The Standing Committee of European Doctors (CPME) 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.

Public survey on the "Transparency Directive" (89/105/EEC)

The Standing Committee of European Doctors (CPME) would like to share its views in relation to the study launched by the Directorate General for Health and Food Safety of the European Commission on the state of functioning of the Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.

First, CPME would like to highlight that the lack of transparency all along the lifecycle of medicines reduces countries' ability to negotiate fair prices. One of the major shortcomings of the Transparency Directive is that currently the "transparency" in the Directive only applies to relations between national competent authorities and pharmaceutical companies. Society should have access to information from across the lifecycle of medicines, including on decisions relating to pricing and reimbursement, as well as other elements with direct impact on price.

Second, CPME considers transparency as a prerequisite for pharmaceutical pricing. The transparency should encompass not only R&D and manufacturing costs but also incentives, such as granted market exclusivity and received public investment at the stages of research and clinical trials. Given that a significant percentage of industry R&D is paid by taxpayers, governments should be encouraged to systematically request more transparency from manufacturers. Whereas the drug regulatory system is highly complex and fragmented, there is a need to take into account and reflect in the final prices prior incentives that companies benefited from as part of the drug development. In this respect, the final price of a drug should be reasonable and not entirely disconnected from the public investment and the manufacturing costs.

Third, guidance on the use of managed entry agreements (MEA) and the confidentiality clauses would be helpful. Such agreements take away opportunities to exercise public scrutiny and accountability on the use of healthcare resources, hamper international discussion and best practice sharing about the use of critical medicines under MEA and prevent the building up of future knowledge on dealing with such medicines. These agreements should therefore only be used in specific, restricted cases, with a clear definition of the intended benefits of such

agreements, what follow-up on those agreements will be in place, as well as a report on how they performed.

Fourth, national approaches differ widely when it comes to define prices and evaluate different criteria such as the therapeutic added value or the value for society. However, sensitive national differences could still be taken into consideration when Member States would be invited to participate in a voluntary cooperation on pricing. Consequently, CPME favours a multidimensional approach to pharmaceutical pricing, based on health technology assessment (HTA), where various factors are taken into account from the therapeutic added value and the value for society to the ability to pay and the cost of drugs. Additionally, the priorities required in pharmaceutical pricing must first concern patient's rights, then be applied to solidarity in care determined by need, and finally concern cost efficiency. Finally, a better integration between HTA and scientific approaches right from the start is needed in order to address real unmet medical needs of the patients, ensure a better positioning of medicinal products in the therapeutic strategy but also ensure the sustainability of healthcare systems.