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Transposition of Directive 2004/27/EC on human medicines: beware!

● **The tight calendar for the planned French transposition of Directive 2004/27/EC, and the fact that it is to be pushed through without parliamentary debate, calls for vigilance on the part of all those concerned with the greater public good.**

In the December 2005 issue of our French edition, we reported that the French authorities were dragging their feet over the transposition of Directive 2004/27/EC, which introduces important changes in the European legislative framework on human medicines (1). Six months after the EU deadline, the French Ministry of Health has at last drawn up a transposition plan.

The plan includes adjustments to French law to reflect community law, and the use of a fast-track parliamentary procedure to push through certain measures without a full debate (2,3). The bill could scheduled to be examined, first in Parliament and then in the Senate, by summer of this year.

Major omissions concerning transparency of the French drug regulatory agency. The bill focuses on the definition of medicinal products and on marketing authorisation, and appears to respect the spirit of the Directive on these points.

It also includes a section on "Transparency", which modifies parts of the Public Health Code governing the French regulatory agency. However, article 126b of the Directive requires the Agency to publish the agenda of its meetings (committees and task forces), along with minutes and decisions taken, voting details, etc., but the proposed bill only slightly modifies French law concerning assessment reports and conflicts of interest. The transposition bill is therefore incomplete with respect to these important issues, which are central to the credibility of the French regulatory agency.

Patients shepherded by drug company wolves! The bill does not include any of the Directive's measures that were warmly welcomed by patients and caregivers, such as independent funding of pharmacovigilance; scrutiny of information leaflets by consumer panels; and printing of INNs on drug packaging, even for products containing up to 3 active ingredients. While it is true that these issues are covered by regulations rather than legislation, we are aware of no plans to issue the necessary decrees. Care must be taken to ensure that these points are not "overlooked" and that the Directive is fully transposed.

The most serious flaw in the proposed bill is that it includes a provision which is not even mentioned in the Directive. The relevant section is entitled "Framework for compliance programmes".

A "Report to the President of the Republic" sheds light on the nature of these "compliance programmes" (4).

The justifications used to support this measure are pathetic (our translation): "*Section 4 concerns programmes designed to support compliance with drug therapy, and other individualised patient assistance programmes proposed by pharmaceutical companies in support of treatments, especially for drugs that are complex or used long-term, based on new modes of patient information and support. They are initiated by physicians during consultations and are intended to improve patient compliance or to provide assistance through the use of individualised tools (telephone reminders, toll-free telephone numbers, tailored patient education, home nursing visits, etc.).*

These programmes can have a positive impact by promoting the proper use of drugs. However, it must be ensured that they only promote appropriate use of prescription drugs, that they respect ethical requirements concerning patient consent, and that they are consistent with product licensing.

Although these programmes are not equivalent to advertising, they do need to be regulated. The aim of this article is to define a specific framework for these programmes by specifying, among other things, that they must first be approved by the French regulatory agency, and that companies who do not respect these dispositions may be sanctioned".

The next sentence is particularly revealing: "*These dispositions are in line with the orientations given by the European Commission during negotiation of the pharmaceutical review, that is designed to allow pharmaceutical companies to provide more information on health issues*".

The authors of the draft bill will no doubt stress the fact that some companies have already launched such programmes, and that it is therefore necessary to create a relevant "framework". However, it would be simpler and far more logical to simply forbid them. In addition, compliance programmes may be confused with follow-up studies requested by the marketing authorisation committee or by the Transparency committee (which assesses new drugs' benefits in France), but this type of study is mainly intended to fill in the gaps left by inadequate initial product assessment.

In summary. The draft bill ignores important provisions for transparency included in the Directive. In addition, it attempts to legalise "patient coaching" by drug companies, including sending "controllers" to patients' homes (see also page 114 of this issue). It is totally inconsistent with the spirit of the Directive.

We must all remain vigilant!

Selected references from Prescrire's literature search.

1- Prescrire Rédaction "Transposition de la Directive 2004/27/CE sur le médicament: la France en retard" *Rev Prescrire* 2005; **25** (267): 817-818.
2- Direction générale de la santé/SD3 "Projet de loi portant diverses dispositions d'adaptation au droit communautaire" 14 December 2005: 9 pages.
3- Direction générale de la santé/SD3 "Ordonnance - Titre 1er: Dispositions relatives aux médicaments à usage humain" 14 December 2005: 8 pages.
4- Direction générale de la santé/SD3: "Ordonnance n° - Rapport au Président de la République" 14 December 2005: 9 pages.