Recommendations from the First technical group: Dialogue on Health in Pharmacovigilance

The first technical group "Health in the Western Mediterranean: 5+5 Dialogue on Health" was held in the "Centre Anti Poison et de Pharmacovigilance du Maroc", on January 15th and 16th, 2015. This meeting was organized at the initiative of the Moroccan Ministry of Health. The overall objective of this meeting was to define areas of collaboration in Pharmacovigilance and to prepare projects of common interest to the ten countries.

The meeting gathered key actors of Pharmacovigilance institutions from Algeria, France, Italy, Morocco, Portugal, Spain and Tunisia with participation of representatives from the World Health Organization "WHO", European Union "EU", "Institut de Prospective Economique du Monde Méditerranéen" "IPEMED", Union for the Mediterranean "UPM" and Maghreb Arab Union "UMA".

During the meeting, countries exchanged experiences in Pharmacovigilance:

- The European countries in their exercise of Pharmacovigilance, are following European guidelines (EU, EMA). They benefit from the synergy of experts assessment and experiences through the Pharmacovigilance Risk Assessment Committee at the European Medicines Agency.

- Concerning countries in South Mediterranean, (Algeria, Morocco and Tunisia), some common points were emphasized:
    - Pharmacovigilance centres are independent from Drug Regulatory Authority, but are coordinating with it,
    - They have developed some singularities such as promoting integration of vigilances systems, Pharmacovigilance and rational use of drugs in hospitals.
    - And the three countries are networking and are involved in training and capacity building in Pharmacovigilance, with African and Arab countries.

In addition, concerning the 5+5 countries, it has been noticed that, technically, there were different degrees of maturity of methods and tools implemented and different degrees of reflection in Pharmacovigilance.

To achieve the goal set for this meeting,
We, participants of the technical group of Pharmacovigilance of the 5+5 dialogue in health, wish to pursue in an operational way the fruitful collaboration we have started and wish to deepen the knowledge of Pharmacovigilance systems between 5+5 countries.

Thus, the following recommendations were approved:
Strengthening exchange of experience between 5+5 countries

- **North to South** with their expertise in Pharmacovigilance and excellence in technologies of information and communication and can concentrate on:

- Building capacities concerning tools, techniques and methods particularly those related to the process of signal detection and risk management plans,
- Sharing European countries experience regarding implementing and enhancing regional Pharmacovigilance centres.

- **Between the 5+5 countries:**

Currently, constitutions dedicate several chapters to the health which emphasize the principle of the sanitary democracy and which place the patient in the focus of the interest of different health systems. Thus, the patient is an actor of his own therapeutic care and is involved in the process of decision-making. In this context, **the promotion of patient involvement and reporting in Pharmacovigilance** becomes imperative. It is necessary to strengthen the capacities of 5 + 5 countries in order to reflect the patient's involvement in its own safety.

For that purpose, it has been decided to schedule **a second larger meeting in September 2015**, reinforced by other Pharmacovigilance experts with the main objective to put patient safety at the main point of Pharmacovigilance.

- **South to south** by sharing specific experiences and data

Regarding the singularity of some experiences in south countries, some topics have been identified for a potential collaboration such us

- Involvement of Pharmacovigilance centres on managing medication errors and promoting patient safety,
- Prospecting about coordination and/or globalization of specific vigilances (for drugs, vaccines, devices, herbals etc...),
- Supporting collaboration in vigilance regarding pregnancy and breastfeeding.

We, all participants, are committed to promote these recommendations near all Pharmacovigilance actors in our respective countries and we kindly ask the ministries of health and foreign affairs to actively support this technical work group.

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