Appendix A – Rapid Alert Form
Counterfeit or illegal product found in the illegal supply chain

| Reference:   | <del>  -</del>  |           |                   |  |  |
|--|---|-----------|-------------------|--|--|
| Date:  | Time:   |           | Initials:         |  |  |
| 1. REPORTING I   | PERSON  |           |                   |  |  |
| Name:  |   | Position: |                   |  |  |
| Organisation   |   |           |                   |  |  |
| Address:   |   |           |                   |  |  |
| Telephone No: W  | ork:  |           | Ext: +            |  |  |
| e-mail address:  |   |           |                   |  |  |
| 2. PRODUCT DETAILS   |   |           |                   |  |  |
| MANUFACTURERS  |   |           |                   |  |  |
| Norditropin<br>SimpelXx  | Novo Nordisk Pharma<br>Internationale laan 55<br>1070 Anderlecht<br>Belgium |           |                   |  |  |
| Supplier : illegal o   | circuit   |           |                   |  |  |
| Legal status: Ba   |   | 「⊠ Unlice | ensed 🗌 Diversion |  |  |
| Batch number YX58071   |   |           |                   |  |  |
| Expiry Date 08/2016 The language on the package is Romanian  |   |           |                   |  |  |
|  |   |           |                   |  |  |
| Date of discovery : 20-10-2015   |   |           |                   |  |  |
| Details of discovery:  |   |           |                   |  |  |
| 4 packages of Norditropin SimpleXx 10 mg/1.5 ml were found in a postal package at Bpost Antwerp during a control by Customs in June 2015. The packages were transmitted to the police who opened an investigation. The advice of the FAMHP was asked and we contacted Novo Nordisk to evaluate the packages. |   |           |                   |  |  |
| References: Police - Crime reference number: BG60RG100208/2015 FAMHP: 15I017   |   |           |                   |  |  |
| Analysed: YES ⊠ / NO □   |   |           |                   |  |  |
| If yes, result of analysis: Novo Nordisk confirmed that Norditropin SimpleXx with batchnumber YX58071 and  |   |           |                   |  |  |
| expiry date 08/2016 is counterfeit. The package is not original Novo Nordisk and no active ingredients were  |   |           |                   |  |  |
| found in the sample.   |   |           |                   |  |  |
|  |   |           |                   |  |  |

| 3. DISTRUBUTION METHOD   |               |  |  |  |
|--|---------------|--|--|--|
| Internet: YES  / NO unknown                                    |               |  |  |  |
| Internet:  | Non internet: |  |  |  |
| URL:   |               |  |  |  |
| Website address:   |               |  |  |  |
| Other details:   |               |  |  |  |
| Language of packaging: Romanian                                |               |  |  |  |
| Currency of payment:   |               |  |  |  |
| Has product reached patients/consumers? unknown                |               |  |  |  |
| 4. RISK TO PUBLIC HEALTH                                       |               |  |  |  |
| Adverse reactions: YES / NO not applicable                     |               |  |  |  |
| If yes, please advise details:                                 |               |  |  |  |
| Medical assessment details:                                    |               |  |  |  |
| 5. NEED FOR PUBLICITY  |               |  |  |  |
| Are you making a public statement? YES / N                     | 10 ⊠          |  |  |  |
| Are you issuing a press release? YES / N                       | 10 ⊠          |  |  |  |
| Are you recalling product? YES \( \subseteq / \text{N}         | IO 🗵          |  |  |  |
| If yes to any of the above, when do you intend to take action? |               |  |  |  |

## 6. PHOTOGRAPH

