March 7th 2011

The Earl Howe
Parliamentary Under Secretary of State for Quality
Richmond House
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Thank you for your letter of February 21st 2011 and for your detailed explanation contained therein.

As an organisation, we have always understood that the decision to withdraw a product from the market rests with the manufacturer and is one that is made on commercial grounds. However, the commercial decision to discontinue Mixtard 30 affects the health, wellbeing and quality of life of people with diabetes and we have responsibilities to them and their needs. In the case of the Mixtard 30 discontinuation, the predicted consequences are proving to be a reality. There are people who, two or more months later, have not achieved the blood glucose control they had with Mixtard 30, there are people who are allergic or have adverse reactions to the alternative insulins and most concerning of all, the visually impaired and those with dexterity problems are unable to self-inject without the Innolet injection device that was available for Mixtard 30. Apart from the removal of independence and loss of quality of life for this vulnerable group of people, the cost to the NHS of the extra care that they need is considerable. It is for this group of people in particular that we have to appeal for some understanding and class them as an exceptional case.

While we can understand that parallel importation may well not be a feasible option because of the relatively small numbers of people affected and because it relies not only on the goodwill or commercial policies of manufacturers, Novo Nordisk, but also on the wholesale dealer's willingness to obtain approval through the EMA. Again the latter is unlikely to happen as Novo Nordisk have chosen to restrict competition by having one only wholesaler for the UK from this month.

Having said this, it seems illogical and irrational that a drug, in this case Actraphane, can have Marketing Authorisation in the UK and perhaps more significantly, in the EU, but it cannot be accessed by Member States for patients in need. The regulations allow it to be accessed on a named patient basis from countries outside the EU as it then falls into the category of an unlicensed medicine, but as you point out, there are associated risks and responsibilities. For people who are allergic or have additional adverse reactions to all other insulins, there is little alternative but to go down this route. However, when Actraphane is available in EU Member States but not accessible, it appears that the regulations work against the best interests of this minority group of patients and are certainly not putting the needs of patients as a priority and at the centre of care.

While I appreciate your detailed explanation of the system, when people with diabetes are in need and their health professionals are seeking our help, I am afraid that we cannot simply sit idly by and accept their reduced quality of life and reduction in their health status when the insulin they need is actually available but inaccessible due to regulations that seem to defy logic. If this group of people cannot be treated as an exceptional case, then we will appeal further in our endeavour to try to ensure that we serve the best interests of people with diabetes.

Jenny Hirst
Co-Chair

Copies to:
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Anna Morton
Rt Hon Stephen Dorrell
Mr Adrian Sanders MP
Professor Kent Woods