

## EVWEB Competency Assessment

### Section 3: Product Report Exam Case

#### Third Attempt

This document contains the ICSR Exam Case for your third and final attempt at Section 3 of the EudraVigilance Competency Assessment.

Please follow carefully the directions below to enter your case:

1. This document contains a mock medicinal product that you are required to enter into the EVWEB tool. You will be entering this case as if you worked for the company Pharma Group Ltd.
2. Please complete the medicinal product report in the EVWEB as you did in the training course using the User Name and Password you were given in the training course.
3. In the field Message number you must enter your full name.

When you have completed the product report message:

1. Please save an electronic copy of the product report message in RTF format.
2. Send the product message to the EV Training system.
3. Finally, attach the RTF copy to an email and send it to Ms. Malgorzata Durka-Grabowska at the European Medicines Agency ([malgorzata.durka-grabowska@ema.europa.eu](mailto:malgorzata.durka-grabowska@ema.europa.eu)) specifying the user name you used to enter the case..

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## PRODUCT REPORT EXAM CASE

### THIRD TRY

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#### CREATE AND SEND A PRODUCT REPORT MESSAGE

#### PRODUCT REPORT WITH OPERATION TYPE "INSERT"

You are invited to create a EudraVigilance Product Report Message that contains the following Product Reports:

Product Report with operation type "Insert" for the authorised medicinal product "Starigaze fentanyl 50mg/ml solution";

Product Report with operation type "Insert" for the development product "PS-349".

**Please enter your full name in the "Message Number" field.**

When you have completed the Product Report Message, **you should print a copy of the report in RTF format and send it to EVTEST.**

**You must also send (through e-mail) the Product Report Message as an RTF file according to the instructions in the email by which you received this Case.**

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All the fictitious information that is provided for the authorised medicinal product and for the development product is only for examination purposes.

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## Starigaze fentanyl 50mg/ml solution

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Please find here below the Summary of Product Characteristic for “Starigaze” as it has been authorised in the United Kingdom.

‘Starigaze fentanyl 50mg/ml solution’ is authorised through the centralised Procedure (new active substances).

Although it is not mandatory to enter information on excipients, you are invited to enter the information here for examination purposes.

“Starigaze fentanyl 50mg/ml solution ” is univocally identified in your local database with the code UK\_0012.

### SUMMARY OF PRODUCT CHARACTERISTICS

#### 1. NAME OF THE MEDICINAL PRODUCT

Starigaze fentanyl 50mg/ml solution

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule contains fentanyl 50mg/ml

#### 3. PHARMACEUTICAL FORM

Solution for injection

Solution for infusion

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

Anaesthesia (low level term in MedDRA version 7.0).

##### 4.2 Posology and method of administration

Starigaze fentanyl 50mg/ml is for intravenous use

##### 4.3 Contraindications

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**4.4 Special warnings and special precautions for use**

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**4.5 Interaction with other medicinal products and other forms of interaction**

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**4.6 Pregnancy and lactation**

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**4.7 Effects on ability to drive and use machines**

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**4.8 Undesirable effects**

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**4.9 Overdose**

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**5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

The Proposed ATC code: N01XX 01

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**5.2 Pharmacokinetic properties**

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**5.3 Preclinical safety data**

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**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

sodium calcium edetate 5ml.

**6.2 Incompatibilities**

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**6.3 Shelf life**

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**6.4 Special precautions for storage**

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**6.5 Nature and contents of container**

Each pack contains 12 ampoules

**6.6 Instructions for use and handling, and disposal**

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**7. MARKETING AUTHORISATION HOLDER**

Pharma Group Ltd  
London  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER**

EU/1/95/002/001  
National authorisation number : PL 0004/1547

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

23/05/1998

**10. DATE OF REVISION OF THE TEXT**

26/06/2001

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**PS-349**

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Please find here below the information as listed in the investigators brochure for the development product "PS-349".

Sponsor: Pharma Group Ltd – London - United Kingdom

Product Code: PS-349

Ampoules of Concentrate for solution for infusion

Intravenous use.

Name of the development substance: remuximab. The previous code associated to this substance was PK848.

Remuximab is studied in two concentrations: 10mg/ml and 15 mg/ml.

New development ATC code- L01XX01