

## 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: 12.06.2019	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
<b>1. REPORTING PERSON</b>		
Name:	Position:	
Organisation:		
Address:		
Telephone No:	Ext:	
e-mail address:		
<b>2. PRODUCT DETAILS</b>		
Product name:		
<b>1. protect vital drink shot 60 ml, batch: 21-005 Exp: 07/2021</b>		
<b>2. protect vital drink shot 60 ml, batch: 65277 Exp: 26.08.2020</b>		
<b>3. protect vital plus 500 mg, batch: 022018 Exp: 07/2022</b>		
<b>4. Liquid XXX plus 60 ml, batch 65277 Exp: 26.08.2020</b>		
<b>The products are labelled as, dietary supplements</b>		
Manufacturer: According to the label: Protec vital GmbH, Schriesheimer Straße 14, 68519 Viernheim, Germany		
Supplier: Protec vital GmbH, Schriesheimer Straße 14, 68519 Viernheim, Germany		
In addition: Office #607, Building 12 Bay Square, Business Bay P.O. Box: 340954, Dubai is also mentioned as distributor on the label of protec vital drink shot		
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input checked="" type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: oral liquid (1,2,4)/capsules 3		
Strength: NA see attachment 1		
Batch / lot no: 21-005		
Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		

If yes to the above, advise batch destination country: Not applicable
Expiry date: see above
Language of packaging: German/English
Date of discovery: Analysis was completed on 23 <sup>rd</sup> May 2019
Details of discovery: The product was seized and analysed by the Official Medicines Control Laboratory (OMCL) of the state of Hesse (InphA GmbH in Bremen)
Analysed: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>
If yes, result of analysis: The results of the analysis indicate that these products contained undeclared active ingredients (see attachment 1)

3. DISTRIBUTION METHOD	
Internet: YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/> (not exclusively through the internet)	
Internet: via webshops (amazon a.o.)	Non internet, advise full details: Possibly sold on herbalist's shops and health food shops
URL:	
Website address:	
Other details: A list of known customers is attached, see attachment 3	
Currency of payment:	
Has product reached patients/consumers? The distribution to costumers has taken place, it is yet unclear which batches have been distributed ant to which extent.	
4. RISK TO PUBLIC HEALTH	
Adverse reactions: YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/>	
In the past, products containing Hydroxythiohomosildenafil have led to reports of patients in Austria who suffered from similar side effects caused by PDE-inhibitors. See RASFF notification No. 357598 and 351131 (2018.0546)	
Medical assessment details:	
5. NEED FOR PUBLICITY	
Details as per original form	
Are you making a public statement? YES <input type="checkbox"/> / NO <input type="checkbox"/> under consideration	

Are you issuing a press release? YES ☐ / NO ☐ under consideration

Are you recalling product? YES ☒ / NO ☐

The recall of the product will be monitored. Distributors will be informed about the product's risk. Further steps (press release / public statement) are under consideration and will be performed after the dimension of distribution has been investigated.

## 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 It is up to the competent authorities and law enforcement authorities to distribute the information further if necessary\_\_\_\_\_

## 7. PHOTOGRAPH

If possible, please attach a photograph of the product. See attachment 2

