

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:	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
1. REPORTING PERSON		
Name:	Position:	
Organisation: Italian Medicines Agency		
Address:		
Telephone No:	Ext:	
e-mail address:		
2. PRODUCT DETAILS		
Product name: See "Details of discovery"		
Manufacturer: Roche		
Supplier:		
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input checked="" type="checkbox"/>		
Dosage form: See "Details of discovery"		
Strength: See "Details of discovery"		
Batch / lot no: See "Details of discovery"		
Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
If yes to the above, advise batch destination country: Italy		
Expiry date: See "Details of discovery"		
Language of packaging: Italian		
Date of discovery: April 24 th , 2015		
Details of discovery: a theft of Roche products occurred on the 24/04/2015 in Italy. The courier delivering the product was intercepted during the last mile of the distribution chain whereby only Roche products were still on board. 283 pieces were stolen, a list of which you can find in Annex.		
Analysed: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		
If yes, result of analysis:		

3. DISTRIBUTION METHOD

Internet: YES / NO

Internet:

Non internet, advise full details:

URL:

Website address:

Other details:

Currency of payment:

Has product reached patients/consumers?

This product may be offered back into the supply chain. At this point in time information is sparse as the investigation is at an early stage. Therefore we would like to urge you to be extra vigilant with regards to any supply of the above listed you may receive. EMA asked all Parallel Trader to notify any suspect offer to the National Competent Authority and the European Medicines Agency via the quality defect mailbox QDEFECT@ema.europa.eu. This is the first hospital products theft occurred in Italy after 1 year: the "Volcano case" investigation triggered extra verification on the EC chain that perhaps made more difficult the infiltration of illegal products, reducing the demand for hospital products. We will update the RA as soon as more information are made available.

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES / NO

If yes, please advise details:

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? Data were shared via the AIFA web platform (end of April), notified to EMA and to the Parallel Traders network (May 4). A public announcement is in publication in the AIFA website.

6. PHOTOGRAPH

If possible, please attach a photograph of the product.

ANNEX: list of stolen products.

MA	PRODUCT	Batch number	Expiry date	Pieces
36680027	Avastin 25 mg/ml conc for infusion	B8003H01	09.07.2016	20
35745025	Copegus 200 mg coated tablets	N0346B01	03.03.2018	20
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34949014	Herceptin 150 mg powder for conc for infusion	N1028B01	23.07.2018	105
34949026	Herceptin 150 mg powder for conc for infusion	B1005B01	26.09.2015	20
30675021	Invirase 500 mg coated tablets	E0452E1	18.11.2017	2
8776066	Konakion prima infanzia 2mg/0,2 ml oral/inj solution	F2139F05	24.02.2018	40
33315019	MabThera 100 mg conc for infusion	N7033B03	01.04.2017	15
33315021	MabThera 500 mg conc for infusion	N7040B03	30.04.2017	20
34430191	NeoRecormon Multidose 50.000 UI lioph + sol for inj	H0670H03	22.04.2017	10
42682017	Perjeta 420 mg conc for infusion	H0088B22	26.08.2016	5
36871034	Tarceva 150 mg coated tablets	N1019B03	12.04.2017	3
41863010	Zelboraf 240 mg coated tablets	M1149M3	17.09.2016	3