The herbal wave sweeping over society is rising rather than falling, so the time seems ripe for a licensing policy that promotes the safety and quality of herbal medicine-like products without imposing an unbearable conventional burden on their manufacturers. The principle of a single regimen for all medicines has already been compromised by the European legislation on homoeopathic medicines.[3] The proposed special route should be open only to herbal products for minor illnesses and complaints, of course, and not to remedies that claim to be of value in serious disorders.

Special licensing procedures for herbal medicines are already in force in Germany, where regulatory evaluations of medicinal herbs have been laid down in more than 300 monographs, and in France, where more than 200 herbs have been listed as acceptable ingredients of phytomedicines.[10] On the other side of the world Australia has developed an integral approach to the herbal market that will also cover various non-Western herbs. Key elements of the Australian system are the need for more compliance with codes of good manufacturing practice, lists of eligible herbs and certain other substances, and directions on labelling and on allowable indications and claims (GM James, personal communication, 1994).

Licensing herbal medicine-like products will not solve all the problems: further steps will be needed to control the quality of raw botanicals and the quality of herbal prescribing,[9] but licensing may well be a step forward towards the safer use of industrially produced herbal products.

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# New draft on European directive on confidential data

## *At last, a step forward for epidemiological research*

The council of the European Union has just agreed and published a new draft of the European directive on "protection of individuals with regard to the processing of personal data and on the free movement of such data."[1] Earlier drafts (in 1990 and 1992) caused considerable concern for the future of epidemiological research.[2-6] Compared with previous versions, the new, third draft allows member states more leeway over decisions on many important issues related to scientific research and government statistics.

Previous threats to epidemiological research included limits on how long data could be kept, the requirement of written consent before health data could be processed, the requirement that the subject of the data should be told about their disclosure to a third party, the subject's right to access to the data, and the obligation to notify the supervisory authority before any data were processed. Earlier drafts of the directive stated that personal data should be kept in an identifiable form for no longer than is necessary for the purposes for which they were recorded. It has now been added that "further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards."

Processing of health data was previously prohibited unless the subjects concerned had given their written consent, but member states could make exemptions on grounds of important public interest. Now only an explicit consent (which may be given orally) is required, and it has been added to the preamble of the directive that public interest includes areas such as public health, social protection, scientific research, and government statistics. The requirement that the subjects of the data should be told about their disclosure to a third party will, according to the new proposal, not apply "where, in particular for processing for statistical purposes or for purposes of historical or scientific research, the provision of information proves impossible or involves a disproportionate effort."

The subject's right to access to the data may, according to the new proposal, be restricted "when data are processed solely for purposes of scientific research." The suggested rules for notification to the supervisory authority before any data are processed have been simplified.

The new draft of the directive thus includes improvements on all the key issues that epidemiologists had criticised, and it allows member states to implement legislation that balances the subject's right to privacy with the possibilities for epidemiological research.

These amendments have followed an extensive exchange of facts and viewpoints between legislators and epidemiologists, but this process has been hampered by the fact that only some of the drafts and proposals that have been negotiated by the member states were made publicly available.[7] The new, third draft is currently under negotiation in the European parliament. We sincerely hope that the parliament will side with the council in ensuring the future of epidemiological research in Europe.

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