MINUTES | SECONDARY TERTIARY CARE COUNCIL
SPRING MEETING 2021
LARNACA, CYPRUS / VIRTUAL JULY 2, 2021
15.00 – 16.00 CY / 14.00 - 15.00 CET

See list of attendees attached

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

2. **Adoption of the agenda**
   a. The agenda was approved

3. **Adoption of the minutes of the Tertiary Care Council Winter Meeting held on 21.01.2021** (distributed)
   a. The minutes were approved

4. **Matters arising from the minutes -** Report on Action points
   a. The ETR template is currently being reviewed and updated where required, taking the recent modification of the UEMS template into account.
   b. Complex care: the team led by Maria Brenner has been developing a position paper in a very short period of time and plans to prepare an EAP Master Class on the topic. Sincere thanks go to Maria for her excellent leadership.

5. **Report on UEMS decisions on paediatric ETRs for Neonatology and Paediatric Endocrinology**
   a. The queries from the UEMS were responded to with minor modifications.
   b. The above-mentioned ETRs were adopted by UEMS in April 2021 and can be found on the EPA website.

6. **Update on the revised European Training Requirements for Paediatric Endocrinology and Diabetes, developed by ESPE** (ESPE)
   a. The queries from the UEMS were responded to with minor modifications.
   c. The above-mentioned ETR was adopted by UEMS in April 2021 and can be found on the EPA website.

7. **Report on EAP Involvement in the Horizon 2020 Project CoreMD**
   a. Based on the EU Directive on Medical Devices, manufacturers need to evaluate the suitability and safety of their products usually in clinical studies and have them approved before being allowed to market them. The directive was implemented in response to safety issues that have arisen with some implantable devices such as endoprotheses and breast implant.
   b. Guidelines as to how such evaluations of medical devices should be performed are lacking. In this context, the EU-funded CORE-MD project will collate scientific and clinical evidence on study designs and required evidence for evaluating high-risk medical devices into advice for EU regulators.

c. Special challenges arise for medical devices for paediatric patients. Almost all medical devices developed in the USA between 2008 and 2011 for use in children were studied only in adults. Use of devices in children to a large part is off-label.
d. 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, to support the rights of children to get the highest attainable standards of health and healthcare (UN Charta for the rights of children).
e. CoreMD aims to develop broadly agreed, evidence-based and feasible regulatory policy for evaluation of paediatric medical devices.
f. Preparatory work started in April 2021. By 2022 the project aims to have the evaluation of evidence and recommendations for high-risk medical devices in children in place.
g. A systematic review of available evidence and best practices will be performed, and consensus recommendations will be developed by means of a workshop with experts from EAP members societies and subspecialty societies.
h. The chair requested everyone present to nominate individual experts from member societies with experience in high-risk implantable devices (e.g., central catheters, dialysis catheters, GI and cardiac stents, closure devices used in interventional cardiology, ventriculoperitoneal shunts, etc.).

8. Planned EAP meeting on Public Private Partnership at the European Parliament in the fourth quarter of 2021

a. A paper was published about Promoting Breastfeeding and interaction of pediatric associations with Providers of Nutritional Products (open access).
b. The 7 societies involved are strong advocates of breastfeeding, and promote it, but under the guidance of the EAP these societies identified the need for the provision of high-quality formula (for example, in children with specific dietary needs) and that this should guided by specific standards.
c. The consensus paper is a great start, but it is not yet enough to publish a paper. The societal stakeholders should go a step further to improve standards and practice of BMS marketing and promote public-private partnership with commercial partners including BMS companies.
d. Discussions with stakeholders should be fostered to create exposure and to achieve broader support.
e. The plan is to host a stakeholder meeting co-hosted by EAP and 3 physician Members of Parliament from "European People's Party", "Renew Europe" and "Socialists and Democrats", who already agreed to co-host.
f. It will likely be a hybrid meeting at the EU Parliament in the fourth quarter of 2021.
g. A broad panel of stakeholders will be invited.
h. At the meeting the aim is to formulate conclusions and disseminate the news broadly through media and publication.

