

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: 09.11.2018	Time:	Initials:
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: TARCEVA 150mg, film-coated tablets		
Manufacturer: original: ROCHE Pharma AG, Germany		
Supplier: -		
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input checked="" type="checkbox"/>		
Dosage form: film-coated tablets		
Strength: 150mg		
Batch / lot no: B4365B02; B4313B04		
Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
If yes to the above, advise batch destination country: Romania		
Expiry date: October 2021; April 2020		
Language of packaging: Romanian		
Date of discovery: 27.10.2018		
Details of discovery: The thefts of 479 packs of Tarceva took place while stored by a Romanian authorised wholesaler H. Essers Logistics S.R.L. (Romania) that is providing logistical/storage services for Roche Romania S.R.L. Batch B4365B02 was exclusively delivered to the outsourced storage of Roche Romania during one transport and no quantities were distributed to local wholesalers. Roche informed the Parallel Trade Association and EMA and decommissioned the unique identifiers for the stolen boxes. Following the reported theft, additional assessment was made by Roche Romania and H. Essers Logistics and a mismatch between the warehouse inventory management system and the actual stocks were detected: another 480 units of Tarceva 150mg, batch B4313B04 were found to be missing. Although there were no explicit indications for criminal activities for this incident, considering the recent evidence collected for the reported theft, the inventory mismatch is highly suspected to be attributed to another theft incident. Batch B4313B04 consists of 1140 units which have been exclusively delivered to Roche Romania in 2017. 660 units of Tarceva batch B4313B04 have been distributed to Romanian customers and 480 units unaccounted for are considered as stolen (Tarceva batch B4313B04 is not serialised).		
Analysed: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		
If yes, result of analysis: -		

3. DISTRIBUTION METHOD

Internet: YES / NO (not exclusively through the internet)

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

Currency of payment:

Has product reached patients/consumers? No

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES / NO

If yes, please advise details: -

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?

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.