FAQs: General Pharmacovigilance

What reporting duties do companies have in Switzerland?

The «qualified person responsible for pharmacovigilance» in Switzerland: What conditions apply?

What rules apply in Switzerland to the contactability of the person responsible for pharmacovigilance (PV)?

What regulations apply when reporting adverse drug effects from Liechtenstein?

The duty to report ADRs from Liechtenstein is governed by the registration status of a therapeutic product.

The market in Liechtenstein is covered by the Swissmedic monitoring network under the terms of the Customs Treaty. Reports of ADRs involving therapeutic products that are registered in Switzerland and may be marketed in Liechtenstein under the terms of the Customs Treaty must be reported to a regional pharmacovigilance centre (RPVC) in Switzerland (healthcare professionals) or to Swissmedic (companies). Therapeutic products registered in the EEA are covered by the European monitoring system. Adverse drug effects and quality defects involving therapeutic products registered in the territory covered by the Agreement with Austria must be reported to the Ministry of Health in Austria.

http://www.llv.li/#/11134/arzneimitteluberwachung

http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20006977

Last updated on: 14.01.2015

What reporting duties apply to a therapeutic product not registered in Switzerland for which a doctor has obtained special authorisation in individual cases?
+ When does lack of efficacy / loss of drug effect / drug ineffective have to be reported as a single report?

+ Does off-label use have to be reported in Switzerland?

+ Which therapeutic products have to be reported / stated as suspect?

+ When does Swissmedic pass on reports to companies?

+ When does Swissmedic pass on enquiries from companies about reports from the Regional Pharmacovigilance Centres (RPVC)?

+ When does Swissmedic pass on questionnaires / information sheets from the companies to the primary reporters?

+ What requirements does Swissmedic expect the medical assessment of individual case reports to fulfil?

+ What should be remembered when writing case narratives?

+ When should follow-up information be requested?

+ Information sheet regarding «Drug exposure during pregnancy» and «Parent-Child reports»:

+ Information sheet regarding reports on adverse events following immunisation (AEFI):

+ How must ADRs from registers, patient programmes, cohort studies and other forms of data compilation be reported? Who is required to report them?

+ How do ADRs from a Category A study have to be reported?