Role of Pharmacovigilance on Vaccines Control*

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Abstract

The pharmacovigilance of vaccines is defined as the science and activities relating to the detection, assessment, understanding, prevention and communication of adverse events of immunization, or any other vaccine, or issues related with immunization. The strengthening of pharmacovigilance is very important in every country because it helps professional health care workers to avoid the problems with immunization, protect the health of people from adverse events during immunization. The success of the immunization system is reducing morbidity and mortality related to the vaccine. The vaccines are biological products used to prevent infectious diseases, but sometimes the vaccines can cause some AEFI (Adverse Events Following Immunization). The detection of adverse events following correct immunization is one very important step for prevention of problems in the immunization system. The vaccines are injected into an infant body on the day of their birth and the safety of these products is vital. In Albania, the Pharmacovigilance department is established as the structure of the National Center of Drug Control. The strengthening of pharmacovigilance in Albania and other countries is necessary, because this will help to identify the risk and the risk factors, and to avoid or minimize the harms.

Key words: pharmacovigilance, vaccines, prevention of adverse events, strengthening health

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The Importance of Pharmacovigilance

The pharmacovigilance is a new department in the National Center Drug Control in Albania and the detection of adverse events is not so easy. At the moment we have only passive surveillance. It is necessary to train health care workers, physicians of hospitals and Healthcare Centers, pediatricians, epidemiologists, pharmacists etc., involved in adverse events. Effective communication in pharmacovigilance requires not only the knowledge of drugs, their impacts and effects, but also an understanding of the roles and responsibilities of the different stakeholders. Today the number of drugs and vaccines are increasing. The amount of vaccines imported in Albania from 2007 to 2011 has increased 5.6 times. Every drug or vaccine must be tested before using for safety and efficacy and the performing of these tests takes time and is costly.

The information collected during the phase of pre-marketing is not known fully because:
1. The tests on animals are not reliable in relation to the effects on a human subject.
2. In clinical trial, the number of selected people and the duration of the trial are limited and conditions of use are different.
3. The informations about serious adverse events and chronic toxicity used in group are so much abundant.

The Responsibilities of Pharmacovigilance

The main responsibilities of pharmacovigilance are:
- Publication & reporting of adverse events
- Gathering of information on and reporting of cases of adverse events
- The recording of evaluations of clinical cases
- Comparing, analyzing of adverse events and forming an evaluation
- The identification of the “noise” from the signal

Sometimes a problem happens that is not related to the immunization and it is the responsibility of pharmacovigilance to explain it.
- The recommendation and initiation of regulatory action in response finally results in good supporting evidence.
- Beginning of the study is related to the importance of adverse events investigation.
- Description of alertness to generation and publication of new risks from adverse events following immunization.
- Sharing of adverse events reports with the WHO Program for International Monitoring of Drugs.
Aim of Pharmacovigilance

The pharmacovigilance has two separate aims: main and final aim is explained below. The main aim of pharmacovigilance is the detection of hypothesis or signals, related to probabilities of adverse events. The early signal can be very unknown, however for a strong argumentation and indentation, must have a further investigation. The international collaboration is important for better decisions about adverse events reported.

- The first detection of action and collaboration for unknown adverse events.
- Detection of the increase of adverse event frequency.
- Identification of risk factors and possible mechanisms that happen during adverse events.
- Evaluation of quantities, aspects of analysis, benefit/risk and spreading of necessary information for improving of advice and about the normal use of the drugs.
- Reasoning and certain use of medical drugs or vaccines.
- Evaluation and transmission of the ratio of risk to/ the benefits of drugs or vaccines on the market.
- Education and information of patients about the reporting of their problems related to medical drugs or vaccines.

The Methods of Survey

Detection of cases will be made in the public health sector and the private sector. It also has two systems of surveillance:

- Passive system (based in the present system in Albania), is based only on recording adverse event in healthcare centers or hospitals. Actually the number of recordings of adverse events following immunization in pharmacovigilance of Albania and in Uppsala Monitoring Center (UMC) is not high. It is necessary to strengthen the reporting system in our country especially for the private health sector that is not involved in recording.
- Active surveillance for selected occurrence and vaccines.
- Monitoring Plan.

Strengthening of Analyzing Data, Investigating and Evaluation of Serious Adverse Events Causes

- Reporting to UMC (Uppsala Monitoring Center, Sweden) for detection of signal and a network of data analyzing.

The gathering of proper data: for example, vaccines used for age and critical number of doses (Figure 1).
Safety of Vaccines, Signal

Detection of signal is the identification of unknown adverse events. The evaluation of data collected at this stage is very important.
- Signal would not elude.
- Signal would be detected early
- “False” signal would be kept to a minimum. Do not publish before explanation of the case.
- Recording the information related to possible causes between vaccines and adverse events.
- Previous unknown relationship or gaps in the documentary
- Serious adverse events or reactions that result in one’s death or hospitalization, the inability to work or lawful inability (for example paralization).

How We Know that Vaccines are Safe?

This scheme may explain how we know that vaccines are safe (Figure 2).

The Factors Related to Adverse Events/Effects of Vaccines

The adverse events/effects are related to a type of virus or bacteria: live vs., killed vs., subcomponents, strains of virus, dilution of vaccines, dose of injection, adjuvant or preservatives used in vaccines, the stabilizing and purifying of vaccines which include contamination and extra products in vaccines and the technique of injecting.

Specific Arrangement for Long-term Strengthening of Safety and Efficacy Related to Pediatrician Use

Arrangement for monitoring of vaccines safety must be implemented by recommendation of CHMP (EMEA/359381/2009) for the plan of pharmacovigilance, as part of a risk management plan (RMP) used with an application for Marketing Authorization for vaccines of pandemic influenza.

During times when vaccines were in use, at least 4000 children divided in 3 groups were monitored:
- infants from 2 months old to 2 years old (500)
- Children from 2 years old to 9 years old (500)
- Children/Teens from 9 years old to 18 years old (3000)

These children were included in a safety group and followed up at least for the next 6- months after their last dose.

Adverse events of special impact (for example, febrile convulsion, polyneuropathies including Guillian-Barré Syndrome) must be identified clearly and recorded. All safety data must be included in the specification of Risk Management Plan6).

What is Necessary for Improving Vaccine Safety Monitoring?

- A well designed epidemiological study implemented for the confirmation or disqualification of safety signal contracted from passive surveillances (especially for serious results of health).
- The participation of representative countries including the developing and developed.
- New variety of vaccines.
- Study plans and organizations that approve the actual limitation in research and infrastructure including lack of denomination of population.
Conclusion

1. Good communication for sharing of information between countries is important, but more important for decisions is epidemiological study in each country.
2. The training of health care workers: physicians, paediatricians and epidemiologists for Adverse Events Following Immunization and causality assessments.
3. Raising awareness of people, health care workers and pharmacists to report adverse events to the pharmacovigilance sector.
4. The fulfillment of correct recording with necessary information of adverse events.

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