HMA WGEO – Rapid Alert Form Counterfeit or illegal product found in the illegal supply chain

Shaded area to be completed by the secretariat

| Reference:   |                 |           |                                  |  |
|--|-----------------|-----------|----------------------------------|--|
| Date:  | Time:           |           | Initials:                        |  |
| Please complete sections   | 1 to 5 providin | g as much | information as possible <u>.</u> |  |
| 1. REPORTING PERSON  |                 |           |                                  |  |
| Name:  |                 | Position: |                                  |  |
| Organisation:  |                 |           |                                  |  |
| Address:   |                 |           |                                  |  |
| Telephone No:  |                 |           | Ext:                             |  |
| e-mail address:  |                 |           |                                  |  |
| 2. PRODUCT DETAILS   |                 |           |                                  |  |
| Product name: Sahimerdan Epimedyumlu Bitkisel Karisimli Macun              |                 |           |                                  |  |
| Manufacturer/Supplier: Pelit Bal Ürünleri, Hal Mah. 6040 No. 26 Mersin     |                 |           |                                  |  |
| Importer: private travelling person entering from Turkey                   |                 |           |                                  |  |
| Address:   |                 |           |                                  |  |
| Supplier:  |                 |           |                                  |  |
| Address:   |                 |           |                                  |  |
| Legal status: Banned ☐ Counterfeit ☐ Unlicensed ☒ Stolen ☐                 |                 |           |                                  |  |
| Dosage form: 30 Glasses containing 240g of Herbal Paste                    |                 |           |                                  |  |
| Strength: main Ingredients: Mulberry Molasses, Pollen, Soyflour, Epimedyum |                 |           |                                  |  |
| (0.79%) Carob, Oat, Ginger, Galangal, Cinnamon, American Ginseng, Dead     |                 |           |                                  |  |
| Nette, Siberian Ginseng, Ginko Biloba, Calabash, Caltrop, Cola             |                 |           |                                  |  |
| Batch / lot no:  |                 |           |                                  |  |
| Is batch number genuine: Yes No □  |                 |           |                                  |  |
| If yes to the above, advise batch destination country: Not applicable      |                 |           |                                  |  |
| Expiry date: 2023  |                 |           |                                  |  |
| Language of packaging: Turkish, English, Russian, Arabic                   |                 |           |                                  |  |
| Date of discovery: Adulteration detected on:                               |                 |           |                                  |  |
| Details of discovery:  |                 |           |                                  |  |
| German customs officers identified the product at Frankfurt airport. The   |                 |           |                                  |  |

| product was analysed by Hessisches Landeslabor Druseltalstr.67 34131 Kassel. Results of analysis were submitted from Hauptzollamt Frankfurt/Main to our Agency on November 19, 2018. It was found to contain Sildenafil, ( |  |  |  |  |
|--|--|--|--|--|
| reported on 13.07.2018)  |  |  |  |  |
| Analysed: YES ⊠ NO □   |  |  |  |  |
| If yes, result of analysis: The results of the analysis indicated that this product contained the following undeclared active substance: <i>Sildenafil: 1315 mg per</i>  |  |  |  |  |
| 240 g of Herbal Paste (1 glass)  |  |  |  |  |
|  |  |  |  |  |
| 3. DISTRUBUTION METHOD   |  |  |  |  |
| Internet: YES / NO⊠ (not exclusively through the internet)   |  |  |  |  |
| Internet:  |  |  |  |  |
| URL:   |  |  |  |  |
| Website address:   |  |  |  |  |
| Other details:   |  |  |  |  |
| Currency of payment:   |  |  |  |  |
| Has product reached patients/consumers? unknown  |  |  |  |  |
| 4. RISK TO PUBLIC HEALTH   |  |  |  |  |
| Adverse reactions: YES ⊠/ NO □   |  |  |  |  |
| If yes, please advise details: Known side effects of Sildenafil, particularly in   |  |  |  |  |
| patients with cardiovascular diseases.   |  |  |  |  |
| Medical assessment details:  |  |  |  |  |
| 5. NEED FOR PUBLICITY  |  |  |  |  |
| Details as per original form   |  |  |  |  |
| 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?   |  |  |  |  |
| Action was taken on 13th December 2018. A note was published on the  |  |  |  |  |
| website of the Regierungspräsidium Darmstadt.  |  |  |  |  |
| 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. See below.              |  |  |

