MINUTES
WINTER MEETING 2021

VIRTUAL DEC 3, 2021
19.45 - 20.30 CET

Please see the attendance register attached.

SECONDARY-TERTIARY CARE COUNCIL

1. **Welcome and introductions** by Berthold Koletzko

2. **Adoption of the agenda** – the agenda was approved

3. **Adoption of the** Minutes of the Tertiary Care Council Spring Meeting held on 02.07.2021 **(distributed)** - the minutes were approved.

4. **Matters arising from the minutes** – no matters arose from the minutes.

5. **Strategy for Training Centre Accreditation:** request from the European Society for Paediatric Endocrinology and Diabetes ESPE)
   a) This point concerns the ESPE strategy for training centre accreditation.
   b) Europe is remarkably diverse and colourful, and so are the practices of paediatric training, UEMS is encouraging the certification of training centres, with clear guidance.
   c) With the goal to we achieve greater harmonization, and better training standards, the aim is to certify training centres throughout Europe of a uniform high standard.
   d) Assessment of training centres is not intended to be punitive, but to ensure the centre can meet the needs of the training programmes and trainees. It should be a constructive process to resolve difficulties and to resolve difficulties and should help to obtain more resources for training.
   e) The criteria will take account of the local set-up. Two smaller centres could combine to offer a training programme with a rotation of trainees.
   f) Process: Structured written application, site visit (usually two experts, 2 days)
   g) Well established for core paediatrics, paediatric allergology, and inborn errors of metabolism
   h) Recent examples of such Training Centre accreditations include for core paediatrics: Çukurova University Department of Pediatric Health and Diseases and Balcalı Training Hospital, Turkey as Centre for Training in Core Paediatrics visited on 2 days by: Adamos

Hadjipanayis, Chair of the committee; Karoly Illy, Mujgan Alikasifoglu, Figen Akalin, Ioanna Saouri, and the joint Training Centre for Inborn Errors of Metabolism in Freiburg/Reutlingen, Germany, with joint application reviews and a site visit for 2 days performed by J. Häberle & A. Morris (SSIEM) and P. Hoyer (EAP).

i) Peter Hoyer reported on further centres that applied for the accreditation of a Training Centre for Inborn Errors of Metabolism. Peter accentuated the importance of the involvement/discussions with trainees to improve their traineeship. This is a crucial step to assist countries where specific specialties are not recognized.
j) The efforts to establish this concept for more European countries is successful but scattered.
k) There is a very large number of training units in Europe, a strong workforce will be needed for such an effort. Well established programmes, like paediatric oncology, will not necessarily benefit from such a programme.
l) For small, less recognized specialties, these programmes are of tremendous value. Paediatric Subspecialty Examinations is another especially useful way to help specialties develop, and subspecialty societies are encouraged to develop exams.
m) A clear criterion to apply for the initiative and a process to identify the countries that need these programmes more urgently should be created.

6. Report on EAP Involvement in the Horizon 2020 Project CoreMD

a) The European Union has adopted a Regulation on Medical Devices (EU 2017/745) that came into force on 26.05.2021 and stipulates that manufacturers of medical devices shall conduct a clinical evaluation, and approval for introduction into the market shall depend on an expert evaluation of data on suitability and safety.
b) Expert Panels have been established and started operating: Expert Panels are designated in relevant medical fields to deliver opinions and views on the level of clinical evidence provided for certain high-risk medical devices and in vitro diagnostic medical devices.
c) Expert panels also give ad hoc advice to the European Commission, the Medical Device Coordination Group (MDCG), EU countries, along with manufacturers and notified bodies.
d) In addition, an In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) has been adopted. Until 25 May 2022, all certificates issued under the in vitro diagnostic medical devices directive (IVDD) are valid until their date of expiry.
e) 26 May 2022 – 25 May 2024 – certificates issued under the IVDD from May 2017 expire latest by 27 May 2024.
f) From May 26, 20217 , devices that conform the in-vitro diagnostic medical devices Regulation (IVDR) may be placed on the market.
g) From 26 May 2024: devices placed on the market must be in conformity with the IVDR.

h) CORE-MD will explore and recommend approaches for evaluating high-risk medical devices.
i) With respect to Medical Devices for children, availability of state-of-the-art devices is essential, but paediatric patients suffer from delayed and limited market introduction of innovative devices. Challenges exist for implementing an evidence-based regulatory policy for medical devices because of limited feasibility of performing large clinical studies in paediatric patients, where often only small numbers of patients need specific devices, and creating firm clinical evidence is often impeded by small sample sizes and large heterogeneity of paediatric patient populations. Also, there are less economic incentives for manufacturers to invest in paediatric trials since generally only much smaller numbers of devices are sold for children than adults.
j) Most medical devices approved in the USA between 2008 and 2011 for use in children were studied only in adults, and the use of devices in children to a large part was off-label.
k) Implementation of the EU MDR for children needs to achieve an adequate balance between full documentation of safety and efficacy, and ensuring access to innovative medical devices., Secure the rights of children to get the highest attainable standards of health & healthcare (UN Charta for the rights of children)
l) EAP is a partner of the CoreMD project and participates in Work Package 2, focussing on Strengthening Evidence for High-Risk Medical Devices.
m) EAP task in Core-MD is to develop widely agreed, evidence-based and feasible regulatory policy for paediatric high-risk medical devices.
n) Since 04/2021: Preparatory work, recruited two people that coordinate EAP tasks (Dr. Kathrin Gürlich, Dr. Bernadeta Patro-Golab)
o) 2022: review of published/other evidence & best practices; Identify competent experts that can contribute & conduct a workshop with experts, part. from EAP member societies to develop recommendations for evaluating suitability and safety

