Table 4

Table 4. Main recommendations for HTA of new medicines in Spain

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| *Current situation in Spain* | *Situation in other countries* | *Recommendation* | *Expected benefits* |
| Clinical HTA body (AEMPS) is an agency of the MoH | HTA bodies in England, Germany and Sweden are independent of the health service | Strengthen legal independence of HTA agencies from political influence | Objective evidence for decision making. |
| Formal separation between AEMPS, (who undertake clinical HTA for P&R of medicines), and AETS (who undertake full HTA, but mainly for other types of healthcare) | HTA agencies in other countries evaluate medicines, devices and diagnostic technologies. | HTA of medicines, devices and diagnostics should be carried out by an integrated Network of HTA agencies with the support of AEMPS | Strengthen interdisciplinary teamwork, training and coordination of technical staff across the Network of Spanish HTA agencies |
| Decision making body (CIPM) includes appointees from Economy, Industry and Finance ministries | Other countries appoint only health experts to the P&R decision making body | Appoint only health experts to the P&R decision making body | Separate healthcare decisions from industrial policy |
| IPT is published. Other information is confidential | No country publishes full information. England, France and Germany publish detailed reasons for decisions | Publish evidence and reasons for decisions, especially in the pricing decision process | Transparency, good governance. |
| Reimbursed price of hospital medicines is not published | Reimbursed price is not published in any country | Consider publishing reimbursed price | Transparency, good governance. |
| Limited participation of patient and professional societies in P&R | England actively encourages participation of accredited patient groups and other stakeholders | Encourage active participation of stakeholder groups and consultation | Good governance, democratic oversight |
| No formal measure of added therapeutic benefit is used | Some countries use a formal measure of added therapeutic benefit (QALY, Added Benefit or ASMR) | Develop /employ a formal measure of added therapeutic benefit | Clearer definition of therapeutic value |
| AEMPS conduct clinical HTA but do not estimate costs or cost-effectiveness | HTA agencies in other countries (except Germany) conduct cost-effectiveness analysis or review the manufacturer’s model, using the price the manufacturer is asking for. | The HTA agency should conduct cost-effectiveness analysis or review the manufacturer’s model, using the price the manufacturer is asking for. | Clearer decision making criteria that link price to therapeutic value based on economic evaluation studies |
| Ambiguity about the role of economic evaluation | England and Sweden have clear role for economic evaluation, France and Germany negotiate price in relation to added therapeutic benefit | Provide clarity about the purpose of economic evaluation and the methodology to employ | Clearer decision making criteria that link price to therapeutic value based on economic evaluation studies |
| MoH reviews manufacturer’s dossier, which is kept confidential | HTA agencies review manufacturer’s dossier, and the review is published | AEMPS should review the manufacturer’s dossier and comment in the IPT | Transparency, good governance. |

Notes: P&R: Pricing and Reimbursement of new medicines. HTA: Health Technology Appraisal. NHS: National Health Service. MoH: Ministry of Health or equivalent government department. CIPM Interministerial Committee for Pricing, AEMPS Agency for Evaluation of Medicines and Healthcare Products. IPT: Therapeutic Position Report. AETS. Network of Regional Spanish HTA agencies. QALY: Quality adjusted life year. ASMR: Amélioration du service médical rendu.