

## 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.		
<b>1. REPORTING PERSON</b>		
Name:	Position:	
Organisation:		
Telephone No:	Ext:	
e-mail address:		
<b>2. PRODUCT DETAILS</b>		
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 <sup>th</sup> 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*

ATTACHEMENT 1

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<b>1. REPORTING PERSON</b>		
Telephone No:	Ext:	
e-mail address		
<b>2. PRODUCT DETAILS</b>		
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>25 µg/h</i>		
Batch / lot no: <i>21010247</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 <sup>th</sup> 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 <input type="checkbox"/> NO <input checked="" type="checkbox"/>
If yes, result of analysis: -

<b>3. DISTRIBUTION METHOD</b>	
Internet: YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>	Non internet, advise full details:
Internet: <i>N/A</i>	
URL: <i>N/A</i>	
Website address: <i>N/A</i>	
Other details: <i>N/A</i>	
Currency of payment: <i>N/A</i>	
Has product reached patients/consumers? No	
<b>4. RISK TO PUBLIC HEALTH</b>	
Adverse reactions: YES <input type="checkbox"/> / NO <input type="checkbox"/> unknown <input checked="" type="checkbox"/>	
If yes, please advise details: -	
Medical assessment details: -	
<b>5. NEED FOR PUBLICITY</b>	
Are you making a public statement? YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>	
Are you issuing a press release? YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>	
Are you recalling product? YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>	
If yes to any of the above, when do you intend to take action?	
<b>6. DISSEMINATION</b>	
Are you content for this Rapid Alert to be shared outside WGEO membership? YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/> (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 <input checked="" type="checkbox"/> Industry Security <input type="checkbox"/> Trade Associations <input checked="" type="checkbox"/> Traders <input checked="" type="checkbox"/> Other <input type="checkbox"/> Please specify _____	
<b>7. PHOTOGRAPH</b>	
<i>Not applicable</i>	

ATTACHEMENT 1

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Date: Time: Initials:

Please complete sections 1 to 5 providing as much information as possible.

**1. REPORTING PERSON**

Name: Position:

Organisation:

Address:

Telephone Ext:

e-mail address:

**2. PRODUCT DETAILS**Product name: *Fentanilo Zentiva*Manufacturer: *Zentiva Portugal, Lda*Supplier: *Zentiva Portugal, Lda*Legal status: Banned  Counterfeit  Unlicensed  Stolen Dosage form: *transdermal patch*Strength: *50 µg/h*Batch / lot no: *21051762* Is batch number genuine: Yes  No If yes to the above, advise batch destination country: *Portugal*Expiry date: *02/2024*Language of packaging: *Portuguese*Date of discovery: *06/01/2022*

Details of discovery:

On the 6<sup>th</sup> Jan 2022, the MAH reports the disappearance of 29 packages of transdermal patches containing fentanyl, namely *Fentanilo Zentiva 12,5 µg/h* [20 packs], *25 µg/h* [3 packs] and *50 µg/h* [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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