Round table number 5 : What role do post registration studies play in the long term risk assessment of drugs : Schedule of conditions and methodologies

To go beyond complexity in order to improve our risk knowledge

Even if we have little hindsight concerning the risk management plans of drugs set up since 2005, a number of good questions have been raised : what procedure to follow in studies carried out after a drug has been authorized ? Can these surveys reinforce the monitoring of risks associated with drugs ? In the past, phase IV studies were not specifically focusing on those aspects. They now do and health authorities are trying to establish a methodological basis with all those involved in order to set up specifications.

' Monitoring plans of drugs are now well established and they are largely dedicated to post registration studies. As they can be applied to all drugs, these studies now lead us to discuss specifications that would give details on methodology as well as take into account the expectations of health authorities. The importance of assessing the risk/benefit ratio after registration is growing and we are becoming more aware that there are thousands of methods to assess and monitor a risk. Many sources of data exist the purpose of which is not necessarily the monitoring of risks. However, these sources can provide us with valuable information on how the product is being used and can support spontaneous notification, the purpose of which is to point out signals. Today, the purpose of this round table was to discuss the various methodologies used in pharmaco-epidemiological surveys and to relate them to questions raised when a risk is suspected or identified. Are we trying to measure it, to describe it or to point out risk factors ? This round table has done an inventory of existing practices. Today everyone is convinced that these elements are extremely valuable. The procedures of risk assessment are complex and it is important to clarify them. There are now European regulations that make MA depend on setting up plans of risk management which can involve the type of surveys discussed here. We have done an inventory of all guidelines, good practices and European initiatives in order to make a few recommendations. The first step was to make a report. We will need to come back to Giens to

elaborate a guidebook of recommendations. On the basis of common sense and each individual's experience our group has managed to bring out a few ways to procede and stratégies to be avoided.'