C.I.P.H.
COMITE INTERNATIONAL DES PHARMACIENS HOMEOPATHES

INTRODUCTION

Thank you Mr. Chairman for the kind introduction. I would like to thank the EMEA for inviting the CIPH at this Workshop on Homeopathic drug products.

We are extremely grateful that such a prestigious institution participates to the debates about the regulatory situation of homeopathic medicinal products in the EU and we would like to thank the National Health Authorities representatives for their participation.
We believe that it is legitimate that the EMEA takes into consideration the homeopathic medicinal products, as these are present and used in Europe for two hundred years.

I first would like to introduce the CIPH (Comité International des Pharmaciens Homéopathes).
CIPH was founded in nineteen fifty five.
The CIPH has 3 basic aims:
- To facilitate both patients' and health professionals' access to homoeopathic medicinal products;
- To improve scientific expertise and develop modern Quality standards;
- To act as an active participant in discussions with regulators and experts on homoeopathic medicinal products.

The CIPH currently comprises members using exclusively French Pharmacopoeia methods and members using exclusively German Homoeopathic Pharmacopoeia methods.

CIPH strongly encourages the active involvement of the European Authorities in the harmonisation process regarding homeopathic medicinal products. Indeed, harmonisation and MRP are the key tools to the free circulation of homeopathic drug products.

The diversity of situations among the twenty five EU countries will make the MRP difficult to achieve. Nevertheless, a strong will exists on the side of the CIPH companies to make the MRP succeed, we are desirous to share our experience and we will try, throughout the day, to illustrate the kind of difficulties that will arise by giving examples:
- discrepancy on labelling requirements: article sixty nine is not interpreted identically in all countries
- manufacturing methods: the problem remains unsolved since fifty years, for instance the French and German Pharmacopoeia are not compatible and lead to a situation where 2 products under the same name and dilution have a different composition.
- viral safety criteria: the large homogeneity in the conception of the manufacturing processes for dilution and potentisation should authorise a global approach for the viral safety evaluation of homeopathic medicinal products of different origins.
- toxicological evaluation: a detailed guidance is needed in order to avoid the discrepancies in the first safe dilutions determination.

Moreover, a clarification is needed about the question: can MRP substitute a revision process? Let’s take the example of a company already present in several countries without any harmonisation in the registration requirements. Most of these countries have to implement a revision process, where a complete evaluation of the dossiers is required. The company in question would have expected that the MRP could be the opportunity to send only one dossier and that this dossier, once evaluated, will be THE reference in all the countries. But instead, if it is not possible to register the same medicinal product within a national revision procedure and an MRP, the company has to deal with every national revision and only reserve MRP to “new” countries. In these conditions, MRP seems less attractive. A common procedure would be welcome! Is it possible to find out a new way to carry out a national revision through the MRP? This would save much efforts and resources to the National Agencies and to the companies.

May this workshop bring the National Health Authorities representatives to share the same goal and provide the opportunity to create a regular group where EMEA will play a role in collaboration with the HMPWG.