



Luxembourg, 02/09/2019

Hendrik KÜHNE

Secrétaire général

Association pharmaceutique

luxembourgeoise

7, rue Alcide de Gasperi

L - 1615 Luxembourg-Kirchberg

cc. : Anna Chioti, Marcel Bruch

Division de la Pharmacie et des

Médicaments

Direction de la Santé, Luxembourg

Subject: QRD Template Appendix V - List of details of the national reporting system in Luxembourg to communicate adverse reactions

Réf. : DPM-2019-051

Dear Sir,

Further to our discussions last week, please find hereunder information and clarification regarding the details of the national reporting system to communicate adverse reactions in Luxembourg.

The Division of Pharmacy and Medicines (DPM) at the Directorate of Health in Luxembourg is the Competent Authority on national level for all matters of Pharmacovigilance, whereas the Regional Center of Pharmacovigilance (CRPV) in Nancy is in charge, on behalf of the DPM, for the management of local case reports, i.e. case evaluation, documentation, data entry and submission to Eudravigilance. This long-term and close collaboration with the CRPV is settled in an agreement between the two parties.



LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de la Santé

Direction de la santé

In this context, both contact points need to be available for patients and healthcare professionals on products information.

Full and updated information for use in section 4.8 “Undesirable effects” of SmPC and section 4 “Possible side effects” of package leaflet for the communication of adverse reaction occurring in Luxembourg is available in QRD Template Appendix V (<https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/product-information-templates>) and is currently the following:

Centre Régional de Pharmacovigilance de Nancy

Bâtiment de Biologie Moléculaire et de Biopathologie (BBB)
CHRU de Nancy – Hôpitaux de Brabois
Rue du Morvan
54 511 VANDOEUVRE LES NANCY CEDEX
Tél: (+33) 3 83 65 60 85 / 87
Fax : (+33) 3 83 65 61 33
E-mail : crpv@chru-nancy.fr

Ou

Direction de la Santé

Division de la Pharmacie et des Médicaments

Allée Marconi - Villa Louvigny
L-2120 Luxembourg
Tél. : (+352) 2478 5592
Fax : (+352) 2479 5615
E-mail : pharmacovigilance@ms.etat.lu

Lien pour le formulaire : <http://www.sante.public.lu/fr/politique-sante/ministere-sante/direction-sante/div-pharmacie-medicaments/index.html>

We are aware and understand that this information might be too long for printed versions, especially of package leaflets. In order to alleviate the burden for Marketing Authorization Holders, an abbreviated version will be accepted **if not otherwise possible**:

Centre Régional de Pharmacovigilance de Nancy

crpv@chru-nancy.fr
Tél. : (+33) 3 83 65 60 85 / 87
Fax : (+33) 3 83 65 61 33

ou

Division de la Pharmacie et des Médicaments, Direction de la santé à Luxembourg

pharmacovigilance@ms.etat.lu
Tél. : (+352) 247-85592
Fax : (+352) 247-95615



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Ministère de la Santé

Direction de la santé

This is to be considered as the **minimum information** that should be available on product information for Luxembourg.

Please feel free to contact us if further clarification is needed.

Best regards,

Anne-Cécile VUILLEMIN, PharmD

Pharmacien-inspecteur
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