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Prescrire

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Reorienting European Medicines Policy

Background

European regulations on medicinal products, adopted during the 1960s and 1970s, have had a major positive impact in European Member States. In particular, they have obliged national policy-makers to create effective drug control and monitoring infrastructures designed to improve health care quality and patient safety, and also to stimulate healthy competition among drug manufacturers.

The European Medicines Evaluation Agency (EMEA) was created in response to the call for greater European integration. More resources and more independence were expected to bring greater transparency and harmonisation.

But, discreetly, by a thousand cuts, EMEA has been driven away from its primary mission as a safeguard of European citizens' health. The pharmaceutical industry now has its foot firmly in the door.

Strangely, EMEA is part of the Enterprise Directorate General rather than the Health and Consumer Protection Directorate of the European Commission. It now receives most of its funds directly from the drug companies. The administrative open door known as the mutual recognition procedure has been institutionalised and a shroud of secrecy has descended. The European pharmacovigilance system has not fully materialised, and most of the data obtained in this field have remained in a black box.

Ever more pressing, the pharmaceutical lobby, supported (and sometimes preceded) by the Enterprise Directorate, has been making strenuous efforts to ensure that the European Directive on medicines for human use are changed to suit the best interests of industry.

Its overriding objective is to make the European market even more permissive, with permanent marketing authorisations granted more rapidly and more easily, with no need to show therapeutic advance; no regular postmarketing reappraisal of the risk-benefit ratio; no public explanation of EMEA decisions; no comparative assessments on which to fix prices more reasonably; and direct-to-consumer advertising of prescription-only drugs under the guise of "information".

We are publishing a series of documents and reviews on current European pharmaceutical policy, aimed at helping individual citizens and policy-makers to reach well-founded conclusions.

Among these papers you'll find a detailed description of the European Medicines Evaluation Agency (EMEA) website, notably underlining its fake transparency.

We offer a description of the instruments and institutions of European pharmaceutical policy, and a review of the current activity of EMEA, the cornerstone of the system. We identify a number of strong points and institutions that should be maintained, but we also identify strategies that are being used to drive the system away from its primary objective: public health.

We also report on the proposals of Directive and Regulation of the European Commission Enterprise Directorate (on behalf of a pharmaceutical lobby group), and the positions of various patient and consumer organisations and professional bodies.

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A CALL TO NATIONAL AND EUROPEAN POLICY-MAKERS

Putting european drugs policy back on tracks

It is vital to restore European pharmaceutical policy to its rightful public health context, for the individual and collective benefit of European citizens, by restoring independence and transparency throughout the system.
If the pharmaceutical industry is to remain dynamic and efficient in the long term, it must be actively re-directed towards true public health needs and therapeutic advance, both in Europe and throughout the world.
We call on members of the European Parliament, ministers of the Council of Europe, and European Commissioners to reconsider the policies outlined in the draft Directive and Regulation on medicinal drugs prepared by the European Commission's Enterprise Directorate.
In the interests of public health, we call them to adopt new priorities.

Our demands are the following:

Public health before industry. *Medications being a cornerstone of any health policy, national and European regulatory bodies charged with authorising new drugs and postmarketing surveillance must be directly accountable to national and EU health authorities.*
Thus,
• European Union health ministers, and not industry ministers, must, in conjunction with the European Parliament, decide European pharmaceutical policy and all relevant Directives and Regulations;
• The European Medicines Evaluation Agency (EMEA) must become part of the Health and Consumer Protection Directorate General instead of the Enterprise Directorate General.

Financial independence. *Given the massive economic stakes, it is essential that the structures and personnel charged with drug registration and control be financially independent from pharmaceutical companies.*
Thus,
• The budgets of EC Member States and of the European Union itself must rapidly be increased to cover the full operating costs of national and European medicines agencies;
• Fees paid by drug companies for marketing applications must be attributed to Member State and EU coffers, and not directly to the medicines agencies concerned, in order to avoid conflicts of interest;
• These fees must be re-adjusted in such a way as to encourage manufacturers to choose the European centralised marketing procedure for products they wish to sell throughout the European Union;
• All conflicts of interest of agency personnel and outside experts must be declared regularly, accessible on the Internet, and be taken into account in practice.

Free access to scientific data. *Drug-related matters must not be an exception to the obligation of transparency in national and European institutions. Indeed, this information is required to ensure optimal use of drug therapy prescribed to European citizens. It is also a moral duty to render public the results of clinical research in which thousands of citizens volunteer to participate.*
Thus,
• National and European medicines agencies must be reorganised to ensure that the public and health professionals have access to detailed and referenced reports of the scientific information on which their decisions are based, whether positive or negative. This must apply not only to national, centralised and mutual recognition procedures, but also to postmarketing data (pharmacovigilance, comparative studies of drug benefits, drug errors, etc.).

