CPME/AD/EC/300710/092_Final/EN

On 30 July 2010, CPME Executive Committee adopted the "CPME response to "Developing a Strategy for the Heads of Medicines Agencies, 2011-15" (CPME 2010/092 Final EN)

CPME response to

"**Developing a Strategy for the Heads of Medicines Agencies, 2011-15"**

The Standing Committee of European Doctors (CPME) aims to promote the highest standards of medical training and medical practice in order to achieve the highest quality of health care for all patients in Europe. CPME is also concerned with the promotion of public health, the relationship between patients and doctors and the free movement of doctors within the European Union. CPME's members are the most representative National Medical Associations of 27 countries in Europe and works closely with the National Medical Associations of countries that have applied for EU membership as well as specialised European medical organisations.

CPME notes that the two main background challenges facing the HMA are set out in the consultation document's introductory paragraphs. These are first, the wide variety of "themes" that have emerged from the HMA's review (Paragraph 1.3). Secondly, the differing roles (Paragraph 2.3) of the 44 National Competent Authorities (NCAs) creates a challenge for a collaborative and consistent approach to the "themes". A third factor is that in most Member States there is a separation between the concepts of evidence-based regulation (the core function of a NCA), and an approach that also embraces relative effectiveness, of which NICE in the UK is an example. The operation of NICE-type bodies can act as a restraint on, or an opposition to the next step beyond regulatory approval - the introduction of a pharmaceutical product into use (see our later comments).

From CPME's point of view, which is to improve the efficiency and effectiveness of the doctor/patient relationship, the themes of most importance are the strengthening of surveillance of the benefits and risks of medicines, good communication, and the best use of IT. With regard to all themes, we accept that NCAs and the European Medicines Agency have complementary roles, but this will be most effective if there is similarity in stakeholder involvement (see our comments on Paragraphs 5.59 to 5.61).

Rue Guimard, 15 - B-1040 Brussels - Belgium
Tel. : +32 (0)2 732 72 02 - Fax : +32 (0)2 732 73 44 - E-mail : secretariat@cpme.eu - Web : http://www.cpme.eu

In addition, as the EMA has clearly identified a need to work more specifically on its outwardly facing role in information provision, and on more efficient pharmacovigilance, it is at least highly desirable that its methods of developing these are as far as possible mirrored in NCA function and structure. This is an approach that will maximise the “added value” that EU-level bodies provide to national ones.

On “Key challenges” (Section 3), the list is comprehensive, but many of the “challenges”, such as economic changes as a result of the recession, and political changes in the EU are more “background” issues over which the HMA currently has minimal influence. There are challenges that are more directly relevant. One groups around demographic and environmental changes, and major health threats, and argues for more structured and interoperable methods of surveillance. Another includes increasing the role of the patient in treatment decisions and a use of health IT that genuinely complements the patient/doctor interaction, and argues for a realistic and practical use of eHealth (such as the developments already under way in the epSOS and CALLIOPE projects, and the restructuring of eHealth governance in DG-INFSO). In both these areas the HMA has an essential function, and scope for development. For instance, we observe the emerging tendency for patient-based pharmacovigilance measures, but we would like to see this area subjected to careful review before it becomes an additional function of NCAs.

CPME feels that more development is needed in two other areas:

The first, already mentioned, is the difference between regulation and relative effectiveness. The consultation document raises the challenges of demographic change, financial crisis and increasing healthcare costs. These cannot be addressed by an organisation, and its network of NCAs, through regulation alone. A “challenge” for the HMA, therefore is whether it needs to move into a position where it also influences what is a much more politically sensitive area, which is by creating a specific function in the area of relative effectiveness. Obviously, given the wide variation in healthcare provision at MS level, this would be general rather than specific, and would be based on general principles, but would represent a move that would involve the HMA more widely in the journey a product takes from innovation through trialling and regulation, to its introduction.

Secondly, the issue of innovation is touched on too lightly. It reappears in the section on Health Technology Assessment (Paragraph 5.31), but more attention needs to be given to the support required for the introduction of innovative therapy, and the early development of technological products. Both areas are characterised by expensive start-up costs and the expense of going through regulatory procedures. Pharmaceutical companies can bear these costs. Small enterprises cannot, and we are disappointed by the weak approach set out in Paragraph 5.33, since it will delay, or even prevent, the development of medical devices of real long-term clinical value. On innovative pharmaceutical product development, a particular problem arises in

Rue Guimard, 15 - B-1040 Brussels - Belgium
Tel. : +32 (0)2 732 72 02 - Fax : +32 (0)2 732 73 44 - E-mail : secretariat@cpme.eu - Web : http://www.cpme.eu

pharmacogenetics. The use of these products is necessarily highly population focused, and the “lead-time” on development through to introduction is far too long, as the EMA’s recent work on drugs for the alleviation of the symptoms of Duchenne Muscular Dystrophy has demonstrated. Finding a way to reclassify these products so that they are fast-tracked is essential for a future that will see more of them being developed.

Finally, we wish to comment on Section C, on “Communication”, especially in relation to Paragraphs 5.59 to 5.62. CPME has a good experience of working with the EMA, especially through its healthcare professionals’ group. Our representative on this also represents HCPs on the parallel EMA group for patient organisations. This interaction is extremely beneficial, and we commend it for NCA implementation. Paragraph 5.59 lists a formidable group of stakeholders. Many of these are at some distance from the core activities of the HMA, but need to be kept informed. Better technology points to the use of the website as a major vehicle for information, and again the reform of the EMA’s website provides a useful example of a successful innovation.

Rue Guimard, 15 - B-1040 Brussels - Belgium
Tel. : +32 (0)2 732 72 02 - Fax : +32 (0)2 732 73 44 - E-mail : secretariat@cpme.eu - Web : http://www.cpme.eu