

**Round table no. 6 - Odile Launay**

Vaccines: specific problems, impact simulation and modelling in medical economics.

**"EXPLAINING THE SPECIFIC CASE OF VACCINES"**

In order to clearly identify the specific nature of vaccines, medicines which are unlike any other, we began by (identifying) listing the key stages in the development of a new vaccine, highlighting the very special constraints associated with the complicated and lengthy research involved. Vaccines follow a special circuit and our aim was to describe this state of affairs to give a better understanding of why vaccines are a special case. On the industrial front, vaccines are more difficult and take longer to develop than standard drugs. Because they are prescribed as a preventive measure, they are designed for subjects in good health to protect both the subjects themselves and, collaterally, the population as a whole (herd immunity effect). When assessing the efficacy of a vaccine, this aspect, which does not apply to other drugs, plays an important role.

Next we addressed the subject of modelling studies. These models are developed as an attempt to predict the epidemiological impact of vaccination at both the individual and the collective level. Among the priorities identified by our working group, developing certain epidemiological tools was seen as indispensable. These tools are still clearly inadequate in the field not only of infectious diseases but also of vaccine-induced diseases.

Finally, we also discussed the economic approach with the possibility of evaluating the cost/benefit of vaccine strategies. Here, once again, the epidemiological data need to be consolidated. With this in mind, it is interesting to clarify the element of measurement. Above what level, for example, do we reckon the strategy will offer benefits, and from what cost threshold will it be worthwhile offering mass vaccination? These are no simple matters. In addition, we do not necessarily know what the vaccine will cost at the time when the decision on a vaccination strategy needs to be made.

France needs to launch more major phase III trials of new vaccines. Conducting these trials in France naturally offers economic advantages, but there are also considerable research issues at stake since these trials produce vast quantities of data. At present, these trials are mainly conducted in the United States or other European countries, the Netherlands for

example, and we devoted some thought to what measures would be needed in France to enable such trials to be held here. A lot of work is needed on consolidating and building networks of general practitioners, and also paediatricians, willing to take part in the trials. The networks could be backed by university structures dedicated to vaccine assessment and coordinating with general practitioners specially trained in clinical research techniques to monitor patient cohorts as part of the trials.

Finally, we considered what measures could be introduced to assess efficacy and also side effects, once vaccine recommendations were established. We need to devise a system capable of responding in real time to potential alerts to prevent public anxiety taking hold. Only reliable data, rapidly communicated, can stop rumour from spreading and maintain confidence.

Public perception of the vaccine and its acceptability are also concepts not to be overlooked. We know that there are those in France, however small their numbers, who are opposed to vaccines. Many have doubts and simply need reassuring. Our group therefore put forward proposals to try and improve the communication of vaccine recommendations, and communication on vaccines in general. The opinions of the Technical Committee on Vaccination and those of the national authority for health (HAS) could, for example, be better publicised. We could also make certain meetings public, as a means of explaining the decisions taken on matters of public health. We would like to see communication improved on the subject of vaccines, which merit greater transparency if the public is to maintain its confidence in these products. Current communication, which focuses exclusively on the benefits without explaining the risks, is still poorly understood by the general public; the subject is one that offers ample scope for work over the years ahead.