UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES
EUROPEAN UNION OF MEDICAL SPECIALISTS

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UEMS SECTION OF RADIOLOGY NEWSLETTER

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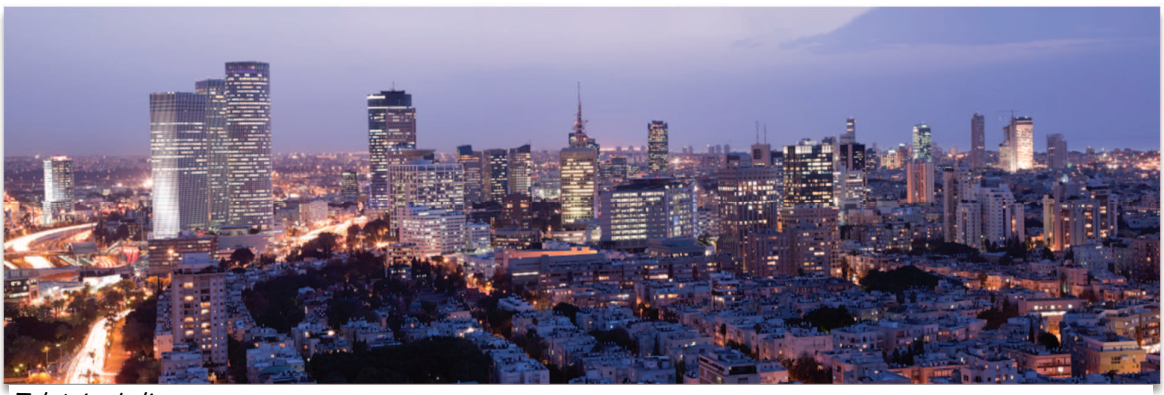
Dear Delegates,

On behalf of the Bureau of the Radiology Section, please find your copy of the Newsletter. As a central topic of this issue, we have decided to focus on the numerous outcomes of the last UEMS Spring Council, held in Tel Aviv on 27th – 28th April.
The Council has seen a huge participation and it has been a crucial occasion to enhance the future dialogue and collaboration between the UEMS and the most notable European Scientific Societies, which will have the occasion to meet during an *ad hoc* UEMS-ESSs meeting, scheduled on Thursday, 19th October 2017.



Tel Aviv skyline

The president of our Section – Prof. Paolo Ricci – is involved in the Working Group responsible for the agenda of the meeting in representation of the Radiology Section.

In addition, you will find a brief report on the annual CESMA spring meeting, celebrated in Glasgow on Saturday, 13th May 2017, the usual highlights from the European Institutions concerning the radiological world and the calendar of the UEMS incoming meetings.

Finally, I would like to take the occasion to inform you that the next meeting of the Section, will take place in Rome – at the Policlinico Umberto I – on **Saturday, 30th September 2017** (10:00 – 16:00). Our President and the entire bureau of the Section are looking forward to meeting you there.

With warmest regards,
Francesco

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Outcomes of the UEMS Spring Council

During the last Council in Tel Aviv, the new UEMS Rules of Procedure have been approved and all the Specialist Sections will be asked to conform to the new text within the maximum time limit of three months starting from the date of their adoption by the plenary Council. Amongst the main differences:

- English becomes the sole working language for issuing official documents. Nomination of all delegates to UEMS bodies – Sections included – has to be confirmed by the respective National Medical Authorities.

- Since the creation of an Advisory Board had been already approved at the Autumn Council 2016, Presidents and Secretaries of the Sections will now sit in the Council in an advisory capacity.

- Voting procedure in the Council will change and the Advisory Board will be given significant - yet non-decisive - powers. Before the meeting of the Council, the Advisory Board will discuss and vote in an open ballot on the topics that are to be voted on by the Council. The outcome of the voting is announced to the Council by the Advisory Board chairperson when that specific topic is considered by the Council. Subsequently, the Council will vote: if the result of the Council voting is in agreement with the previous opinion of the Advisory Board, that decision is final; in case of discrepancy, the UEMS Executive will conduct further discussions aiming at achieving a consensus and the matter will be voted on again at the next Advisory Board and Council meetings. The decision of the Council made at that meeting will be final.

- The Council meetings will take place twice a year (spring and autumn) and at least once in Brussels. If the meeting of a Specialist Section takes place in Brussels, it is expected to be held at the *Domus Medica Europaea*.

- The new conditions to be elected a national Delegate within a Specialist Section are the following: each National Medical Authority (NMA) should be represented by two doctors in active practice, competent in English, appointed with the agreement of the respective NMA. The same conditions apply to all the UEMS bodies, including CESMA, Multidisciplinary Joint Committees and Thematic Federations.

- Elections of Section´s Presidents and Secretaries will follow the same rules, timeline and quorum of the UEMS President´s election (Art. V.1 of the new RoP).