7. Report on planned EAP meeting on Public Private Partnership in collaboration with the European Parliament

a) Workshop on Public Private Partnership with three members of the Europ. Parliament planned, following the published consensus paper of 7 European Paediatric Associations led by EAP.
b) Goals are to promote and protect breastfeeding, improve standards and practice of BMS marketing & promote public private partnership with commercial partners, including BMS companies.
c) Next step: discussion with stakeholders to achieve broad support
d) Related to this issue is the issue of CME: UEMS / Biomed Alliance in Europe: Commercial enterprises must not direct and offer CME activities for HCPs, because the existing conflicts of interest make it highly unlikely that bias can be avoided.
e) Our position is that CME should be offered by trusted information providers are learned paediatric societies, professional organisations, and governmental bodies, but not commercial organisations that have an

interested in marketing products or services to health care professionals and hence are unlikely to provide unbiased information.

f) Organising bodies should follow core values (such as humanity, integrity, quality, independence, respect, accountability, and transparency), ensure that programmes are balanced & evidence-based, and strictly exclude any influence of commercial interests on programmes
g) Paediatric national and subspecialty association should warn their members against CME activities initiated by commercial companies.
h) Next Steps: agree on a date when face to face meeting can be held at Brussels, after Covid-restrictions have been lifted or reduced.

8. Other European matters of interest

8.1 Calls for Horizon Europe launched

a) Opportunities for paediatric research, but lack of calls focussing on child health. As EAP, we need to continue to make our voice heard
b) EU Innovative Health Initiative (IHI): Successor of the Innovative Medicines Initiative.
c) The latter mentioned project entails a broader scope beyond pharmaceuticals, with EU Commission and industry partners COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe – to be launched in 2022.

   Specific Objectives of IHI include:

   a) Better understand determinants of health & priority diseases.
   b) Bring together health industry and other stakeholders, for development of tools, data, platforms, technologies for prediction, prevention, diagnosis, treatment, and management.
   c) Demonstrate feasibility of integrated health care solutions
   d) Exploit potential of digitalisation & data exchange in health care
   e) Enable development of methodologies and models for an assessment of added value of innovative/integrated solutions

8.2 Health Emergency Preparedness and Response Authority (HERA)

a) Created to prepare the EU for a future pandemic and other emergencies
b) Modeled after US Biomedical Advanced Research and Development Authority (BARDA) established 2006 and responsible for the procurement and development of medical countermeasures against bioterrorism, chemical, radiological, and nuclear threats, influenza, and emerging diseases.
c) HERA shall assess potential health threats, promote research, ensure availability of critical production, help build stockpiles. During a health crisis, agency would activate emergency funding and help coordinate monitoring, acquisition and purchase of medical equipment or treatments

9. Any other business - No other business was brought up.

List of Attendees:

Name	Surname	Secondary-Tertiary Care Council Session on 3 Dec 2021 from 19.45 - 20.30 CET (Chair: Prof. Berthold Koletzko)
Lars	Gelander	I confirm my attendance
Vaidotas	Urbonas	I confirm my attendance
Hoyer	Peter	I confirm my attendance
Risto	Lapatto	I confirm my attendance
Veronika	Jilichová Nova	I confirm my attendance
Miguel	Martins	I confirm my attendance
Mateja	Vintar Spreitzer	I confirm my attendance
Sian	Copley	I confirm my attendance
Ivan	Bambir	I confirm my attendance
RUBEL	Francis	I confirm my attendance
Geitmann	Karin	I confirm my attendance
Arunas	Valiulis	I confirm my attendance
Martin J	White	I confirm my attendance
Liesbeth	Siderius	I confirm my attendance
Aida	Mujkic	I confirm my attendance
Joana	Rios	I confirm my attendance
Lukasz	Dembinski	I confirm my attendance
Martin J	White	I confirm my attendance
De Guchtenaere	Ann	I confirm my attendance
Isabelle	Kieffer	I confirm my attendance
Artur	Mazur	I confirm my attendance
Veronika	Letychevska	I confirm my attendance
Suleyman	Yildiz	I confirm my attendance
Kaulfersch	Wilhelm	I confirm my attendance
Rob	Ross Russell	I confirm my attendance
Mateja	Vintar Spreitzer	I confirm my attendance
Marina	Mamenko	I confirm my attendance
Maria Gutu	Gutu	I confirm my attendance
Stefano	DEL TORSO	I confirm my attendance
Vaidotas	Urbonas	I confirm my attendance
Natasa	Toplak	I confirm my attendance
Berthold	Koletzko	(Session chair)