HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Reference:		
Date: 12.06.2017	Time: 11:45	Initials: MW

Please complete sections 1 to 5 providing as much information as possible.

1. REPORTING PERSON

Name:	Position:
Organisation: Pfalz, Dienstort [illegible]	
Address:	
Telephone No:	Ext:
e-mail address: [illegible]	

2. PRODUCT DETAILS

Product name: **Ametis Plus**

Manufacturer:

Supplier:

Legal status: Banned ☐ Counterfeit ☐ Unlicensed ☒ Stolen ☐

Dosage form: **capsules**

Strength:

Batch / lot no: Is batch number genuine: Yes ☐ No ☐

If yes to the above, advise batch destination country:

Expiry date: **25/01/19 and 29/03/19**

Language of packaging: **English, Thai**

Date of discovery: 06/06/2017

Details of discovery: **Within the scope of a customs check in May 2017 concerning a delivery coming from Thailand 8 packages Ametis Plus (each with 30 Capsules) were found. According to the labelling the product contains 13 different ingredients mostly of herbal nature. A chemical analysis at the Official Medicines Control Laboratory at Mainz found Sibutramine in the capsules. The API is not mentioned on the label.**

Analysed: YES ☒ NO ☐

If yes, result of analysis: **The packages showed two different expiry dates, therefore for each expiry date an analysis by HPLC /UV-VIS of the concerning Ametis Plus capsules was conducted. The capsules with expiry in March 2019 contained an average of 32.4 MG Sibutramine in each capsule. Capsules with expiry in March 2019 showed an average content of 20.9 MG Sibutramine in each capsule.**

3. DISTRUBUTION METHOD

Internet: YES ☒ / NO ☐

Internet:	Non internet, advise full details:
URL:	
Website address:	
Other details:	

Currency of payment:

Has product reached patients/consumers? Unknown

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES ☒/ NO ☐ (not observed, but possible)

If yes, please advise details: **Because of the high dose of Sibutramine found in the capsules (which is higher than the doses in the once marketed medicinal product) adverse effects are possible. In 2010 the European Commission informed that marketing authorisations for medicines containing Sibutramine should be suspended throughout Europe because CHMP concluded that the benefits of Sibutramine do not outweigh its risks. .**

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. **See attachement**


Anetis
Dietary Supplement Product
Anetis
00162537
30 Capsules