

Minutes of the Videoconference of the SIG (Special Interest Group) Networking on September 25, 2003

Participants:

Dr. N. Lill, Aventis (NL)
Dr. K. Bechtold-Peters, Boehringer Ingelheim (KBP)
Dr. W. Wolf, Rentschler (WW)
Dr. H.C. Mahler, Merck (HCM)
Dr. H. Lindner, Ferring (HL)
Dr. J. Dirach, NovoNordisk (JD)
Dr. A. Töpsch, Vetter (AT)
Dr. K. Michaelis, AAI (KM)
Dr. C. Velten, Scitari (afterwards, via phone) (CV)

Unable to attend:

Dr. Rainer Alex, Roche (RA)
Dr. Sven Stegemann, Capsugel/Pfizer (SS)

Item 1: Networking with other organizations and networks

KBP reported on the current interactions with the AAPS (Biotech Section), which views the EAPB as a European partner in Biopharma matters. Mutual networking between the two organizations has already taken place, with the planned contribution by the EAPB of a symposium in each case at the Annual Conference in October 2003 (26 – 30.10.) in Salt Lake City and the National Biotech Meeting in May 2004 (17 – 19 May) in Boston ("Traditional and innovative Approaches towards Protein Stability" and "Regulatory, Quality and Safety Aspects of Gene Therapy"). On the other hand, Wayne Gombotz, Corixa, of the AAPS Biotech Section Board, is also a member of the Editorial Board of the EAPB "New Drugs" journal. Since some SIG members will be taking part in both conferences, EAPB meetings are to be organized, and/or a joint meeting planned with the AAPS Biotech Section in the sense of networking, in Salt Lake City and Boston (for action: KBP and SS). While the SIG participants would basically welcome the link with the AAPS, concerns were expressed that the EAPB, as a European organization, should be focusing on EUROPEAN networking. The interaction should be restricted to a friendly relationship.

In order to strengthen European networking in the field of Biopharma as a counterweight against the American biotech business, there was a proposal initially to identify and contact partner organizations in certain focus countries (UK, France, Southern Europe = Italy/Spain/Greece, Scandinavia). EAPB and SIG Networking are too Germany-centric at present, which needs to be remedied (for action: WW, KM, AT, contact the respective organizations as described).

At events where EAPB flyers are distributed, there should either be an EAPB booth managed by competent individuals (if EAPB cooperates with the relevant organization) or EAPB/SIG members should personally hand out the flyers with corresponding explanations. If company stands are used for flyer distribution, suitable briefings should take place to ensure that the booth personnel can provide good information about the EAPB. The EAPB flyers should be printed in a handier format (currently DIN A 4 ⇒ reduce size by folding, for action: KBP to discuss this with R.H. Müller).

Item 2: Mission / Profiling of the EAPB and important goal of organization of "qualified contacts"

NL expressed his impression that the mission and objective of the EAPB / Networking Group is still not clearly defined. This was followed by a controversial discussion: according to its stated mission "EAPB is the representative and central network to promote and develop Pharma biotechnology in

Europe, linking academia, industry and *regulatory bodies*" at a conference or similar event, e.g. an EAPB booth might be organized with contacts from licensing authorities, thus ensuring networking with regulatory bodies as well. The meeting participants agreed to contact BioEurope, which already operates as a European organization - albeit with a commercial orientation - (for action: KM and WW) and to organize an attractive workshop there, and also to approach EAPB members and member companies with a view to ensuring that Biopharma is represented as fully as possible at this event. Although there are already many partnering conferences and contact forums, it would be desirable to create THE European biopharma event, by analogy with the claims of the BIO (in USA), in order to strengthen European biopharma. In view of the win-win situation on both sides, BioEurope should allow the workshop to be held at no charge, and speakers from the EAPB should be responsible for the workshop programme and present the findings of the SIG Networking Group at the Workshop.

Post-meeting notes: members criticised the desire to make the EAPB and SIGs into the desired powerful organization via the reaching of technical achievements. Rather, we should be thinking, in the foreseeable future, about appointing full-time personnel / lobbying organization. (For action: KBP will present this proposal and the need to establish a corresponding timetable at the next Board Meeting).

Item 3: Guidance for SMEs for licensing

The checklist proposed by HL was highly praised and considered helpful by all participants. The aim is to benefit "big" biopharma by providing guidance for the smaller licensor companies regarding the appropriate presentation of their products, having established the important criteria beforehand. However, since the list was produced particularly for the evaluation of Drug Delivery Systems and devices, HL offered to add a brief introduction and to make the list more suitable for general use. Detailed checklists can, and should, be drawn up for the individual areas of in-licensing (DDS, expression systems, therapeutic macromolecules, diagnostic kits, biopharmaceutical processes or process steps, tissue engineering products, assays for research targets). All SIG members are asked to test HL's revised list on specific projects and to provide feedback on possible improvements as soon as possible (for action: HL, all). The finalized checklist produced after this feedback process should then be made available to all on a site reserved for SIG Networking, while the detailed lists, on the other hand, should only be supplied on request. Advantage: the EAPB/SIG gains an overview of the use of the checklist. (For action: KBP to organize the setting up of an SIG Networking site on the EAPB website and the implementation of the checklist).

KBP expressed her willingness to produce detailed checklists for Expression Systems (together with WW) and Tissue Engineering Products.

The workshop proposed in item 2 offers the ideal opportunity to present and discuss the checklist and expectations of sponsors in respect of licensors. It must be in the interests of European biopharma to strengthen the SMEs through professional advice, otherwise the sell-off of European companies and discoveries to the USA will continue apace. Average review times / decision times should also be presented in the workshop in order to make it clear to licensor companies that out-licensing takes a relatively long time (and requires deep pockets). (For action: KBP: survey the SIG participants as to the typical periods until a licensing decision is reached).

Item 4: Checklist for the classification of EAPB members / Corporate Members

It was agreed that letters should be sent to all members, i.e. both corporate and personal members, since this will cover biopharma companies that are still not members of the EAPB.

As regards the extent of the questionnaire, a synthesis of the questionnaires drawn up by CV and SS was considered to be the best solution, i.e. this is achieved by adding to the very concise paper prepared by SS the question: "what network do you want to work with?"* in accordance with CV's proposal. The contact details should also appear at the end. After the feedback has been received, a second round is to follow with a rather more detailed questionnaire. HCM underlined the need for the questionnaires to be available in both electronic form, for completion on the Internet, and for printing

out on paper. Both forms must possess a user-friendly layout. It was also agreed that it must be possible to complete the first questionnaire in much less than 5 minutes. The second questionnaire should also take little time to complete and should not contain open questions (given the time aspect and the fact that standardization of the evaluation would otherwise be difficult). (For action: SS and KBP to improve the questionnaire; use of EAPB secretariat for its distribution; evaluation by the next meeting; use of the IS Service, which will also facilitate electronic selection, to design the Internet form).

Item 5: Next meeting

The next video- or teleconference is scheduled for the end of November / beginning of December. It would be good to arrange this to coincide with the upcoming Board Meeting, and we might then be able to use the premises of Schering (for action: KBP to ask Gesine Hildebrandt). This solution would be preferable to a meeting in Basel, since it would involve less travelling for the members.

Karoline Bechtold-Peters

* Proposal (avoiding the expression "Qualified Contacts", which requires explanation):

What kind of network do you want to work with?

- Academia / Industry
- Regulatory bodies / Industry
- Smaller to mid-size / "big" Biopharma
- Consultants / Industry
- Service or equipment providers / Users
- Sponsors / Licensors
- EU program funds / participants in EU programs