

HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Reference:		
Date:	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
1. REPORTING PERSON		
Name:	Position:	
Organisation:		
Telephone No:	Ext:	
e-mail address:		
2. PRODUCT DETAILS		
Product name: <i>Fentanilo Zentiva</i>		
Manufacturer: <i>Zentiva Portugal, Lda</i>		
Supplier: <i>Zentiva Portugal, Lda</i>		
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input checked="" type="checkbox"/>		
Dosage form: <i>transdermal patch</i>		
Strength: <i>12,5 µg/h</i>		
Batch / lot no: <i>21010246</i> Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
If yes to the above, advise batch destination country: <i>Portugal</i>		
Expiry date: <i>12/2023</i>		
Language of packaging: <i>Portuguese</i>		
Date of discovery: <i>06/01/2022</i>		
Details of discovery: On the 6 th Jan 2022, the MAH reports the disappearance of 29 packages of transdermal patches containing fentanyl, namely <i>Fentanilo Zentiva 12,5 µg/h</i> [20 packs], <i>25 µg/h</i> [3 packs] and <i>50 µg/h</i> [6 packs] from a customer, Coopropar-Medlog, an approved medicines distributor in Portugal. Investigations performed by the customer and by the MAH logistic operator		

were inconclusive.

The event was reported to the Judiciary Police.

Analysed: YES ☐ NO ☒

If yes, result of analysis: -

3. DISTRIBUTION METHOD

Internet: YES ☐ / NO ☒

Internet: N/A

Non internet, advise full details:

URL: N/A

Website address: N/A

Other details: N/A

Currency of payment: N/A

Has product reached patients/consumers? No

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES ☐ / NO ☐ unknown ☒

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

Not applicable

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Dosage form: <i>transdermal patch</i>		
Strength: <i>25 µg/h</i>		
Batch / lot no: <i>21010247</i> Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
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Dosage form: <i>transdermal patch</i>		
Strength: <i>50 µg/h</i>		
Batch / lot no: <i>21051762</i> Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
If yes to the above, advise batch destination country: <i>Portugal</i>		
Expiry date: <i>02/2024</i>		
Language of packaging: <i>Portuguese</i>		
Date of discovery: <i>06/01/2022</i>		
Details of discovery: On the 6 th Jan 2022, the MAH reports the disappearance of 29 packages of transdermal patches containing fentanyl, namely <i>Fentanilo Zentiva 12,5 µg/h</i> [20 packs], <i>25 µg/h</i> [3 packs] and <i>50 µg/h</i> [6 packs] from a customer, Cooprofar-Medlog, an approved medicines distributor in Portugal. Investigations performed by the customer and by the MAH logistic operator		

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