



Reorienting European policy on medicines for human use

We don't want 'secret remedies'

Patients must know exactly what drugs they are using. The international non proprietary name (INN) of each active substance must appear on the packaging, the patient information leaflet and the advertisements.

Secret remedies were the rule in past centuries: you would take Doctor What's-his-name's tablets for your stomachache but you were totally unaware of exactly what were the substance and the dose.

Labeling regulations were reinforced during the 20th century in European countries, not only for medicines, but also for most consumer goods, including pre-packed food.

Secret remedies were forbidden, i.e. medicines whose packaging did not mention the type and dose of the active substances. Manufacturers were also obliged to provide a leaflet listing the same information, along with other essential one.

Patient information was further enhanced with the introduction of international non proprietary names (INN) by the World Health Organisation (WHO) in the 1950s. INNs are universally adopted, WHO-approved names for specific drug substances. They form a common scientific language, enabling patients to know exactly what their doctor or pharmacist has recommended, and whether two drugs with different trade names contain the same or different substances.

In Europe, it has been obligatory to use INNs on drug packaging and the patient information leaflet for more than half a century. European harmonisation of the regulations governing medicinal

products, which started in the 1970s, confirmed these rules, thereby guaranteeing patients a high level of protection.

The use of international non proprietary names is more than ever necessary in 2003, especially with the boom in generic drugs. At the first reading of the draft Directive and Regulation on medicinal products, members of the European Parliament voted amendments aimed at ensuring that the INN of each active substance figures systematically on the drug packaging.

So we were dumbfounded to learn that these amendments had not been upheld in the draft texts proposed for the second reading. If the Council's recommendations are adopted, pharmaceutical firms would not have to mention the INNs on the packaging (box and leaflet) of preparations containing more than one active substance.

Thus, an antihypertensive combination of two active substances could be designated by its trade name only. The same would apply to a contraceptive pill combining an estrogen and a progestin (even though not all compounds in these categories carry the same risks), and also to multi-vitamin preparations, that may contain iron, fluoride, etc. In other words, patients would know less about their drugs than about their breakfast cereals.

We hope this is a simple administrative error – one that

will be corrected without delay.

Drug packaging and patient information leaflet must mention all active substances and their doses. It is high time to hammer the last nail into the coffin of secret remedies dear to Middle-Age peddlers. Drug companies may want to promote their trade names, but what patients need most is detailed information on precisely what substances and what doses they are taking.

Just as unacceptable is the proposal contained in the current draft Directive authorising firms to mention only the trade name of their product on recall advertisements.

These advertisements are designed to ram home the trade name until the prescriber (or the patient) adopts it instinctively. But we are not talking about washing powder or socks here. Recall ads are already legally exempted from mentioning a large body of information, including side effects. At the very least they should be required to carry the international non proprietary names of all the active substances contained in the product concerned.

Advertisements touting what amounts to secret remedies are totally unacceptable in the 21st century. Companies want to impose their trade names, but what health professionals and patients need

most is thorough, reliable information.

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