HEALTH ACTION INTERNATIONAL EUROPE

Health Action International - Europe

Input to the *Reflection process for a new EU Health Strategy*

Health Action International Europe (HAI Europe) welcomes the opportunity to engage in the process of developing a new European Union (EU) health strategy. HAI Europe welcomes especially the assertion that 'good health must become a driving force behind all policy-making (p2)' and hopes that the end result of the current consultation process will be a strategy that can bring about improved health and reduced health inequalities in the EU.

Before detailing a number of specific points, HAI Europe would first like to establish that it considers that although good health may certainly be a means to achieving economic growth, it is fundamentally an end in itself. States' responsibility to fulfil their citizens' right to health is paramount. The policies and operations of EU institutions should act at all times in support of the fulfilment of the right to health of EU citizens. HAI Europe appreciates the acknowledgement that the European public health programme 'has nowhere near the resources needed to achieve good health p10)'. HAI Europe believes that the best way to develop and find the resources for a health programme more truly proportional to EU health needs is to found that programme on a commitment to improving health *per se*, prior to secondary benefits that that may bring in terms of economic growth.

Tying together the goals of public health and of economic growth leads to an overemphasis on public health solutions that can most readily be assumed to also ensure the profitability of pharmaceutical companies. Public health solutions centred on supporting the production of a succession of new medicines reflect a commitment to safeguarding the competitiveness of the pharmaceutical industry first, and a commitment to safeguarding the right to health second. HAI Europe welcomes the discovery and circulation of innovative medicines which offer a decisive therapeutic advantage on those already available, but believes that only a small proportion of new medicines genuinely meet this criterion. Rather HAI Europe believes that an EU health strategy must be based on two key elements: firstly, a concerted effort at tackling the causes of ill-health, which the discussion paper draws attention to; and secondly, the rational use of medicines based on an objective assessment of benefit and risk.

The rational use of medicines is threatened by a failure to directly confront the tension between public health goals and those of the pharmaceutical industry. The latter's priority is to maximise profits by concentrating on producing medicines for

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which markets are secure, rather than those for which public need is strongest. Already rewarded by patent protection for its cautious approach of investing only where profits can be expected, the pharmaceutical industry positions itself as though in need of further incentives or release from regulatory 'barriers to innovation'. The tone of the *Reflection Process* is supportive of the need to help boost the industry's competitiveness. The adherence to a view that the pharmaceutical industry has only a positive contribution to make to achieving public health goals runs in contrast to the greater scepticism directed towards manufacturers of food products. Recent examples of anti-depressants and Vioxx undermine the case that regulatory practices can be loosened. They also raise the question of whether European consumers' taxes and insurance contributions are being used efficiently. HAI Europe believes that the EU and member governments have a responsibility to explore alternative, more sustainable mechanisms to finance public needs-driven therapeutic innovation.

The discussion paper underlines the importance of enabling EU citizens to have access to 'clear and reliable information on how to be in good health and about diseases and treatment options (p10)'. This should be a matter both of providing information directly to patients – reflecting the range of levels of 'health literacy' – and to health professionals, as those best able to filter information to the patient's best interest. Targeted to patients or to health professionals as appropriate, the commitment to openness apparent in the paper should include access to pre-marketing trial data, to the assessments on which marketing authorisation is granted and to ongoing evaluations of adverse reactions after a medicine comes on to the market. The new EU pharmaceuticals legislation brought progress in terms of the second of these three elements, but more needs to be done to enable patients to make choices on the basis of knowing how a medicine has behaved both before and after marketing. HAI Europe concurs with the conclusion of the European Medicines Evaluation Agency (EMEA), following its own process of consultation with patients, that there is a need to "clearly define the concept of 'commercially confidential information' in order to allow for transparent communication[1]". Too often the excuse that information is 'commercially confidential' is used to disguise evidence that the results of clinical trials are not uniformly positive.

Towards the same goal of allowing patients and health professionals to properly gauge the benefits and risks of medicines, HAI Europe urges that one element of the EU health strategy should be the identification of ways of collating, verifying and acting upon patients' own reports of adverse reactions to medicines. Although HAI Europe recognises there are problems in interpreting and standardising patients' data, pharmacovigilance based solely on the spontaneous reporting of health professionals is a necessary, but not sufficient, means of ensuring the ongoing monitoring of medicines' safety. Broadening the avenues for receiving reports of adverse reactions would itself be a demonstration of the intent to listen and be receptive to patients.

HAI Europe acknowledges that the paper makes clear a willingness to listen to the views of a broad range of stakeholders and that there is a trend to look to patients'

[1] EMEA / CPMP Working Group with Patients Organisations, outcome of discussions: recommendations and proposals for action, p8; EMEA/CPMP/5819/04/Final, 20 April 2004

representatives to take places on working groups and now also on the management board of the EMEA. HAI Europe welcomes this trend, but cautions that such representation be neither tokenistic nor steered towards non-governmental partners with financial or other links to the pharmaceutical industry. There should be transparency in declaring interests from all representatives on consultative and decision-making bodies, whether from industry, government or non-governmental organisations.

Finally, HAI Europe would like to acknowledge the commitment to accord a greater priority to the EU's international role of health. The countries of the EU possess much experience in disease prevention and control, and the transfer of the knowledge and technology available in Europe to developing countries is both in keeping with obligations under international treaties, and reflective of responsible engagement in Europe's global civic duty. Such initiatives as the European and Developing Countries Clinical Trials Partnership (EDCTP) hold great promise in improving world health and are to be encouraged. HAI Europe believes the EDCTP could serve as a useful model for stimulating research into neglected diseases, which reflect a failure in global and national policies to protect the right to health. The EU should lead the world in amending those of its policies that continue to hamper enjoyment of this right, including where necessary trade, customs, and intellectual property laws that impede the capacity of the EU to support other countries in protecting the health of their citizens.

HAI Europe hopes that these comments are received in the same spirit in which they are offered and looks forward to a continued engagement with the Directorate-General for Health and Consumer Protection in the evolution and implementation of its health strategy.

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