Some proposals on health technologies assessments

Public consultation by the Ministry of Health on the Draft Royal Decree regulating health technologies assessment

The Ministry of Health has published for public consultation the draft Royal Decree on health technologies assessment. These are our proposals:

Definition of "health technology" and other terms

1. To use the same terminology as the European regulations. This will avoid confusion about the scope of application of the legislation and the meaning of defined terms.

The legal nature of assessment reports (ARs) and their relationship to the procedures for the inclusion of health technologies (HTs) in public funding

2. To clearly define the legal nature of ARs and the relationship between ARs and the procedures for the inclusion of HTs in public funding.

3. To configure ARs as autonomous administrative acts, not necessarily linked to funding and pricing procedures.

4. To configure ARs as "non-binding" reports for funding and pricing procedures, meaning that failure to complete the ARs within the pre-established timeframe for reasons beyond the control of the HT developer should not hinder such procedures.

5. To define ARs as mandatory only in the case of HTs whose characteristics require it.

6. To prevent ARs from acting as an obstacle for HTs that are not subject to public funding procedures. It is also recommended that HTs that are fully or partially funded by the industry (e.g. patient support programmes or similar initiatives) should not be subject to ARs.

Early dialogue, technical advice and dossier to be submitted by the developer

7. To provide for the possibility of an early dialogue between the developers of HTs and the bodies responsible for the drafting/approval of HTs in order to lay the foundations for the subsequent evaluation work. In the case of medicinal products, this dialogue would be desirable prior to the positive opinion of the CHMP.

8. To provide for the possibility for HT developers to make scientific/technical consultations to the authorities related to the evaluations of their HT.

9. To allow HT developers, not the administration, to prepare the first drafts of the economic evaluation studies and/or the budget impact analysis as part of an "HTA Dossier" to be submitted at the beginning of the assessment procedure.

Direct interaction with industry

10. To set up and promote the possibility of face-to-face meetings between HT developers

and the bodies/experts responsible for the preparation/approval of the ARs.

Procedure for the preparation of ARs

11. To define the procedure for the preparation of ARs, including details of the stages and maximum timeframes for each stage. The regulation should be complete, reduce the scope for administrative interpretation and provide a high degree of legal certainty for all parties involved.

12. To define the procedure and the persons responsible for approving technical and methodological guides for carrying out evaluations. In any case, these guides should:

    (a) Be developed in collaboration with all stakeholders, including HT developers.

    (b) Be approved with a high degree of consensus.

    (c) Be drafted in a clear, specific manner so as to limit the scope for administrative interpretation.

    (d) Be used to develop basic terms that should be defined in the standard (e.g., "clinical benefit", "additional clinical benefit", and "relevant additional clinical benefit").

    (e) Recognise the specificities of each type of HT under evaluation (e.g. drugs, digital therapies, etc.).

13. To define the preparation of ARs as an administrative procedure, which should comply with the provisions of Law 39/2015. In particular, this procedure should recognise the rights of the "interested parties", which in any case would be limited to the developers of HT under analysis. These rights should include the following, among others:

    (a) The right to know the status of the proceedings at any time.

    (b) The right to access and obtain copies of the documents in the procedure. The new regulation should clearly recognise that the HT developer must have access to the complete AR dossier, including all the contributions made by the different bodies, persons, the administration, expert groups, patient associations and scientific societies. Full and unrestricted access to the dossier by the HT developer is a basic requirement for the developer to be able to exercise their right to make allegations and to participate fully and effectively in the evaluation.

    (c) The right to identify the authorities and public administration personnel under whose responsibility the procedures are carried out. If an expert/body/agency involved in the process of drafting/approving the AR makes a specific contribution that changes the general orientation or conclusions of the AR, the developer should be explicitly informed of this fact and of the authorship of the contribution.

    (d) The right to make allegations and submit documents at any stage of the process and to have these considered by the competent body in the preparation of the AR proposal.

14. To provide for the HT developers to be the last to make allegations, so that they can comment on all aspects of the AR and on all submissions and contributions made by the administration and/or other stakeholders

(e.g. scientific societies, patient associations, etc.).

15. To provide for the possibility for "other stakeholders" (e.g. patient associations, scientific societies, developers of HTs mentioned in the AR, etc.) to make allegations on the draft AR.

16. To provide for ARs to be prepared/approved by independent, impartial, transparent and separate bodies from those responsible for the funding and pricing of HTs decision, so that the "assessment" is as far as possible removed from the "decision".

17. To ensure that staff and experts involved in the preparation and/or approval of Ars make a declaration of conflict of interest, are suitably qualified, independent and fully impartial.

18. To provide for a First In First Out system for the development/approval of Ars, which may only be modified in exceptional cases (e.g. orphan or paediatric medicines, and other cases of public health interest).

19. To establish a maximum timeframe for the completion of ARs, both for final approval and publication, and for the different phases.

Clinical and economic evaluation

20. To provide for the results of the clinical and economic evaluations to be presented separately.

21. To provide for the economic evaluation to be conducted with a broad societal perspective, including non-healthcare aspects, so that all demonstrated benefits and savings are captured.

22. The criterion of "effectiveness" should not be the only criterion to be considered for the positioning of an HT, but should be assessed in conjunction with the other criteria laid down in the regulations. This consideration is particularly relevant in the case of orphan and paediatric medicines.

23. The evaluation of HTs targeting rare and ultra-rare diseases should receive special consideration, taking into account the specificities of this type of diseases, particularly the reduced number of patients.

Comparators

24. To recognise the specificities of industrially manufactured medicinal products that have a marketing authorisation (MA) compared to other treatments that do not have an MA (e.g. non-industrially manufactured medicinal products, magistral formulae, officinal formulae etc.).

Reassessments at different levels

25. To implement a "staircase" system so that evaluation at a previous level prevents re-evaluation of the same aspect at a lower level, while respecting the areas of competence at each level. This would minimise re-evaluations of HTs that are not objectively justified.

Means of appeal

26. To establish an appeals system that gives HT developers a real opportunity to challenge the AR both administratively and judicially. The new system should provide for the possibility of an autonomous appeal against an ARs.

27. In the case of medicinal products, MA Holders of medicinal products that are referred to in the AR of another medicinal product should have the right to appeal

against such AR as far as their medicinal product is concerned.

Confidentiality

28. To ensure the confidentiality of all information provided by HT developers during the process of preparing ARs.

29. To ensure that the final AR to be published does not contain information that could be considered confidential or subject to the rights of the HT holder.

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