Annual report

May 2014 to May 2015

WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting

netherlands pharmacovigilance centrelareb

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Introduction

In May 2013 the Netherlands Pharmacovigilance Centre was appointed as a WHO Collaborating Centre for Pharmacovigilance in Education and Patient reporting (WHO CC). In this report we summarize the activities conducted during our second year as a WHO CC.

Organization

The Netherlands Pharmacovigilance Centre Lareb is subsidized by the Ministry of Health in the Netherlands. The core task of Lareb is the identification of risks from the use of drugs and vaccines in daily practice and spreading knowledge about this.

The core activities of Lareb are

> Maintaining the spontaneous reporting system for drugs, including vaccines
> Proactive gathering information on adverse drug reactions, for instance by intensive monitoring and patient surveys
> Knowledge centre on adverse drug reactions for health care professionals and the general public
> Knowledge centre on risk of drug and other exposures during pregnancy and lactation.

For the work as a WHO CC Lareb does not receive any additional funding. In order to carry out the tasks as a CC maximal synergy with the core activities has to be achieved.

The director of Lareb dr. Agnes Kant is responsible for the CC as a whole. Dr. Linda Härmark is responsible for the daily affairs of the CC.

Website

In this period a dedicated website for the WHO CC was created within the Lareb website. On www.lareb.nl/whocc information relating to our terms of reference as a WHO CC (Education and Patient reporting) are gathered.

Education

Core curriculum

One of the tasks of the CC is to develop a pharmacovigilance core curriculum for medical, pharmacy and paramedical students. As the first step in the process of developing the curriculum a questionnaire which was developed and sent to relevant partners in pharmacovigilance to collect information on content for the pharmacovigilance core curriculum. During the design phase of the questionnaire there was contact with both the Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring and the International Society of Pharmacovigilance. The questionnaire was distributed at the end of October 2014 and data was collected until 31st of January 2015. The questionnaire was sent out to all members of the WHO International Drug Monitoring Programme. The questionnaire was also distributed to members of the International Society of Pharmacovigilance, persons active in pharmacy education through the academic research network of the Federation Internationale de Pharmacie, FIP and persons active in medical education through the EACPT Network of teachers in pharmacotherapy. In total more than 300 responses were collected and data analysis is still ongoing.

Educative initiatives

In addition to these tasks, Lareb continues to look for new ways to incorporate pharmacovigilance in education. In the period reported in this annual report a new initiative was started with the Dutch Society for Clinical Pharmacology & Biopharmacy (NVKF&B) and the Research and Expertise Centre In Pharmacotherapy Education. A program for pharmacovigilance Education was developed. This program can be used by all Dutch universities in their clinical pharmacology and pharmacotherapy curricula for medical students. The program encompasses problem solving based on clinical cases and a lecture. The cases are intended for undergraduate students. It focusses on the context and pharmacology of adverse drug reactions. Cases involving drug use during pregnancy and lactation are also part of the program. The second element of the program is a 'training' lecture on the recognition and reporting of adverse drug reactions in daily practice, which can be used to teach students before or during their clerkships. Students get an assignment to report at least one adverse drug reaction to Lareb during their clerkships, in order to practice recognition of adverse drug reactions and to get familiar with the reporting procedure.

Patient reporting

Support

As a specialist in patient reporting Lareb was invited as a collaborative partner to the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) joint action which aims to help medicine regulators operate pharmacovigilance systems to the EU legislative requirements. Regulators are collaborating to improve skills and capability in the network which will help safeguard public health in both national territories and the EU as a whole. Lareb participated in working package 4, which aims to provide an overview of national ADR reporting systems, including patient reports and identify best practices.

Lareb also provided information about its patient reporting system to Health Action International, who have prepared a report entitled "Direct Patient Reporting in the European Union, A Snapshot of Reporting Systems in Seven member states".

The head of the New Zealand Pharmacovigilance Centre visited Lareb for 2 days in April, 2015.

Training course

On 23-24 April, 2015 we organized the first Lareb conference on patient reporting. The conference attracted 60 participants from 20 different countries. During the conference topics relating to the role of patients in pharmacovigilance, the role of patient reports in signal detection, how to set up and run patient reporting systems and how to communicate with the general public were discussed. Interaction between speakers and the participants was facilitated by panel discussions and workshops. The evaluation of the conference was very positive and we consider to organize a conference again in 2017.

