The French regulatory agency. The bill does not include any 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!