

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:	
Address:	
Telephone No:	Ext:
e-mail address:	
2. PRODUCT DETAILS	
Product name: Humira (<i>Adalimumabum</i>) 40 mg/0,8 ml, solution for injection, 2 pre-filled syringes, batch: 87392XD03, EAN 5909990005055	
Manufacturer:	
Supplier:	
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input checked="" type="checkbox"/>	
Dosage form: 2 pre-filled syringes	
Strength: 40 mg/0,8 ml	
Batch / lot no: 87392XD03 Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
If yes to the above, advise batch destination country:	
Expiry date:	
Language of packaging: Polish	
Date of discovery: 21-22 November 2018	
Details of discovery: The Chief Pharmaceutical Inspector received information from the AbbVie Sp. z o.o. about theft of 12 packages of medicinal product Humira (batch mentioned above). Theft took place on November 21-22 2018 in the Polish pharmaceutical wholesaler: Poltraf Sp. z o.o. with office in Pass 05-870 Błonie, Stefana Batorego Str. 4. Product is owned by AbbVie Sp. z o.o. Up until this notification, the Company received from Poltraf Sp. z o.o. information on finding 6 packages of Humira. Recovered medicinal products will be disposed. Company has submitted a notice of the above crime to the District Prosecutor's Office.	

Analysed: YES NO

the lack of an active substance

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? no information

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?

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.

Głównego Inspektora Farmaceutycznego


Joanna Szajnik – Solska
Dyrektor Departamentu Nadzoru