

**Impressions –
from BfArM (Germ. med. agency and authority) hearing, march 30th, 2006**
by Carl Classen, VKHD

There were 176 (!) people on the participants list, including BfArM staff, 3 reps from BKHD, Curt Kösters from DZVhÄ (hom MDs), Arne Krüger from German Heilpraktikers, Bea Marcin from Lachesis, reps from pluralistic MDs but mostly representatives from German manufacturers.

First of all an issue for which the attitude of the British agency and/or authority may be interesting.

One of the issues we presented was the need for Korsakov potencies, in order to maintain high potencies above C1000. Korsakov potencies don't exist neither in the French nor in the German pharmacopoe, thus they won't be introduced in the Ph.Eur. Other pharmacopeias are not official and thus they are not suitable to be taken into consideration for the European pharmacopeia (Ph.Eur.).

In a break I had a talk about this with a BfArM officer. He said for the German side there is no possibility to bring forward such a proposal, but may be the English side could do so, IF there is an OFFICIAL prescription for the marketing authorisation of Korsakov potencies.

I am not at all sure if there is a chance to introduce British regulations into the European pharmacopeia, if it was just an excuse to refer to England. I do not know enough about the English system of registration and marketing authorisation for hom. remedies. Anyway, I think we should find out more about this.

Our impression is that in general there is not very much support esp. for our demands concerning high potencies. Not for Korsakov potencies and not for a "safe by dilution alone and per se" concept. Germany and France both have a pretty strong position in the European process, not only because they cover more than 70% of the European market, but also because they are the only countries with official pharmacopeias. The German manufactures are lamenting about the regulations becoming more and more strict, but at the same time the BfArM shows itself as a partner of the German industry to get a good position in Europe. A kind of double bind situation. I think Dr Knöss, the new BfArM department chief and successor of Dr Keller, tries to be fair and I don't have the impression that he would manipulate, it rather seems they are trapped all together within their own systems.

So the reactions to Curt Kösters from the DZVhÄ were as if someone had come from another planet when he stated, that dilutions beyond C12, being safe without further requirements, should allow the use of not autoclavated nosodes. Same when he stated that 20y shelf life are appropriate for highly potentised hom remedies. These are positions from our common paper which don't seem enforcable at the moment. Nevertheless I feel we should stand for this.

There is a kind of roadmap on a European level, to begin with the more easy solvable problems and to postpone the discussion of the nosodes issue. I asked: isn't there the danger that the box will be shut as soon as there are regulations good for 90 or 95% of the market, and the rest is going to become complicated.

The answer: The German HAB prescriptions, which include nosodes, will be maintained. For Germany.....

There is a point of "not discriminating national pharmacopeias", but what about other countries with different manufacturing (e.g. Korsakov-method) and without official pharmacopeias?

One aspect about France. Opinions from a break talk, nevertheless interesting: In France, there often seems to be a contradiction between the official attitude from the authority --- which is e.g. really hostile against nosodes! --- and their practice: in their own country, they allow a lot of things which do not fulfill the official requirements. I said: sounds like an issue of mentality. But the BfArM officer who told this does not like it, because this makes it difficult to play fair between Germany and France in the Ph.Eur. consensus process etc. There was another example of "cheat", concerning methanol in mother tinctures, I told about this a year ago.

Concerning intransparency of the HWPWG work (no publication of relevant documents on HoA website), it was admitted that this was due to lack of consensus within the group.

I asked if it wouldn't make sense to apply the safe dilution concept, presented in the latest PtC draft from the HMPWG, on animal origin remedies and nosodes as well. They said, in other words, that making too much noise about the nosodes may have the reverse effect, because there are strong opponents against nosodes, from other European countries, including France.

Maybe there is something strategically true about this, but the other danger is to delay the nosode issue until the box will be closed. But it became clear that it is very important to work for pharmacy issues in many countries, and not in one or two. We have to lobby in many countries for an understanding of homeopathy, and that such strange things as nosodes are an integral, inseparable part of homeopathy. The hostility of one or two EU Member States can block the whole system.

On the meeting, I stressed the necessity to include all relevant parties in a balanced way, and not to do the job with administration / authorities and industry only. Our common position paper was within the supplied documents, and I saw some of the manufacturer representatives reading it with interest. But the agenda included "statements of associations", and there were two statements of manufacturer associations only. Saying goodbye to Dr Knöss I suggested that user associations could have been included here, maybe the next time.

Summary:

(1) in Germany I watch a double bind situation of the manufactures feeling overregulated by the authority, but at the same time the authority represents itself as a partner of the industry, helping them to get a good position on the European market,

(2) it is very important to lobby for homeopathy in many European countries, also France has a key role,

(3) we could explore if there is any possible influence from England onto the Ph.Eur. process -- once the Ph.Eur. is finished, it will be practically impossible to get through any major amendments!,

(4) all issues concerning high potencies (safety by dilution alone, Korsakov, shelf life...) are very exotic for the vast majority of those present on such hearings,

(5) we have to talk about strategies concerning nosodes.