GET THE NORDICS!

Information package for pharmaceutical companies on pharmacovigilance obligations in the Nordics

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The goal of pharmacovigilance activities is to ensure the safe use of medicines throughout their life cycle. Pharmacovigilance activities are carried out by several stakeholders, such as the European Medicines Agency (EMA), the national competent authorities of the EU member states, the European Commission, and the World Health Organization (WHO). Pharmaceutical companies are also strongly involved in pharmacovigilance and in promoting patient safety.

In the Nordic countries, there are several pharmacovigilance obligations that pharmaceutical companies must consider when their medicines are introduced to the market. Oriola's pharmacovigilance experts, who help pharmaceutical companies deal with their pharmacovigilance obligations in the Nordics, have compiled this handy information package on common local obligations that pharmaceutical companies face in this area. We hope you find this useful!

If you have questions or need help with handling pharmacovigilance duties in the Nordics, please do not hesitate to contact us. You can find our contact details and learn more about our services here.

Kind regards,
Oriola's Pharmacovigilance Team

RELEVANT LEGISLATION AND GUIDELINES	Directive 2001/83/EC Regulation (EC) 726/2004	Commission Implementing Regulation (EU) 520/2012	Good Pharmacovigilance Practices
Finland	**Sweden**	**Norway**	**Denmark**
Some relevant Finnish national legislation and guidelines: Lääkelaki 395/1987 (Finnish Medicines Act; in Finnish, with an informal English translation available) Finnish Medicines Agency Administrative Regulation 4/2013. Pharmacovigilance. (Finnish Medicines Agency; unofficial translation.) Reporting of Adverse Reactions. (Finnish Medicines Agency's guideline.)	Some relevant Swedish national legislation and guidelines: Läkemedelslag (Swedish Medicines Act; in Swedish) Läkemedelsförordning (Swedish Medicines Decree; in Swedish) LVFS 2012/14 konsoliderad 2017 (regulation LVFS 2021:14 by the Swedish Medical Products Agency, consolidated version, 2017; in Swedish)	Some relevant Norwegian national legislation and guidelines: Legemiddelloven (Norwegian Medicines Act; in Norwegian) Forskrift om legemidler (Norwegian Medicines Decree; in Norwegian) Bivirkningsregisterforskriften (Norwegian Decree on reporting adverse effects; in Norwegian)	Some relevant Danish national legislation and guidelines: Lægemiddelloven (Danish Medicines Act; in Danish) Bekendtgørelse om bivirkningsovervågning af lægemidler (proclamation on the monitoring of adverse effects; in Danish)
National competent authorities for medicinal products			
Fimea (Lääkealan turvallisuus- ja kehittämiskeskus) (Finnish Medicines Agency)	MPA (Läkemedelsverket) (Swedish Medical Products Agency)	NOMA (Legemiddelverket) (Norwegian Medicines Agency)	DKMA (Lægemiddelstyrelsen) (Danish Medicines Agency)

LOCAL CONTACT POINT FOR PHARMACOVIGILANCE

Acting as the Local Contact Point for Pharmacovigilance to the local authority.

Directive 2001/83/EC, article 104 (3):

► The marketing authorisation holder (MAH) shall have permanently at his disposal an appropriately qualified person responsible for pharmacovigilance, and their contact details shall be included in the pharmacovigilance system.

► The MAH shall submit the name and contact details of the qualified person to the competent authority and to EMA.

Directive 2001/83/EC, article 104 (4):

"Notwithstanding the provisions of paragraph 3, national competent authorities may request the nomination of a contact person for pharmacovigilance issues at national level reporting to the qualified person responsible for pharmacovigilance activities."