Universal and strict centralised procedure. *The measures taken since 1995 to harmonise and concentrate resources through the creation of the European Medicines Evaluation Agency (EMEA) and the European centralised marketing authorisation procedure must be continued and amplified.*
Thus,
• The mutual recognition procedure must be phased out as rapidly as possible, in favour of an efficient and transparent centralised procedure for all drugs intended to be marketed in more than one European Union Member State;
• The European Medicines Evaluation Agency budget must be considerably increased, so that this cornerstone of European pharmaceutical policy has the means to fulfil its responsibilities in terms of expertise, independence, transparency and surveillance;
• The time allocated to examine marketing applications (both national and European) must not be systematically shortened. Agencies must have the time necessary for thorough critical assessment of these applications, with

the overriding aim of protecting patients. This time should only be shortened in strictly defined situations involving serious diseases for which no treatment is available;
• Periodic re-examination of marketing authorisations, both national and European, must be strengthened and actually applied. This re-assessment must focus not only on efficacy and side effects, but also on the overall value of individual drugs in light of new data and new therapeutic options (drug and non drug).

Quality information for rational use. *Rational drug use, especially the prevention of side effects and medication errors, requires that citizens and health professionals be adequately informed.*
Thus,
• National and European authorities must take all the necessary measures to ensure that European citizens and health professionals have access to reliable information. That means information independent of drug companies, well documented and referenced, comparative, and designed in transparent manner, on diseases and available treatments, together with preventive, diagnostic and screening tools, and their correct use;
• International nonproprietary names rather than trade names must be adopted as the main medicine identifiers throughout the European Union, by regulators, patients and health professionals;
• Drug companies must be strongly encouraged to improve the information in patient leaflets and on drug packaging;
• Drug advertising must be tightly regulated in all Member States: advertisements for non prescription drugs must be approved before their release; direct-to-consumer advertising of prescription-only drugs must be banned; advertisements targeting health professionals must be controlled retrospectively; and effective sanctions must be applied rapidly to all offenders.

Transparency in drug cost. *Drugs can serve a public-health oriented policy only if they are universally accessible and if their prices are compatible with health budgets.*
Thus, in order to deal with the current spectacular increase in drug prices,
• National and European policy-makers must undertake strict studies of drug production costs, and particularly the true cost of biomedical research and development;
• The European Union, and its individual Member States, must create adequately funded bodies capable of sponsoring, co-ordinating and stimulating clinical research aimed at answering the numerous questions that are left pending by industry-sponsored studies;
• They must also create institutional structures designed to provide patients, health professionals, organisations paying for medicines with clear, synthetic, referenced, up-to-date comparative drug information on which to base rational choices among available therapeutic options.

Several years of sustained effort are required.

Reference documents

The following documents are essential for a thorough understanding of the current debate on European medicines policy.

• "The ISDB Declaration on Therapeutic Advance in the Use of Medicines" Paris, 15-16 November 2001. The Declaration puts patients' needs at the forefront, and separates real advance from mere "innovation".
Available in several languages on the ISDB website: *www.isdbweb.org*

• "Helsinki Declaration: Ethical Principles for Medical Research Involving Human Subjects" World Medical Association 2000 edition. News treatments must be assessed in comparison with reference options (whenever available) rather than against placebo.
Available on the ISDB website: *www.isdbweb.org*

• "Uppsala Declaration: Statement of The International Working group on Transparency and Accountability in Drug Regulation" (1996), by Health Action International and Dag Hammarskjöld Swedish Foundation, Uppsala, 11-14 September 1996. How to tackle obstacles to transparency and public control of official measures involving medicines.
Available on the ISDB website: *www.isdbweb.org*

• "Erice Declaration: On Communicating Drug Safety Information" (1997), by (among other parties) the Uppsala Monitoring Centre on adverse drug reactions, under the aegis of the World Health Organisation (WHO). What regulatory authorities should do to carry out their mission in terms of information to professionals and the public?
Available on the ISDB website: *www.isdbweb.org*

• "Penser et prescrire en DCI: une bonne pratique professionnelle" (la *revue Prescrire* n° 209);"Les médicaments génériques". Prescribing and dispensing medicines under international nonproprietary names (INN) or generic names is a first step towards rational use of drugs.
Available in French only, on request.

• "Prix des médicaments remboursables: quelle logique ?" la *revue Prescrire* n° 222 and 233.
Available in French only, on request.