

Dear Colleague

A call to arms!

A proposed Directive and Regulation on medicines will be submitted shortly for adoption by the European Parliament and the Council of Europe. A review of these proposals can be found in *European Medicines Policy/Prescrire International*, available on request.

If the proposals are adopted as they stand, they will lead to a number of extremely worrying changes throughout the Europe Community:

- evaluation of marketing applications would be accelerated (and not only for patients urgently needing new treatments), and authorisation would be granted once and for all, abandoning the current system of regular re-appraisals;
- pharmacovigilance would be kept in secrecy, hindering rational management of drug-related problems;
- the role of health professionals would be diminished by direct-to-consumer advertising of prescription drugs on the one hand, and by continuing retention of key scientific data on the other .

Common sense dictates that the European medicines agency should be linked to the EU Health and Consumer Protection Directorate-General of the European Commission, rather than the Enterprise Directorate as at present. Also, being funded mainly by fees paid directly by drug companies, the agency has a serious competing interest.

Faced with a deliberate policy to serve industry first, health professionals and patients must act before it is too late.

A petition is enclosed with this letter. Please photocopy it and distribute it as widely as possible.

For more details please feel free to contact us.

Adresse postale
BP 459
F 75527 Paris Cedex 11
France

Tél. : 01 49 23 72 80
Fax : 01 48 07 87 32
revue@prescrire.org

Bureaux
83 boulevard Voltaire
75011 Paris

Service aux Abonnés
Tél. : 01 49 23 72 86
Fax : 01 48 07 87 32
abonnements@prescrire.org

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Dr Jacques Juillard

*President of Association Mieux Prescrire
Head of Publication
La revue Prescrire*

PS. Two copies of the petition are enclosed. We invite you to send the first to the President of the European Parliament on your behalf, and the second to your European Member of Parliament.

PETITION TO THE PRESIDENT OF THE EUROPEAN PARLIAMENT

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 European Council, 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-General. 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 (pharmacovigilance, comparative studies of drug benefits, drug any health policy, national and European regulatory bodies in charge of errors, etc.). 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 (EMA) must depend on 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 in charge of drug registration and control be financially independent from pharmaceutical companies. The measures taken since 1995 to harmonise and concentrate resources through creation of the European Medicines Evaluation Agency (EMA) and the European centralised marketing authorisation procedure must be continued and amplified.

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 make public the results of clinical research in which thousands of citizens volunteer to participate.

Thus,

¥ National and European medicines agencies must be re-organised 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

Strict and transparent centralised procedure. The measures taken since 1995 to harmonise and concentrate resources through creation of the European Medicines Evaluation Agency (EMA) 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 no 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.

These proposals are not unrealistic but several years of sustained effort are required.

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PETITION TO THE PRESIDENT OF THE EUROPEAN PARLIAMENT

I, the undersigned

Ms

Mr

First name:

Second Name:

Address:

Postal code:

City:

Country:

Nationality:

Occupation:

Sign up to the attached petition "Putting European drugs policy back on tracks".

I would appreciate it if you could pay attention to this major issue.

Date:

Signature:

To be filled in and signed, then sent **by post or fax** to la revue Prescrire (Medicines in Europe Forum). We shall collect all the petitions and send them to the President of the European Parliament.

Revue Prescrire
(Collectif Europe et Médicament)
BP 459
75527 Paris Cedex 11
Fax: 33 (0) 1 4807 8732

Should you need further information, contact la revue Prescrire (Medicines in Europe Forum)

Phone: 33 (0)1 4923 7280

E-mail : revue@prescrire.org

Preferably before August 15