

HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Reference:		
Date:	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
1. REPORTING PERSON		
Name:	Position:	
Organisation:		
Address:		
Telephone No:	Ext:	
e-mail address:		
2. PRODUCT DETAILS		
Product name: Norditropin® SimpleXx®		
Manufacturer: Novo Nordisk A/S		
Supplier: -		
Legal status: Banned <input type="checkbox"/> Counterfeit <input checked="" type="checkbox"/> Unlicensed <input checked="" type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: Solution for injection in cartridge		
Strength: 15 mg/1,5 ml		
Batch / lot no: IF21841 Is batch number genuine: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
If yes to the above, advise batch destination country:		
Expiry date: Unknown		
Language of packaging: Danish and Icelandic		
Date of discovery: Unknown		
Details of discovery: The Danish Police seized a shipment of the products during an investigation. Novo Nordisk has done an investigation of the products and has concluded that the products are falsified. The batch number, IF21841 printed on the label of the cartons and the cartridges is not a valid Novo Nordisk batch number. The secondary packaging material (blister, cartons and inserts) as well as the primary packaging material (code top, rubber plunger and rubber laminate) are not genuine. Furthermore, chemical analysis of the solution of one cartridge shows		

that results are out of the specified limits for the tested parameters; dimers, related substances and Somatropin. Moreover, the solutions of the cartridges were cloudy with particles. In conclusion, all parts of the samples were found to be falsified.

Analysed: YES NO

If yes, result of analysis: **See above**

3. DISTRIBUTION METHOD

Internet: YES / NO **Unknown**

Internet:

Non internet, advise full details:

URL:

Website address:

Other details:

Currency of payment:

Has product reached patients/consumers?

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES / NO

If yes, please advise details:

Medical assessment details:

5. NEED FOR PUBLICITY

Are you making a public statement? YES / NO

Are you issuing a press release? YES / NO

Are you recalling product? YES / NO

If yes to any of the above, when do you intend to take action?

6. DISSEMINATION

Are you content for this Rapid Alert to be shared outside WGEO membership?

YES / NO (please see below)

If yes, please specify which of the below you are content for this to be shared with (you may tick more than 1 box)

Law Enforcement Industry Security Trade Associations

Traders Other Please specify _____

7. PHOTOGRAPH

If possible, please attach a photograph of the product.