Union Européenne des Médecins Omnipraticiens / Médecins de Famille
European Union of General Practitioners / Family Physicians

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UEMO board statement on the European Commission's proposal for a regulation on HTA

- UEMO, European Union of General practitioners/FamilyDoctors aims to study and promote the highest standard of **training**, **practice** and **patient care** within the field of **general practice** throughout Europe; one important point defended by UEMO is general practitioner's **freedom of practice** in the interest of the patient, permitting a person centred medicine. For UEMO the role of GP is to adapt evidence to individual patient's situation in local health care communities.
- UEMO defends the idea that it is impossible to qualify all Gp's activity as technology, including some medical procedures and measures, belonging to **clinical expertise**. Of course individual clinical expertise must be integrated with best available external evidence.
- For reasons mentionned above, UEMO welcomes the « Proposal for a regulation of the European Parliament and the Council on HTA », defining clearly HTA as an evidence based process, centred on clinical aspects, with non clinical aspects remaining in the hands of Member States according national context.
- The proposal, creating a permanent structure is a good framework to avoid multiple requests, duplication, variation, and administrative burden.
- At article19c, Commission supports voluntary cooperation for assessments on **health technologies other than medicinal products or medical devices**. Health technology, as defined by Directive 2011/24/EU, means a medicinal product, a medical device or **medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment** used in healthcare. UEMO is aware that in some Member States' regulation on medical profession with quality standards increase bureaucratic workload without any evidence on health outcomes[1]. The definition of health technology according to WHO[2] is "the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life." In this respect, we suggest to specify that the support for assessments of other technologies than medicinal product or medical devices (like the system of standards for increasing the quality of medical services and patient safety, using as a method the evaluation and accreditation of service providers) must also be evidence based and reglemented through the proposed Regulation.

The UEMO would like to further underline 4 points:

- 1. For the selection of medical devices, potential danger can also be an important criteria according the non maleficience principle.

- 2. For the creation of coordination group and sub-groups more transparency could be important, for example with a declaration of interests.
- 3. Joint scientific consultation is only open to health technology developers. This should be extended to other health stakeholders.
- 4. Criteria for the selection of stakeholders' organisation (established in the open call) could be more transparent.

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