8. Other European matters of interest

a. Calls for the first round of Horizon Europe were published. There are opportunities for paediatric research, but lack of calls with a specific focus on child health.
b. Paediatricians should do all they can to make their voices heard by lobbying for more European support and funding for child health research.
c. The EU Innovative Health Initiative was developed as a response to COVID-19: this is a successor of the Innovative Medicines Initiative, with a broader scope beyond pharmaceuticals (including medical and diagnostic devices).

Collaboration is expected from the EU Commission and industry partners (COCIR, EFPOA, EuropaBio, MedTech Europe, Vaccines Europe). The European Commission contributes up to EUR 1200 000 000, industry partners will contribute EUR 1000 000 000

d. Objectives include:
    - To contribute towards the creation of a Union-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations.
    - Foster the development of safe, effective, people-centred, and cost-effective innovations that respond to strategic unmet public health needs.
    - Drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.
e. Continuing Medical Education (CME): UEMS/Biomed Alliance in Europe have declared that commercial enterprises must not direct and offer CME activities for Health Care Professionals, because the existing conflicts of interest make it highly unlikely that bias can be avoided. Trusted information providers are learned paediatric societies, professional organisation, and governmental bodies. This is being challenged by the industry: EFPIA position papers in 2019 state that "Companies can be engaged in Medical Education…". Commercial companies and pharma and infant food providers can contact third parties to create or create their own "non-profit" organisations (academies or institutes) to offer CME activities and promote their products. This is a great concern to the quality of medical education, and it is a threat to the credibility of the medical profession. All medical professionals should advocate that education and CME activities should be organised by non-profit organisations, completely independent of commercial activity to ensure that programmes are balanced and evidence-based, whether on national or international level.

10. Any other business / comments

a. Artur Mazur greatly welcomed the adoption of the ETRS on paediatric endocrinology and diabetes curriculum. The requirements that were developed have been translated to the national level in Poland.
b. The group applauded this exemplary action and encouraged other country representatives to aim for similar actions.
c. The chair thanked all attendees for their participation and adjourned the meeting.

List of Attendees:

Timestamp	Name	Surname	I confirm my attendance at the Secondary-Tertiary Care Council Session on 2 July 2021 | 14.00 - 15.00 CET
7/2/2021 13:02	Iuliia	Zaharova	I confirm my attendance
7/2/2021 13:03	Joana	Rios	I confirm my attendance
7/2/2021 13:10	Miqueas Augusto	Fontana	I confirm my attendance

7/2/2021 13:20	Süleyman	YILDIZ	I confirm my attendance
7/2/2021 13:23	Mohamed	Ghazi	I confirm my attendance
7/2/2021 13:40	Risto	Lapatto	I confirm my attendance
7/2/2021 14:28	Lars	Gelander	I confirm my attendance
7/2/2021 14:32	Pavelescu	Carmen	I confirm my attendance
7/2/2021 14:32	Geitmann	Karin	I confirm my attendance
7/2/2021 14:54	Daniela	Kohlfürst	I confirm my attendance
7/2/2021 15:12	Chris	Pruunsild	I confirm my attendance
7/2/2021 15:21	Marta	Petryshyn	I confirm my attendance
7/2/2021 15:21	Alexiu	Sandra Adalgiza	I did not attend this session
7/2/2021 15:22	Maria	Gutu	I confirm my attendance
7/2/2021 16:16	Lia	Syridou	I confirm my attendance
7/2/2021 16:32	Koray	Boduroglu	I confirm my attendance
7/2/2021 16:36	RUBEL	Francis	I confirm my attendance
7/2/2021 17:13	Stanislava	Hadzhieva	I confirm my attendance
7/2/2021 17:18	Sofia	Hernandez	I confirm my attendance
In person	Adamos	Hadjipanayis	Attendance confirmed
In person	Marina	Mamenko	Attendance confirmed
In person	Berthold	Koletzko	Attendance confirmed
In person	Ivan	Bambir	Attendance confirmed
In person	Yevgenii	Grechukha	Attendance confirmed
In person	Ann	De Guchtenaere	Attendance confirmed
In person	Miguel	Martins	Attendance confirmed
In person	Artur	Mazur	Attendance confirmed
In person	Aida	Mujkic	Attendance confirmed
In person	Liesbeth	Siderius	Attendance confirmed
In person	Arunas	Valiulis	Attendance confirmed
In person	Karoly	Illy	Attendance confirmed
In person	Ivanna	Romankevych	Attendance confirmed