



**MINUTES | SECONDARY TERTIARY CARE COUNCIL
SPRING MEETING 2022**

Hybrid, Friday 13 May 2022, 16:00-17:30 h CEST,
Grand Hotel Excelsior, Valletta, Malta

- 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 03.12.2021** (distributed)
 - a. The minutes were approved
- 4. Matters arising from the minutes -**
No issues were raised.
- 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 European Training Requirements**

Berthold Koletzko shared the status of ETRs. The ETRs for the fields Inborn Errors of Metabolism; Child & Adolescent Psychiatry/Psychother; Paediatr Haematology& Oncology; Neuropaediatrics; Paediatr Respiratory Diseases; and Paediatr Cardiology have expired, i.e. for these subspecialties there is currently no EU accepted subspecialty standards. Updates should be developed with high priority

Subspecialty	Society	UEMS Adopted	Update due
Paediatr endocrinology & diabetes	ESPE	2021	2027
Neonatology	ESPR	2021	2027
Paediatr surgery	EUPSA	2020	2026
Paediatr nephrology	ESPN	2020	2025
Paediatr urology	EUPSA&EAU	2020	2025

Paediatr gastroent, hepatol & nutrition	ESPGHAN	2019	2024
Paediatr emergency medicine	EUSEM	2019	2024
Paediatr infectious disease&immunolgy	ESPID	2019	2024
Paediatr allergology	EAACI	2019	2024
Paediatr rheumatology	PRES	2018	2023
Inborn errors metabolism	SSIEM	2014	2019
Child & adolescent psychiatry/psychother	ESCAP	2014	2019
Pediatr haematology&oncology	SIOPE	2013	2018
Neuropaediatrics	EPNS	2009	2014
Paediatr Respiratory Diseases	ERS PS	2009	2014
Paediatr Cardiology	AEPC	??	!!

7. Strategy for Training Center Certification

UEMS has emphasized the need to establish certified training centres in specialties and subspecialties throughout Europe with high standards to facility good quality of medical training. The process of certification is not intended to be punitive, but to ensure centres can meet needs of training programmes. Criteria will take account of local set-up, e.g. two smaller centres may combine to offer a training programme with trainee rotation. The subspecialty societies are encouraged to establish Programmes for Training Center Certification.

8. EAP Paediatric Guideline APP

The EAP Paediatric Guideline APP has been established and launched, in collaboration and with support of the Child Health Foundation. Currently information on three guidelines are shared, i.e. Celiac Disease, Parenteral Nutrition, and Care for Migrant Children. All societies are asked to propose further guidelines with relevance for a broad group of paediatric practitioners for which further APP-modules could be developed.

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

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. The currently developed concepts on registration of high risk (class III) medical devices for patients in the paediatric age group bear the risk that the offer of such products will be markedly reduced, with potential severe consequences for patient care. Key barriers are the need to submit documented clinical data on suitability and safety which is limited by the difficulty to perform clinical studies in small numbers of patients that require paediatric (or "orphan") devices, high costs for registration which is outsourced to commercial, profit

making “notified bodies”, and very long time periods for product registrations that can apparently reach 18-24 months. Thus it is feared that manufacturers will withdraw medical devices for children sold only in small numbers from the market.

The paediatric work package in the EU funded CoreMD project led by EAP aims to develop broadly agreed, evidence-based and feasible regulatory policy for evaluation of paediatric medical devices. Preparatory work started in April 2021. In 2022 the project aims to evaluate the available evidence on clinical evaluation approaches of high-risk medical devices in infants, children and adolescents with a systematic scoping review approach. Based on these results, consensus recommendations shall be developed in a workshop with experts from EAP member societies and subspecialty societies. The chair requested everyone to suggest 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. EAP meeting on Promoting breastfeeding and interaction of paediatric associations with commercial providers of nutritional products – are they compatible? To be held on 6 Sept. 2022 at the European Parliament, Brussels

EAP led an initiative joint by six other European paediatric associations to define their joint position on Promoting Breastfeeding and interaction of paediatric associations with Providers of Nutritional Products (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7723897/>).

