Response to concerns about NovoRapid® - *Updated 20 September 2017*

Results of laboratory investigations of NovoRapid® complaint samples and manufacturing batch retention samples:

In early August 2017, Novo Nordisk became aware of a Facebook forum post and Queensland newspaper article describing side effects with specific NovoRapid® (soluble insulin aspart) batches. Novo Nordisk has completed testing of the insulin sample from the original complainant, and of insulin manufacturing batch retention samples from this initial marketplace complaint. The following parameters were examined:

- identity ('is the product NovoRapid®?'),
- potency ('is the product strength within approved limits?'), and
- degradation products ('has the product quality been degraded?')
- pH (level of acidity, a measure of product quality)

Furthermore, the Australian regulatory authority (the TGA) has also completed independent laboratory testing of:

- separate complaint samples from the original complainant, and
- manufacturing batch retention samples from the initial complaint batch.

TGA and Novo Nordisk laboratory investigations show that there is no evidence of a product quality issue with NovoRapid®.

NovoRapid® quality is of utmost importance to Novo Nordisk , so any concern for you is also of concern for us. Please be assured that Novo Nordisk has taken this series of product complaints extremely seriously. It is important to note that diabetes is a complex disease, and fluctuations in blood glucose levels can occur for many reasons beyond the insulin given.

For more information

We continue to encourage you or anyone with outstanding questions on this matter to discuss them with your/their healthcare professional, and to also contact our NovoCare® Customer Care Centre on 1800 668 626 (Australia), 0800 733 737 (New Zealand) or by email to aunrccc@novonordisk.com.