedure for importation of a centrally authorised medicinal product into the UK from another member state would be through parallel distribution. This is carried out by a company in possession of a wholesale dealer's licence, which would then need to obtain approval for parallel distribution through the European Medicines Agency (EMA). The EMA would evaluate the notification and ensure that the packaging and leaflets would be suitable for UK patients, that the distribution chain is covered by appropriate licences and that the cold chain (in the case of insulin) is maintained. Whether to pursue this route of supply is a decision for the companies concerned, and is dependent on whether supplies can be obtained in the countries in which the product is marketed.

Therefore, although Actraphane is sold in other countries, it is neither routinely available nor routinely used in the UK. Obtaining the product and guaranteeing continuity of supply for UK patients would not be straightforward.

Finally, although NovoNordisk sought advice from the Department of Health (as well as patient groups and diabetes specialists) on its communication and support package in relation to the discontinuation of Mixtard 30, it is for the company itself to inform patients and healthcare professionals as it sees fit.

I hope that this clarifies the situation.

With kindest regards.

Yours sincerely.

Earl Howe

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