CPME/AD/EC/12022015/008_Final/EN

On 12 February 2015, the CPME Executive Committee adopted the 'CPME response to the EMA public consultation "Draft proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited – EMA/42176/2014"' (CPME 2015/008 FINAL)

CPME response to the EMA public consultation
"Draft proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited – EMA/42176/2014"

The Standing Committee of European Doctors (CPME)[1] represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME welcomes the European Medicines Agency (EMA) public consultation on the Draft proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited – EMA/42176/2014".

Transparency of clinical trial data and results is essential to the good conduct of medical research, to the development of new medicines and medical treatments, to expand scientific knowledge on those medicines and treatments and for patient safety. CPME has a longstanding policy on medical research and repeatedly advocates for the need to ensure full transparency of clinical research (CPME 2012/132; CPME 2013/019; CPME 2013/088).

Ensuring transparency is a matter of drug efficacy and safety, whereby information on clinical trials is publicly disclosed and hence made available to patients, prescribers and researchers. The broad access to data is crucial to develop innovation and stimulate further research.

Transparency is also a matter of public trust and confidence in the European research community and the EU regulatory system for a safe evaluation and supervision of drugs in Europe.

CPME would like to highlight the following points:

- The EMA draft proposal for an addendum states that "Commercially confidential information can be considered as meaning any information contained in the data or documents submitted to the database that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the sponsor" (l. 457-759, p. 13/28). While it is

[1] CPME is registered in the Transparency Register with the ID number 9276943405-41.

understood that commercially confidential information can be critical to pharmaceutical companies, CPME insists that all results of clinical trials, whether they are positive, negative or inconclusive, should be made publicly available. The legitimate economic interest of the sponsor should therefore be defined in a restrictive way and should not take precedence over the public legitimate interest to gain knowledge and be informed in a timely manner about prescription and non-prescription medicines that are on the EU market or that are being investigated. In many countries, ethical rules do not allow for physicians to be involved in clinical trials where the outcomes are not transparent/public.

- Similarly, the notion of "overriding public interest" (l. 480-484, p. 14/28), through which the confidentiality status of a commercial information can be lifted, should be understood and defined in a broad manner, thus allowing the general public, the research and medical community a wider access to vital information.
- The above comments apply similarly to clinical trials on products that have already obtained a marketing authorisation and to those for which no marketing authorisation has yet been delivered (sections 4.4.2 and 4.4.3.6). Not all clinical trials will lead to a marketing authorisation. The data of these trials should however still be made public. Indeed, the legitimate interest of the public to access information on eg. sister molecules or generic drugs should not be considered lower than for the investigation on originator drugs. The same disclosure policy should apply to these clinical trials.
- Section 4.2. defines the different data that will be made public for every clinical trial. CPME suggests that the financial sources of clinical trials are included in the disclosure. Section 4.2. should hence contain the following bullet point: *"the entity(ies) or individual(s) that finance the clinical trial."*