

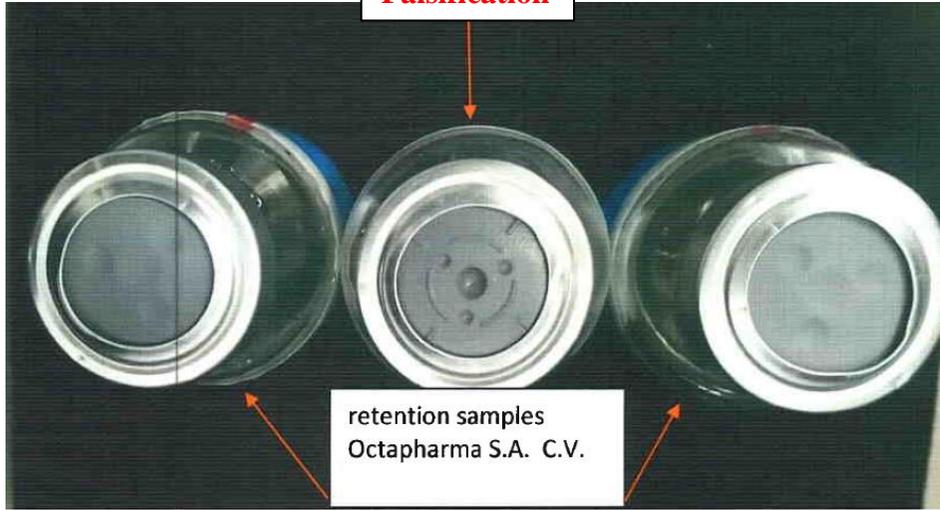
HMA WGEO Rapid Alert Form

Falsified or illegal product found in the illegal supply chain

Unique Reference N0 (to be filled by Member State issuing alert): AUSTRIA INS-670018-2020-06		
Date: 06.04.2020	Time: 10:00 local time	Initials: HAWU
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: Octagam 10%		
Manufacturer: Octapharma Pharmazeutika ProduktionsgesmbH, Oberlaaer Strasse 235, 1100 Vienna		
Supplier: Octapharma S.A. de C.V.		
Legal status: Banned <input type="checkbox"/> Falsified <input checked="" type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: Vial		
Strength: 10% 5g		
Batch / lot no: K818A8544 Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
If yes to the above, advise batch destination country: Mexico		
Expiry date: 04/2020		
Language of packaging: Spanish		
Date of discovery: 24.02.2020		
Details of discovery: at a hospital, Octagam was administered to a patient; massive adverse reactions started an investigation on the vial, which showed particles in the liquid inside.		
Analysed: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>		
If yes, result of analysis: no protein at all was found in the liquid		

3. DISTRIBUTION METHOD	
Internet: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	
Internet: -	Non internet, advise full details:
URL: -	-
Website address:-	
Other details: -	
Currency of payment: -	
Has product reached patients/consumers? – yes, unfortunately	
4. RISK TO PUBLIC HEALTH	
Adverse reactions: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	
If yes, please advise details: nausea, vomiting, diarrhoea, hypotension, hypothermia, subsequently fever	
Medical assessment details: -	
5. NEED FOR PUBLICITY	
Are you making a public statement? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	
Are you issuing a press release? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	
Are you recalling product? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	
If yes to any of the above, when do you intend to take action?	
Product was distributed in Mexico	
6. DISSEMINATION	
Are you content for this Rapid Alert to be shared outside WGEO membership? YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> (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 <input checked="" type="checkbox"/> Industry Security <input checked="" type="checkbox"/> Trade Associations <input checked="" type="checkbox"/>	
Traders <input checked="" type="checkbox"/> Customs (nominal data) <input type="checkbox"/> Other <input type="checkbox"/>	
Please specify _____	
7. PHOTOGRAPH	
If possible, please attach a photograph of the product.	

Falsification



Falsification

