Capsulas

Progress in the regulation of health technology assessment

The Ministry publishes the Draft Royal Decree, and the deadline for submitting allegations is 20 September

Work to regulate health technology assessment (HTA) activities specifically aimed at informing government decisions on incorporation, financing, pricing, reimbursement or disinvestment is coming to an end. In this capsulas we present some thoughts on aspects of the proposal that we believe could be revised:

Relationship between evaluation and price and reimbursement procedure

We believe that the evaluation should have its own separate entity from the price and reimbursement procedure. The evaluator "evaluates" and the decision-maker "decides", both procedures being distinct, with different methods and criteria. Although this theoretical affirmation is generally agreed on, there are some aspects of this Draft that do not seem to be in line with it. For example, according to the Draft, the evaluation exercise concludes with a "final evaluation" of the assessment report to be carried out by the Health Technologies Positioning Group, a group made up, among others, of representatives of the Autonomous Regions and the Directorate General for the Common Portfolio of NHS Services and Pharmacy.

Nature of the reports and rights of the developers

In our opinion, the assessment reports should constitute an administrative act finalising an autonomous administrative procedure, which guarantees developers that the full and unrestricted exercise of the rights provided for in art. 53 of Law 39/2015 (hearing, access to the administrative file, appeals, etc.). The Draft is not clear on this matter.

Participation of the developers in the evaluations

The Draft incorporates interesting ideas in this area (e.g. arts. 7.8, 9.4 or 19). However, there is room for improvement. We find it questionable, for example, that developers are not allowed to make contributions to the assessment reports beyond "pointing out purely technical or factual inaccuracies" (art. 14.6). Contributions which, can be made by "patients, clinical and other relevant experts" (Art. 14.5).

Deadlines

The Draft foresees deadlines for the completion of the assessment reports (90+30 calendar days, art. 14); but it does not establish a deadline for the completion of the final assessment by the Positioning Group that closes the evaluation stage. This raises doubts about the total time that the assessment exercise may take, and leaves developers unprotected against unjustified delays.

Prioritisation of evaluations

The possibility of prioritising certain evaluations when the characteristics of the technology so requires seems very important to us, especially from the point of view of speeding up access to certain disruptive technologies. The Draft con-

templates the possibility of prioritising the evaluation of medical devices (art. 7.2) but not that of medicinal products.

Identification of comparators

Although this is an issue that will probably be addressed in the "Instruction documents for health technology assessment" (art. 22), we cannot fail to mention it because of its relevance; and the fact that we think it would have been very appropriate to incorporate it in the text of the Royal Decree itself. It is vital to recognise that not all situations are the same or comparable, and that in certain cases the comparison must be made with extreme caution (for example, if industrially manufactured medicinal products with a marketing authorisation are compared with off-label uses, magistral formulae or similar).

Confidentiality

Some provisions of the Draft raise doubts about the essential guarantee of confidentiality that should be predicated on the documents provided by health technology developers and the confidential parts of the assessment reports. For example, it is unclear whether or not the draft reports that will be accessible to "patients, clinical and other relevant experts" (Art. 14.5) may contain confidential information from the developer.

Obligations of developers

In our view, it is important to ensure that the information required from the developer is proportional, relevant and useful to the development of the assessment; and that the developer is not obliged to provide information that does not meet these requirements.

Conflicts of interest

It is essential to strike a balance between the need to have the best possible expertise available for evaluations and the guarantee of the principle of impartiality. The regulation of conflicts of interest in the Draft could, in our opinion, be improved from this perspective.

Re- evaluation

The new rule should promote (and require) a scheme that, while respecting the powers of each administration, eliminates re-evaluations that are not objectively indispensable and duly justified. Although the Draft points out some ideas in this regard, it could do more to ensure this key objective