For what concerns the general life of UEMS Specialist Sections:

- The European Training Requirements (ETR) in Nuclear Medicine, Psychiatry, Medical Genetics and Gastroenterology have been approved by the Council as well as the creation of the MJC Thoracic Oncology. ETR *Guidelines & Document on visitation of Training Centers* have been adopted.

CESMA celebrated in Scotland its 10th anniversary

On Saturday, 13th May 2017, CESMA delegations met in Glasgow, the place where the *Council for European Specialists Medical Assessment* was created ten years ago. Alongside the celebration of this historical anniversary, which will be followed by the UEMS's 60th birthday next year, Mr. Bertrand Daval - UEMS Chief Executive Officer - has marked the accomplishments already achieved by the European Union of Medical Specialists in this past decade. Encompassing 39 different Member Countries and 43 Specialist Sections, the UEMS is now one of the biggest medical organisations worldwide with its own home, the Domus Medica Europaea in Brussels.

A bird´s-eye view of Glasgow

CESMA Chairman – Prof. Zeev Goldik – whose mandate has been prolonged *ad interim* until the next winter meeting, has remarked how CESMA's future role will be focused on the adoption of guidelines for the organisation of European Specialty Examinations (writing multiple-choice questions, proper examination procedures and the possibility of appeal mechanisms). A proposal for endorsement by the Council of a policy document on European Specialty Diplomas/European Assessments – a more updated version of the original Glasgow Declaration – was also formulated.

The creation of a central database of successful candidates, the definition of a future European Assessment Model and a comprehensive advocacy strategy for the recognition of UEMS European Diplomas, have been some of the other relevant topics discussed in Glasgow. Finally, CESMA Secretary – Dr. Owen Sparrow – illustrated the results of the last survey conducted amongst specialties, Boards, Societies and MJCs which are currently conducting the examinations.

Save the date

Meeting with delegates of the Neuroradiology division: Malmö, 16th September 2017.

CIRSE congress: Copenhagen, 16th – 20th September 2017 (the meeting of the Interventional Radiology division will take place during CIRSE 2017, exact day to be defined)

Meeting with delegates of the Radiology Section: Rome, 30th September 2017

UEMS ESSs meeting: Brussels, 19th October 2017

UEMS Autumn Council: Brussels, 20th – 21st October 2017

ACI – ETAP and ESR Annual Leadership Meeting: Barcelona, 17th November 2017

Voices from Brussels: A new regulation for European Medical Devices

Over the last decade, the European Union has implemented several measures concerning the regulation of Medical Devices, which are essential to the healthcare and wellbeing of European citizens, from x-ray machines to artificial hips, also including *in vitro* diagnostic devices (e.g. HIV blood tests or blood sugar monitoring systems for diabetics).

On 5th April, a plenary vote of the European Parliament completed the revision process of the old regulatory framework started by the Commission in 2012 and established a modernised and more robust legislative scheme which will grant a better protection of public health and patient safety.

By replacing the outdated rules with new stricter requirements – especially for high-risk tools – this legislation will help to ensure that all medical and *in vitro* diagnostic devices circulating across Europe are safe and perform well, reflecting the latest scientific and technological state-of-the-art. The rules will increase traceability, market transparency and legal certainty for producers, manufacturers and importers and could also help to strengthen international competitiveness and innovation in this strategic sector.

Elżbieta Bieńkowska, Commissioner for Internal Market, Industry, Entrepreneurship and SMEs, declared: "*I'm extremely happy that our push for stricter controls of medical devices on the EU market will now become a reality. (…) We should not wait for another scandal instead we should start a discussion how to strengthen European oversight over Member States' market surveillance activities.*"

Improve the quality, safety and reliability: The new rules will impose tighter controls on high-risk devices such as breast implants, requiring a pool of experts at the EU level to be consulted before placing the device on the market. Controls will also be tightened on clinical trials as well as on the bodies that can approve the marketing of medical devices. The new rules will also cover certain, previously unregulated aesthetic products (e.g. coloured contact lenses). In addition, a new system for risk classification in line with international guidelines will specifically apply to *in vitro* diagnostic medical devices. A financial mechanism will ensure patients are compensated in case defective medical devices harm them.

Strengthen transparency of information for consumers: The new regulations will make sure that vital information is easy to find. For instance, patients will receive an implant card with all the essential information, and a unique device identifier will be mandatory for every product so that it can be found in the new European database of medical devices (EUDAMED).

Enhance vigilance and market surveillance: Once devices are available for use on the market, manufacturers will be obliged to collect data about their performance and EU member states will coordinate more closely in the field of market surveillance.

To allow manufacturers and authorities to adapt, however, the new rules will only apply after a transitional period, namely 3 years after publication for the Regulation on medical

devices and 5 years after publication for the regulation on *in vitro* diagnostic medical devices.

Link:

http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=9119

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