Finland	Sweden	Norway	Denmark
Lääkelaki 395/1987 (Finnish Medicines Act), Section 30 c: Fimea may request the nomination of a Pharmcovigilance contact person at national level in individual cases. Note also, that as per Fimea's Administrative regulation 4/2013, Pharmacovigilance: "...communication with Fimea and the national implementation of measures required by medicines authorities in relation to pharmacovigilance must not be prevented or delayed due to inadequate familiarity with pharmacovigilance and local conditions, including language proficiency." EMA/INS/PhV/567683/2020 states: "Fimea recommends the MAH to nominate a contact person for pharmacovigilance issues at national level. The contact person does not need to hold a specific medical degree, but a good knowledge of pharmacovigilance practices and regulatory requirements would be beneficial. If the MAH does not nominate the contact person, all individual case safety report (ICSR) related communication will be directed to the EU QPPV."	**Läkemedelslag** (2015:315) (Swedish Medicines Act) – 6 kap. Säkerhetsövervakning, kontroll och återkallelse (Chapter 6. "Safety monitoring, supervision and recall", in Swedish): "Den som har fått ett läkemedel godkänt för försäljning är skyldig att till sitt förfogande ha en sakkunnig med tillräcklig kompetens som fortlöpande ansvarar för säkerhetsövervakning av läkemedlet. Den sakkunnige ska vara bosatt och verksam i EES." (**Informal translation:** "The MAH of a medicine must have access to an adequately qualified expert who has continuous responsibility for the safety monitoring of the medicine. The expert must reside and operate in the EEA.") It is not necessary to nominate a local contact person.	**Forskrift om legemidler** (Norwegian Medicines Decree), § 10–2: Krav til innehaverens legemiddelovervåkingsapparat ("Requirements concerning the pharmacovigilance system of the MAH"; in Norwegian) "Som en del av legemiddelovervåkingssystem skal markedsføringstillatelsens innehaver til enhver tid ha til rådighet en tilstrekkelig kvalifisert person med ansvar for legemiddelovervåking. Vedkommendes navn og kontaktopplysninger skal sendes til Statens legemiddelverk og EMA. Vedkommende skal være bosatt og arbeide innen EØS-området." (**Informal translation:** "As part of the pharmacovigilance system, the MAH must at all times have an adequately qualified person responsible for pharmacovigilance. The name and contact details of the qualified person must be submitted to the Norwegian Medicines Agency and the EMA. The qualified person must reside and operate in the EEA.") Only the details of the QPPV should be submitted to the Norwegian authority. It is not necessary to nominate a local contact person.	**Lægemiddelloven** – Kapitel 5, § 53, stk. 3 (Danish Medicines Act, Chapter 5, Section 53, Sub-section 3): The Danish Medicines Act states that the authority may request the nomination of a pharmacovigilance contact person at national level in individual cases. "Sundhedsstyrelsen kan, når lægemiddelovervågning gør det påkrævet, pålægge indehaveren af markedsføringstilladelsen til et lægemiddel til mennesker at udpege en kontaktperson i Danmark for den i stk. 1, nr. 7, nævnte sagkyndige." (**Informal translation:** "The Danish Health Authority may, if this is necessary for pharmacovigilance, request that the MAH of a medicine for humans assigns a contact person in Denmark for the expert mentioned in section 1, number 7.") It is not necessary to nominate a local contact person, unless this was specifically requested by DHMA. However, as per Information on the Member States requirement for the nomination of a pharmacovigilance (PhV) contact person at national level EMA/INS/PhV/567683/2020: "Up until now this has not yet been required of any MAH".

LOCAL SCIENTIFIC LITERATURE SCREENING

Oriola can help you determine which journals should be included in the scope of the local literature review.

Directive 2001/83/EC, article 107(3):

"...marketing authorisation holders shall not be required to report to the Eudravigilance database the suspected adverse reactions recorded in the listed medical literature, but they shall monitor all other medical literature and report any suspected adverse reactions."

GVP, Module VI, VI.B.1.1.2:

"...marketing authorisation holders should have procedures in place to monitor scientific and medical publications in local journals in countries where medicinal products have a MA, and to bring them to the attention of the company safety department as appropriate."

Finland	Sweden	Norway	Denmark
There are locally published scientific and medical journals (in Finnish).	There are locally published scientific and medical journals (in Swedish).	There are locally published scientific and medical journals (in Norwegian).	There are locally published scientific and medical journals (in Danish).

INDIVIDUAL CASE SAFETY REPORT SOURCE DATA MANAGEMENT

Commission Implementing Regulation (EU) 520/2012, Article 16(2):

"Pharmacovigilance data and documents relating to individual authorised medicinal products shall be retained as long as the product is authorised and for at least 10 years after the marketing authorisation has expired. However, the documents shall be retained for a longer period where Union law or national law so requires."

Finland	Sweden	Norway	Denmark
The national requirements as per the Finnish Medicines Act, Section 30 e, are stricter than those of EU legislation: Data on adverse events must be retained for 50 years after the marketing authorisation or registration has expired. After this, the data must be destroyed within a year, unless otherwise instructed by the Finnish Medicines Agency.	No additional national requirements for MAHs on the retention of pharmacovigilance data and documents: GVP requirements must be applied.	No additional national requirements for MAHs on the retention of pharmacovigilance data and documents: GVP requirements must be applied.	No additional national requirements for MAHs on the retention of pharmacovigilance data and documents: GVP requirements must be applied.

Please note that Oriola assumes no responsibility for the accuracy or completeness of the information presented on this paper.

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