Notification of adverse effect(s) suspected to be associated with one or more medicinal product(s) for human use - **healthcare professional form**

The information leaflet on data protection, which explains how personal data is processed for pharmacovigilance declarations, can be referred to online at www.guichet.lu/pharmacovigilance

Patient Initial letter of the patient's first name __ __ __ Initial letter of the patient's surname __ Gender ☐ F ☐ M Weight ____ (kg) Height ____ (m)	Date of birth (dd/mm/yyyy) ___ /___ /_____ Or Age ____ (years) ____ (months)	Is the patient pregnant? ☐ yes ☐ no Expected delivery date (dd/mm/yyyy) ___ /___ /_____ Is the patient nursing? ☐ yes ☐ no	Known allergies

Current illnesses, medical or surgical history

Others :

☐Alcohol consumption	☐Tobacco consumption	☐Drug use	☐Diet
☐Radiation therapy	☐Implants	☐Hormonal contraception	☐Disturbed metabolism

Adverse effects

General description of the adverse effect

Please describe the effect felt in detail. Specify whether the effect observed is the worsening of an existing illness. If additional tests were carried out, specify which ones and give the results. You can also include if possible a report of hospitalization or additional tests (anonymized).

Outcome of the adverse effect as on the date of the last observation :
☐ Life-threatening
☐ Caused or prolonged hospitalisation
☐ Caused or sustained significant or lasting disability
☐ Congenital abnormality or birth defect
☐ Death
☐ Other medically significant condition

Details of the adverse effect(s) experienced: *(add lines if necessary)*

Effect	Start and end date (dd/mm/yyy)	Evolution	Treatment of the adverse effect	If yes, specify
1.	From __/__/____ To __/__/____	☐ No improvement ☐ Recovering ☐ Recovery without sequelae ☐ Recovery with sequelae ☐ Death ☐ Unknown	☐ No ☐ Yes ☐ Unknown	
2.	From __/__/____ To __/__/____	☐ No improvement ☐ Recovering ☐ Recovery without sequelae ☐ Recovery with sequelae ☐ Death ☐ Unknown	☐ No ☐ Yes ☐ Unknown	
3.	From __/__/____ To __/__/____	☐ No improvement ☐ Recovering ☐ Recovery without sequelae ☐ Recovery with sequelae ☐ Death ☐ Unknown	☐ No ☐ Yes ☐ Unknown	

Adverse effects disappeared after stopping medication? ☐ yes ☐no ☐ not applicable
Adverse effects reappeared after resuming medication? ☐ yes ☐no ☐ not applicable

Medication(s)

Please list below all medications taken by the patient at the time of the adverse effect or some time before its onset (including medications used for chronic illnesses and over-the-counter medications). Please tick the 'suspected' box for the medication(s) you suspect to be the cause of the declared adverse effect(s).

Commercial name of the medication and batch number	At least one medication must be suspected	Dosage and method of administration	Start date of the treatment (dd/mm/yyyy)	End date of the treatment (dd/mm/yyyy)	Reason of treatment
1.	☐ Yes ☐ No ☐ Don't know		___/___/_____	___/___/_____ ☐ Still ongoing	
2.	☐ Yes ☐ No ☐ Don't know		___/___/_____	___/___/_____ ☐ Still ongoing	
3.	☐ Yes ☐ No ☐ Don't know		___/___/_____	___/___/_____ ☐ Still ongoing	

4.	☐ Yes ☐ No ☐ Don't know		__/___/_____	__/___/_____ ☐ Still ongoing	

Action taken along with the medication
☐ Dose adjusted New dose : from __/__/____ for which medication : _____
☐ Dose unchanged ☐ Don't know ☐ Not applicable

According to you, with respect to the suspected medication(s), was there also any
☐ Abuse ☐ Medication error ☐ Misuse ☐ Overdose ☐ Contact with a medication at work

Details of the declarant

Your contact information will potentially enable us to contact you for further details regarding the event(s) you are declaring and to send you an acknowledgment of receipt for your declaration.

Surname : _____ First name : _____
Qualification : _____

I prefer to be contacted by
☐ e-mail_____
☐ Phone *(also specify the country code)* _____
☐ Postal Street, number : _____
City, postal code : _____
Country : _____

Contact details for the declaration:

Please send the completed form:
- preferably by e-mail to the CRPV (Regional Pharmacovigilance Centres) and the DPM (Pharmacy and Medicines Division);
- or by post to one of the following 2 addresses.

Feel free to attach any other relevant medical document related to your declaration to the PDF form (photos, report, analysis results).

Centre Régional de Pharmacovigilance de Nancy **ou** **Division de la Pharmacie et des Médicaments**

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