

9th ISOP (International Society of Pharmacovigilance)

Annual Meeting-Reims, France

06/09 October 2009: "From Pharmacovigilance to risk management"

Opening Session speech

Jean Marimbert, Director General of Afssaps

(French Agency for the safety of Health products)

Dear Mr President of ISOP,

Mr Representative of the mayor of Reims,

Dear Mr Director of the Pharmacovigilance center of Reims,

Mr Director General of the hospital of Reims,

Ladies and Gentlemen,

I feel very pleased and honoured to open this morning the 9th ISOP annual meeting that takes place in Reims.

You perhaps already know that this town is full of history and symbol for us Frenchmen, since it is the city where the kings were anointed before God. Then they had to go to Saint-Denis, near Paris, to be crowned before their people, at least their representatives, and then they proceeded towards Paris.

Afssaps premises lie today in the middle of this royal journey, since they are located in Saint-Denis!

Coming back to our modern times and to the theme of your international meeting, I want to emphasize that it is particularly relevant and of the utmost importance, both from a short term point of view and from a broader and long-run perspective.

In the short term, the outbreak of A/H1N1v pandemics puts in the forefront the need for a robust and proactive surveillance system, concerning possible adverse effects not only of vaccines but of antivirals as well.

This strengthened monitoring approach must be able to secure both an early identification of any safety signal, and a capacity to assess the public health significance of such possible signal. During the pandemic period,

evaluation of adverse events against the background epidemiological data of diseases that could or could not be linked to health products, will be essential for information of regulators, health professionals and the public.

As many of our colleagues across Europe and across the whole world, we are actively setting up this surveillance framework, in close collaboration with academics, health professionals and patient associations, combining in particular the tools of spontaneous reporting, pharmacoepidemiology, and the techniques of information and communication.

To meet this impressive and crucial short term challenge, we can rely on the work that has already been done during the last five years with a view to strengthening and enlarging the scope of post-marketing surveillance. This brings me back to the middle-term perspective I want to underline beyond the pandemic requirements, and to the title of the keynote speech Peter Arlett will deliver just after this opening session: "From pharmacovigilance to risk Management".

Let us remember for a while the situation we were confronted with 5 years ago at the beginning of the fall season. The withdrawal of a widespread product (VIOXX) had just been announced, suddenly and without real prior consultation with the medicines regulators. That event, happening 3 years after the withdrawal of CERIVASTATIN, stirred a lot of upheaval worldwide.

It led many people to question the efficiency and reliability of the regulatory safeguards, and it undermined at least momentarily trust in medicines among the general public.

We regulators had to react to the concerns that were raised outside our realm, sometimes very strongly. And if we leave aside this morning the extremely significant development of transparency in assessment and regulatory processes, the most essential response we devised was an enlarged and more anticipatory vision of post marketing surveillance.

This is now embodied in the widespread notion of risk-management plans, and more recently in its American FDA-made counterpart, the notion of risk evaluation mitigation strategies (REMS). However, it goes beyond the sheer notion of a toolkit. It is part of a broader approach whereby medicines regulators see their role in a life-cycle

perspective, from the early stages of the development of medicines to post-marketing monitoring, based on evolving risk management plans that are built before marketing authorisation is granted.

Based on this renewed vision, marketing authorisation is no longer the birth certificate of medicines, as commentators used to say 20 years ago, neither is it of course the end of the story.

Devising and implementing a broadened framework of post marketing surveillance was necessary in many respects.

The first - and compelling - reason was of course to be able to soothe criticism and doubts that had been raised, sometimes with a bit of exaggeration and unfairness, against the former functioning of pharmacovigilance.

But we should also keep in mind that it was necessary to take into account the development of anticipated access and fast-track procedures such as exceptional circumstances or compassionate use within the most recent European legislation. Granting marketing authorisation to products on the basis of data that are promising for patients but should be further completed, implies a robust system of post-marketing surveillance able to track possible unexpected adverse effects as well as to verify the expected benefits, so as to make sure that the initial benefit/risk appraisal, that opened the gate on a conditional basis, is confirmed.

And let us be clear to anybody outside the regulatory network that the new and more comprehensive vision of post-marketing surveillance that has emerged and will keep developing in the future is not and should not be a substitute for a scientifically robust and transparent initial assessment.

We also should remain aware that an efficient post-marketing surveillance system, combining in particular "classical" pharmacovigilance based on spontaneous reporting and pharmacoepidemiology, requires a sound dosage of centralisation in some selected areas and decentralisation in other fields.

For example, within the European regulatory framework, a certain amount of scientific centralised pooling of data and networking is both possible and valuable. But an enlarged pharmacovigilance should remain closely connected with national agencies that keep in touch and communicate with health professionals and patients, taking due account of specific national cultures, perceptions and health-care organisations. And it should preserve the interaction of these agencies with sub national bodies and networks, whether academic or hospital

or research-based. These actors can and should continue to bring a significant contribution to the operation of post-marketing surveillance, such as the Regional Centers of Pharmacovigilance in France and other member states.

The few ideas I wanted to formulate before you are meant for the sake of public health and for the benefit of the patients that we have to constantly keep in mind.

Let me now close my intervention with two thoughts.

First, a warm tribute to the commitment of Afssaps post-marketing teams, led by Anne Castot with the precious support of Carmen Kreft-Jais, for the tremendous work they have already done in Afssaps as well as within the European network and international fora.

Second, a sincere wish of success for your meeting in this city of Reims, full of history but now turned to the future.

Thank you for your attention.