

	Notification FORM Complaints - Adverse Event	
	FORM-PV-001	Replaced version: N/A
	Version: 01	Implementation date: 1/01/2021

Please send this document within **the same working day** after receipt of the notification to:

Complaint notification: safety@kchc.be / Phone: +32 2 793 09 38

If possible, deliver the relevant packaging and/ or take photos.

Vigilance notification: safety@kchc.be / Phone: +32 2 793 09 38

To report: **1. Medicines:** Suspected side effects/ Interactions/ Use during pregnancy and breastfeeding/ Lack of efficacy/ Overdoses/ Misuse, wrong use (on purpose)/ Fault in prescription, medication error/ Off-label use/ Unwanted exposure/ Falsified Medicine/ Suspected transmission of an infectious agent through a client product. **2. Medical Devices:** Incident/ malfunctioning device. **3. Cosmetics:** undesired effect/ abnormality in the product. **4. Foodsupplements.**
5. Others: Biocides, ...

Complaint: Yes/ No		Vigilance: Yes/ No	
REPORTER			
Type (Physician, Pharmacist, Patient,...)			
Name of the reporter			
Address of the reporter			
Phone nr. of the reporter			
E-mail reporter			
Wishes reporter feedback (Yes/ No)			
PRODUCT			
Name of the product			
Doses and packages			
Batch number			
Expiry date			
DETAILED DESCRIPTION OF THE COMPLAINT (+ any other medication taken, indication for which the product is used, duration of treatment, ...)			
PATIENT (vigilance report)			
Initials patient			
Gender of the patient			
Age (date of birth)			
Document completed by			
Date			