

HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Reference		
Date: 15.01.2019	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
1. REPORTING PERSON		
Name:	Position:	
Organisation:		
Address:		
Telephone No:	Reception desk:	
e-mail address:		
2. PRODUCT DETAILS		
Product name: Iclusig 15mg, 60 tablets		
Manufacturer (of original): Incyte Biosciences International Sàrl, CH-1066 Epalinges, Switzerland		
Supplier/MAH: Incyte Biosciences International Sàrl (former name until July 2016: ARIAD Pharma Ltd)		
Legal status: Banned <input type="checkbox"/> Counterfeit <input checked="" type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: Film-coated tablets		
Strength: 15mg		
Batch / lot no: 25A19E09 Exp. 10/2020		
Is batch number genuine: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> (please see below)		
If yes to the above, advise batch destination country		
Expiry date: 10/2020		
Language of packaging: English		
Date of discovery: 08.01.2019 (by Swiss wholesaler F.) (Incyte discovered already in Oct 2018)		
Details of discovery: The MAH Incyte (informed by an anonymous source) notified EMA about the falsification of Iclusig and EMA informed all EU parallel distributors by email on 6th December 2018 (see attachment).		

The licensed Swiss wholesaler F. heard about this EMA communication and notified Swissmedic on 8th January that they had bought 6 packs Iclusig of Batch 25A19E09 from the Turkish wholesaler E. On 04.12.2018, F. had supplied 1 pack to an approved client in Argentina. The remaining 5 packs in their inventory were quarantined. End of last week, Swissmedic received these 5 packs for analysis by Swissmedic OMCL.

Another Swiss wholesaler (E.) had been offered Iclusig units of batch 25A19E09 from a Turkish wholesaler (K.) in october 2018. E. did not purchase that Iclusig from K. as they checked with MAH Incyte.

Therefore, probably more falsified packs are in circulation, and we refer to EMAs comments in attached email. Please note that EMA mentions a second falsified batch (Iclusig 45mg, Batch PR072875).

The names of the Turkish wholesalers can be obtained on request from Swissmedic.

Analysed: YES ☒ NO ☐

Preliminary information from Swissmedic OMCL: Iclusig 15mg tablets, Batch 25A19E09: **The tablets contain only paracetamol. Estimation of content: 86mg/tablet**

3. DISTRIBUTION METHOD

Internet: YES ☐ / NO ☒

Internet:

URL:

Website address:

Other details:

Non internet, advise full details:

Currency of payment:

Has product reached patients/consumers?

Yes. On 04.12.2018, 1 pack has been supplied from the Swiss wholesaler F. to a client in Argentina (and recalled).

4. RISK TO PUBLIC HEALTH

YES ☒ / NO ☐

If yes, please advise details:

Serious public health risk due to the lack of ponatinib.

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.



These pictures of the falsification were taken by Swissmedic OMCL. As soon as an original sample will be received, comparative photos will be circulated.

