

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:

Organisation:

Address:

Telephone No:

Ext:

e-mail address:

2. PRODUCT DETAILS

Product name: Xarelto

Manufacturer: Bayer Pharma AG

Supplier:

Legal status: Banned ☐ Counterfeit ☐ Unlicensed ☐ Stolen ☒

Dosage form: tablets (14 tablets in package)

Strength: 20 mg

Batch / lot no: BXHFBV1; BXHFBV2 Is batch number genuine: Yes ☒ No ☐

If yes to the above, advise batch destination country:

Expiry date: 31.08.2019;

Language of packaging: Polish

Date of discovery: 21 April 2017

Details of discovery: The Chief Pharmaceutical Inspector received information from polish wholesaler the Farmacol-Logistyka sp. z o.o. about theft of medicinal product Xarelto 20 mg– 177 package BXHFBV1 and 3 package BXHFBV2. At the moment Police are conducting investigations in this case.

Analysed: YES ☐ NO ☒**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? unknown

4. RISK TO PUBLIC HEALTHAdverse reactions: YES ☐ / NO ☐

If yes, please advise details:

Medical assessment details:

5. NEED FOR PUBLICITYAre 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. DISSEMINATIONAre 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.



acting Chief Pharmaceutical Inspector