

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

Reference:		
Date: 29.03.2022	Time: 13:50	Initials: KP
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: Elmex Fluid		
Manufacturer: not known; CP Gaba GmbH Hamburg is the marketing authorisation holder of Elmex Fluid		
Supplier: Enzkreis-Fairdental, Marxzeller Straße 55, 75305 Neuenbürg		
Legal status: Banned <input type="checkbox"/> Counterfeit <input checked="" type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: Fluid		
Strength: 50ml		
Batch / lot no: 0190FR63A1		
Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
If yes to the above, advise batch destination country: Germany		
Expiry date: 05/2023		
Language of packaging: German		
Date of discovery: 11.02.2022		
Details of discovery: The not registered wholesaler Enzkreis-Fairdental, Marxzeller Straße 55 in 75305 Neuenbürg has distributed the mentioned falsified medicinal product via Internet. Dentists who bought the product have		

informed CP Gaba Hamburg because of the different packaging/color of the product. According to information from the company, the counterfeit drug has the real batch number 0190FR63A1 and the expiration date 05/2023. However, obsolete packaging material (labels, patient leaflet, folding box) was used for the counterfeit medicine. Also the batch number on the primary packaging and the anti tampering device are missing. The company investigates who had access to the packing materials used in the counterfeit product. There are no saved data yet.

The wholesaler Enzkreis-Fairdental bought the fluids from the Austrian company MD Trade Medizin- und Dentalhandels GmbH, Petzoldstraße 20, 4020 Linz. There is a suspicion that the company MD Trade does not have a wholesale authorisation. BfArM is asked to inform the Austrian competent authority. Public prosecutor was informed as the Enzkreis Fairdental ist not registered according to §52a.

Analysed: YES ☒ NO ☐

If yes, result of analysis: not available

3. DISTRIBUTION METHOD	
Internet: YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/>	
Internet: not not known	Non internet, advise full details:
URL: not known	
Website address: https://www.area-online.de	
Other details: not known	
Currency of payment: not known	
Has product reached patients/consumers? yes	
4. RISK TO PUBLIC HEALTH	
Adverse reactions: YES <input type="checkbox"/> / NO <input type="checkbox"/>	
If yes, please advise details: not known	

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.

The counterfeit product is shown on the right and the original on the left sight. Original product comparison with counterfeit product.

