

**NOTES OF TERTIARY GROUP MEETING**  
**(11 December 2004, Brussels)**

**Attendees:-**

Hans-Jacob Bangstad, David Branski, Samy Cadranel, Andrew Cant, Anselmo Costa, Stenvert Drop, Fügen Gullu, Patricia Hamilton, Peter Hindmarsh, Robert Holl, Peter Hoyer, Willem Kamps, Laszlo Kovacs, Pekka Lahdenne, James Leonard, Fran Malcic, Zsofia Meszner, Peter Milla, David Neubauer, Ljupco Nikolovski, Lars Palm, Isabel Polanco, Flemming Skovby, Tauny Southwood, Alfred Tenore, Mehmet Vural, Marietta Xanthou, Max Zach (**Chair**)

**1) Opening Remarks – Max Zach**

Minutes of the Tertiary Group meeting held in Sigtuna in May 2004 were approved. (Tauny Southwood's name to be added to the list of attendees).

**2) Medicines for Children**

Max Zach welcomed all attendees and reported:-

- i) Executive Committee with consideration of forming the European Academy of Pediatrics;
- ii) New regulations will require proper testing of medicines used in children (law likely to be in place in 2005 / 2006). This is a positive step, but paediatrics is not greatly involved in this initiative which is being led by the EU and pharmaceutical companies. Max Zach envisaged a role for this committee advising the EU on this matter, for example: in new drugs used in paediatric gastroenterology. Robert Holl said that plans had already been made and each country will send 2 delegates to the EU Committee on Medicines for Children. We need to link these people to CESP committee members. James Leonard stressed the importance of tertiary specialist involvement to explain the importance of medication for children with rare conditions, and how regulations could hinder this. Peter Hindmarsh stressed that unlicensed drugs could still be used. Max Zach commented that legislation could be very good as this will ensure that proper trials are carried out in children. Willem Kamps spoke of the opportunity paediatric oncologists had had to influence this with European Members of Parliament. Samy Cadranel said that a body that harmonised prescription across Europe would be very useful. Peter Milla pointed out that legislation is about licensing and marketing new drugs, not about "compassionate" and "off label" usage. Off label usage may be restricted to ensure that proper clinical trials are carried out. Peter also said that this initiative should provide incentives for multi-nationals to return activity to Europe from the USA. The European Medicines Agency would contact expert paediatricians and encourage people to participate in their workshops. European registration can only be given after European trials.

**3) Immunology Modules**

- i) The modular idea had been suggested by the CESP Board.

ii) Andrew Cant expressed his thanks for all the support, encouragement and practical suggestions received from Board members which had greatly enhanced modules, in particular from Max Zach, Peter Milla and Peter Hoyer.

iii) Concept - to promote knowledge and clinical skills in paediatrics, harmonised across Europe; no one speciality “owns” immunology, but rather there is a need to provide training for those developing immunological aspects of various sub-specialities, and ensure that there are a cadre of tertiary paediatricians with knowledge and clinical skills to care for children with complex immunological disorders.

iv) Very grateful to:-

Ronald de Groot	- ESPID
Esther de Vries	- ESID
Professor Holmberg	- Renal
Peter Milla	- Gastroenterology
José Lopes dos Santos	- Allergology
Tauny Southwood	- Rheumatology
Marietta Xanthou	- Neonatology
Max Zach	- Respiratory.

v) Structure

2 obligatory modules – knowledge and research. Not time based.

2 desirable modules – 6 months each.

6 months to 1 year could be covered within the current sub-speciality programme, providing the syllabus was fulfilled.

Must do 2 desirable modules.

vi) Issues

Trainees would need to be informed of modules and encouraged to follow them.

A visitation questionnaire and inspection of centres seeking to deliver modules would need to be organised (? part of sub-speciality accreditation).

Max Zach proposed to put the modules to the plenary session of CESP.

José Lopes dos Santos suggested that immunodeficiency should be obligatory and that trainees should also do either / or allergy or rheumatology from the desirable modules.

Andrew Cant responded and agreed that this selection of modules would provide the best training for paediatricians looking after children with primary immunodeficiency and complex problems of immuno-regulation. However, the modules also needed to have broader flexibility to make this useful for sub-specialists, viz renal paediatricians who wanted training to help to better explore immunological aspects of their own sub-specialities.

Discussion took place regarding monitoring and identifying gaps. Visitation and discussion with trainees will be crucial. Suggested a working group of those who helped draw up the modules (? Involve ESID and ESPHI and other specialist societies).

#### 4) **Training Visitation**

This is especially important for countries with no national visitation programme. Max Zach asked regarding the implementation of visitation.

##### Infectious Diseases – ESPID

12 centres expressed interest – mainly in countries where paediatric infectious diseases is not recognised in the country.

##### Neurology

Discussion regarding national visitation where countries recognised. Some countries are so small (viz Slovenia and Czech Republic) that there are not enough centres to constitute a programme of visitation – therefore look to Europe.

##### Endocrinology

Ready to go; discussion regarding training assessor. Need minimum standards for visitation to see if current national visitation is okay. Some requests are now over 1 year old including Finland.

##### Cardiology

Not yet established formal visitation; lots of informal visitation for teaching and centre comparison.

##### Metabolic

2 visits already conducted, albeit inadvertently not following planned guidelines. Very small sub-speciality; some countries only have one centre. Assessment now in line with European guidelines and so will be submitted via CESP shortly. Both centres found the process positive and helpful in developing the service.

##### Respiratory

No visitation so far; no centres asked to be visited! Max Zach is working on this with the European Pediatric Respiratory Society.

##### Gastroenterology

Visitation very much needed in countries that do not recognise paediatric sub-specialities. It has been suggested that visitation could be carried out within European regions that speak the same language.

##### Allergology

European Academy of Allergology and Clinical Immunology - accepted CESP documentation on visitation. Would like to start individual certification then centre certification.

##### Renal

Considerable interest in visitation and accreditation. Survey of key indicators and criteria for training centre. Need to collate this work over the next year. Issues of finance – if 10 specialities at 6000 Euros = 60000 every 5 years.

##### Rheumatology

2 centre visitations. 1 centre no change; other centre – pre-planned change. Must involve Chief Executive of hospital if going to bring about improvements.

Haematology / Oncology

Ready to go.

**Issues raised included:-**

- How to make arrangements for visitation. Should this be via CESP or directly?  
?Small speciality better direct; large via CESP?
- The cost: 6000 Euros was considered to be too much for centres in some countries.
- A more gradual approach was advocated by one delegate.

Max Zach commented that costs should not exceed 6000 Euros, but the visitation committee can waive part or all of the costs. However, the central secretary must co-ordinate to ensure uniformity and consistency of visitation. It will also be impossible without central co-ordination for larger sub-specialities such as gastroenterology. Peter Milla supported this view and went on to say that decisions will need to be made about which national visitation programme will be accepted. CESP will need to liaise with specialist societies regarding visitors and criteria to be met. Arrangements for visitation should be made via José Ramet or Max Zach.

**Conclusion – encouragement to get on with visitation!**

Andrew J Cant  
**Delegate for ESPID**