To continue highlighting the importance of patient reporting a position paper based on the discussions during the conference is being prepared.

The days before the Lareb conference on patient reporting, the International Meyler course in pharmacovigilance was held. During the course an introduction to the practical aspects of collecting information about adverse drug reactions and the organization of pharmacovigilance worldwide was given. The course was attended by 26 participants from 12 different countries.

We have also started a study to investigate what the needs are of national centres concerning patient reporting. Semi-structured interviews were held with representatives from 10 different countries during the 1st Lareb conference on patient reporting. The interviews have been analysed and a questionnaire has been developed, which is currently being field-tested. The questionnaire will be sent to participants in the WHO International Programme for Drug Monitoring in November 2015.

Contact with other organisations

Uppsala Monitoring Centre

Last year we have intensified our collaboration with the Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring. In March a large delegation from Lareb visited the UMC and we had good interactions and discussions how to collaborate. Especially in the field of training, collaborations are possible.

CIOMS

CIOMS had a call for new topics for a CIOMS working group. Lareb responded to this call with a proposal for a working group about patient reporting. This proposal was received positively by CIOMS and a Lareb representative will present the proposal at the CIOMS Executive Board Meeting in December.

During the reporting period Lareb has participated as a consortium member for the WEB-RADR project. The project is funded by the Innovative Medicines Initiative, Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients. The aim of the project is to develop, implement an evaluate reporting by healthcare professionals (HCPs) and patients by means of mobile devices and the strengthening of safety signals from social media platforms. The app will be launched in the Netherlands in the end of 2015.

Lareb staff as speakers

At the pre-meeting of the National Centres meeting in Tianjin (2014) organized by the UMC, two presentations were provided from Lareb staff (Agnes Kant and Linda Härmark) on the topic 'How to create an ADR reporting culture'.

At the National Centres meeting in Tianjijn (2014) an update was given during a plenary lecture about 'Integrating pharmacovigilance in curricula: what and how' (Linda Härmark).

During the NC meeting in Tianjin, Lareb presented on 'Supporting WHO and the countries in Pharmacovigilance: what the WHO Collaborating Centres can offer'. Lareb also presented the activities that were undertaken when it comes to undergraduate pharmacovigilance education (Linda Härmark).

ISoP pre-conference training course presentation about patient reporting, Tianjin, China (Linda Härmark) (2014).

Presentation about patient reporting, Europharma meeting, Warzaw, Poland (Linda Härmark) (2014).

UMC pharmacovigilance course, Uppsala, Sweden (Florence van Hunsel, Linda Härmark) (2015).

First Asia-Pacific pharmacovigilance training course, Mysore, India (webinar) (Florence van Hunsel) (2015).

SOPI meeting, Aligarh, India (Eugene van Puijenbroek) (2015).

SCOPE face to face meeting, Zagreb, Croatia (Linda Härmark) (2015).

Presentation on Signal detection for HALMED staf, Zagreb, Croatia (Linda Härmark).

Publications

Articles

Van Balveren-Slingerland L, Kant A, Härmark L. Web-based Intensive monitoring of adverse events following influenza vaccination in General practice. Vaccine. 2015 May; 5;33(19):2283-8

Härmark L, van Hunsel F, Grundmark B. ADR reporting by the General Public: Lessons learnt from the Dutch and Swedish Systems. Drug Safety 2015 Apr 38(4):337-47

Rolfes L, van Hunsel F, van Grootheest K, van Puijenbroek E. Feedback for patients reporting adverse drug reactions; satisfaction and expectations. Expert Opinion on Drug Safety 2015 May;14(5):625-32

Rolfes, L, van Hunsel, F, Wilkes, S, van Puijenbroek, E, van Grootheest, AC. Adverse drug reaction reports of patients and healthcare professionals-differences in reported information. Pharmacoepidemiology and Drug Safety 2015 Feb; 24(2):152-58

Abstract

ICPE 2015. Van Balveren L, Kant A, Härmark L. Active monitoring of local inflammations within a cohort of patients vaccinated with influenza vaccine. Pharmacoepidem Drug Saf 2015;24 (9):178

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