The 7 societies involved are strong advocates of breastfeeding, and promote it, but also identified the need for the provision of high-quality formula (for example, in children with specific dietary needs) and that this should be guided by specific standards. They also supported continued collaboration with manufacturers of infant food products under the conditions of current codes of conduct following ethical and societal standards and with full transparency.

The participating associations supported further discussion with broad stakeholders to create exposure and to achieve broader support. Therefore, a stakeholder meeting co-hosted by EAP and 3 physician Members of the European Parliament from "European People's Party", "Renew Europe" and "Socialists and Democrats" is planned, which should be realized in the fall of 2021, inviting an abroad panel of stakeholders will be invited. At the meeting the aim is to formulate conclusions and disseminate the news broadly through a publication.

10. Other European matters of interest

Many European biomedical associations, including EAP, have published position statements on the Russian war in Ukraine, predominantly addressing the impact on health and health care. The participants welcome these initiatives and encourage the EAP member societies to follow these examples

Assoc	URL	Assoc	URL	Assoc.	URL
EFIS	https://www.efis.org	AACI	https://www.aaci.org/news/med/news/med-top/4654-aaoci-ucua	ESE	https://www.esse-bombona.org/who/who/solidarity-support-for-the-ukrainian-endocrine-community-esse-statements-and-actions/
EFLM	https://www.efim.eu/upload/docs/EFLM-stands-for-peace.png	EACTS	https://www.eacts.org/ukraine-message/	ESHRE	https://www.eshre.eu/ and https://www.eshre.eu/Press-Room/E-SHRE-News
EFORT	https://www.efort.org/message-of-support-for-ukraine/	EAN	https://www.europanet.org/2022/03/18/signed-at-position/	ESICM	https://www.esicm.org/solidarity-statement-for-all-people-impacted-by-the-conflict-in-ukraine/
EHA	https://efaweb.org/organization/newsroom/news-and-updates/eha-national-societies-and-ukraine/	EAP	https://www.espaediatrics.eu/wp-content/uploads/2022/02/EAP-statement-on-Ukraine.pdf	ESMI	https://e-smi.eu/solidarity-with-ukraine/
EORTC	https://twitter.com/EORTC/status/148004404500294037	EAS	https://www.eur-society.org/news/08104/EAS-Newsletter-March-08-2022.htm ; https://www.eur-society.org/news/50785/7he-EAS-stands-in-solidarity-with-the-people-of-Ukraine.htm	ESPGHAN	https://www.espghan.org/our-organisation/Announcements
ERA	https://www.era-online.org/en/the-declaration-of-support-for-ukraine/	EASL	https://easl.eu/news/solidarity-ukraine/	ESR	https://www.myser.org/articles/3430
ERS	https://www.ersnet.org/news-and-statements/news/ers-statement-in-support-of-ukraine/	EAU	https://eurweb.org/news/updated-statement-on-the-war-in-ukraine	EUFOREA	https://www.euforea.eu/sites/default/files/EUFOREA%20Comm%20and%20Managem%20Team%20statement.pdf
ESAIC	https://www.esac.org/esa-news/esaic-message-of-support-for-ukraine/ and https://www.esac.org/supporting-resources/	ECNP	https://www.ecnp.eu/?c_id=12546&E4100-47CA-9094-9E975050090	EULAR	https://www.eular.org/eular-stands-for-peace.htm
ESC	https://www.incardio.org/The-EESC-Member-National-Cardiac-Societies-EESC-Statement-on-the-War-in-Ukraine	ECO	https://www.europancancer.org/resources/246-eco-statement-of-support-for-ukraine.html	UEG	https://ueg.eu/about/who-we-are/koletzko

11. Candidate for the next chair of the Secondary Tertiary Care Council

At the winter meeting in December 2022, the next chair of the Secondary Tertiary Care Council should be elected. All members of this council are encouraged to propose a candidate.

12. Any other business / comments

Berthold Koletzko in his role as the chair thank all attendees for their participation and contribution, and adjourned the meeting.



Prof. Berthold Koletzko
Chair, EAP Secondary Tertiary Care Council