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# Health Action International Response to the EU Commission Consultation on the Future of Pharmaceuticals

The draft as it currently stands appears to mainly support industrial competitiveness at the expense of public health and protection of the safety of European citizens. As a fundamental principle, public health needs should not be overridden by commercial interests and it is the European Union's mandate and duty to safeguard its citizens and promote health and well-being.

## Redefining Research & Development

The European Union has a role to play in the overall redefinition of research and development priorities for medicines. This entails, among other initiatives, the financing and sustainability of public research to develop medicines for neglected diseases, ensuring that the fruits of public financed research remain in the public domain.

## Clinical Trials

The way should be cleared for more non-commercial independent clinical trials. The European Union can take a proactive role in financing and administrating large-scale clinical trials to answer questions of importance to public health in Europe and internationally, which are unlikely to be addressed by the commercial agenda of the pharmaceutical industry. This should include for example comparative trials of drug and non-drug approaches to disease prevention and treatment.

Medicines are increasingly being tested in low-income and developing countries. If these trials are carried out on behalf of companies based in Europe, the European Union has a responsibility to ensure that high standards of informed consent and safeguards of trial participants are incorporated.

## Transparency of pharmaceutical regulation

The first priority in meeting unmet public information needs should be to ensure all information on drug safety and effectiveness that is submitted to regulatory authorities should be publicly available, including all pre-market laboratory and clinical data and post-marketing studies.

National regulatory authorities and the EMEA are gatekeepers to information. Regulatory agencies are also responsible for ensuring the availability and quality of patient information leaflets, assessment reports, and also information on drug safety, as required by EU transparency obligations. However, European Public Assessment Reports (EPAR) are only available for centrally authorized products, which represent a low percentage of the overall medicines available in the EU. In addition, the information provided in the EPAR summary on product efficacy or safety is not sufficient to allow a thorough appraisal of treatment options by patients.

'Commercial confidentiality' cannot be a legitimate reason to withhold information on medicines that is relevant for patients and healthcare professionals. In any case, the official definition of this

term now employed by the EMEA is too wide-ranging and should be changed. Health professionals, patients and the public have a fundamental right to the complete body of scientific evidence on the health effects of medicines. Without access to this information all medicine use is by definition uninformed. When this information access is partial and biased – for example the common practice for companies to publish the results of one more positive trial and fail to publish a second more negative trial – medicine use is consciously misinformed. There is an important role to be played by healthcare professionals in the provision of information about medicines to patients, they should not be considered as mere intermediaries for information provided by pharmaceutical companies.

### Informing European Citizens about medicines

Following a period of dynamic research and development output, the pharmaceutical industry has been facing hard times, with patents on blockbuster drugs expiring and fewer promising new products in the pipeline. Confronted with these difficulties, pharmaceutical companies have devised a range of commercial strategies, one of which is to advertise their products –including prescription drugs – directly to the public. In the push to allow direct communication with patients in the European Union, pharmaceutical companies are marketing advertising as 'information'. Information from pharmaceutical companies does not assist patients to make informed choices. It simply creates demand for particular medicines by manipulating consumers.

Demand for particular medicines is created in two ways: by generating demand for one medicine over other treatments – usually a newer more expensive medicine that is still on patent; or by making consumers think they need a medicine when they do not, by promoting medicines as solutions to less severe symptoms or by disease creation – making people think they are sick when they are well.

The European Commission is proposing public-private partnerships as a solution to the "information desert" that it assumes Europe has become. Private-public-partnerships in information provision, involving either the pharmaceutical or the medical device industry, represent clear conflicts of interest and it is very likely that this will lead to irrational use of medicines and increased costs.

The Pharmaceutical industry should not have a role in providing the public with information on drug and other medical treatments, because of the inherent conflict of interest reflected in such a role. Pharmaceutical companies have a responsibility to their shareholders to promote sales and profitability. This is inconsistent with the needs of patients and the public for independent, unbiased information.

HAI Europe stresses the importance of article 88 of Directive 2001/83/EC, which is the only legislative safeguard against introduction of direct-to-consumer advertising of prescription drugs. Article 88 should be maintained intact. There is no public health rationale for weakening or amending this prohibition.

### Ensuring the safety of medicines within the European Union

The draft as it stands confuses the notions of counterfeit and substandard medicines. The latter is the major concern for public health. However this is mainly a problem outside of Europe. The reports of counterfeiting within the European Union have been anecdotal and there is no evidence supporting a major hazard to public health, as is stated in the consultation draft.

The true challenge remains in assessing the consequences of medicines use in Europe. Thus far, there is no Pan-European research on the health outcomes of medicine use. Overall rates of adverse drug events per country are unavailable, as are the rates of clinical benefit deriving from

some of the most frequently used medicines. Bearing in mind recent estimates of widespread harm to public health caused by rofecoxib, there is a need for a broader and more systematic assessment of the public health impacts of drug treatments. Such assessment should be integrated into public health surveillance, similarly to disease epidemiology and accident and injury rates.

Pharmacovigilance should not be considered as a trade-off for inadequate pre-market assessments and authorization. Prevention of harm should always be given priority over faster drug approvals, and citizens need to know that medicines have been shown to be efficacious in terms of outcomes of importance to their health. Risk management programmes are no substitute for pre-market evidence of adequate safety and effectiveness. A worrying trend is the implementation of risk management programmes without adequate attention to development of systematic methodology nor assurance that results are of the highest possible scientific standard. These studies should be carried out publicly rather than being led by manufacturers, as the latter have an inherent conflict of interest between the need for returns on investments and discovery of new serious harmful effects that could lead to market withdrawals.

The role of patient reports of adverse drug events should be strengthened, thereby contributing to better medicine use and earlier detection of harm.

### What can be done to improve Europe's international competitiveness

This is not of general concern to patients and healthcare professionals. What matters is access to safe and effective drugs that correspond to real healthcare needs. If the aim is to improve access to drugs that represent a real therapeutic advance and that benefit patients, then the Commission is on the wrong track. The Commission should be looking instead at mechanisms to ensure that conditions of marketing support R&D to meet health needs. For example, in order to obtain market approval, companies should be required to show that their new drug is superior to existing alternatives. This would create an incentive to produce drugs with true therapeutic value. Similarly, companies could be penalized for unethical promotion of medicines, for example through withdrawal of market authorization.

### Convergence of pricing and reimbursement

There is a need for greater transparency of pricing, with centralized information available on prices of medicines throughout the EU. Unlike many other products, the prices of drugs have fundamental implications for society and public health, since they determine access to necessary medical care. Decisions on pricing and reimbursement should remain with individual member states. However, the criteria through which a medicine's effectiveness is appraised should be harmonized. For example, not all member states require pharmaco-economic evaluations. Additionally, reimbursement decisions should be fully transparent. Currently, a major barrier to transparency is commercial confidentiality of drug safety and effectiveness and pricing data. Information on the actual cost of production should also be made public to avoid situations in which citizens are overburdened or denied potentially life-saving treatments due to unrealistically high medicine prices.