Response to concerns about NovoRapid®

Novo Nordisk has received questions related to a series of adverse event reports received during the week commencing 7th August 2017 regarding specific NovoRapid® Penfill® batches.

The issue raised about NovoRapid® is being treated very seriously, **but there is no indication of a causal link between the adverse event reports and a product defect**. Furthermore, retention samples from the manufacturing batch raised in the initial query have been retested. Parameters of identity, potency and degradation products were examined and a pH analysis was also performed. The retesting has shown that the batch in question complies with all specifications and as such, quality of the product at time of manufacture has been confirmed. **Consequently, our investigation shows that there is no manufacturing issue with NovoRapid®.**

All batches of NovoRapid® (indeed all Novo Nordisk products) are thoroughly tested prior to release from their respective production sites, and storage and transportation of all product is verified at all stages until the product is delivered to pharmaceutical wholesalers – so as to ensure storage is within approved conditions (ie temperature, etc). No increased rates of reporting of adverse events of the local (Australian, New Zealand) batches have been noted in other countries where the batches have been supplied.

Novo Nordisk is following all local and global regulatory processes, including logging reported adverse events, reviewing adverse event reporting for NovoRapid®, and raising the reported concern with the TGA and Medsafe as well as with our Global Safety team at Novo Nordisk for further investigation.

It is also important to note that diabetes is a complex disease – and fluctuations in blood glucose can occur for many reasons beyond the insulin given.

NovoRapid® is an important product in the lives of many people with diabetes – so any concern for you is also of concern to us, and that is why we continue to investigate any individual patient query. We continue to encourage anyone with concerns on this matter to discuss it with their Healthcare Professional, and to also contact our NovoCare® Customer Care Centre on 1800 668 626 (Australia), 0800 733 737 (New Zealand) or AUNRCCC@novonordisk.com.