Changes are afoot in the Spanish reimbursement system: Spain introduces new national therapeutic positioning process

After over 20 years of autonomous regions carrying out their own HTAs, sometimes yielding contradictory recommendations, the Spanish reimbursement process is changing. The new process intends to rationalise, standardise and expedite the assessment of new drugs and lend transparency to the Spanish reimbursement process.

Central to the new process will be the new national therapeutic positioning report (informe de posicionamiento terapéutico, IPT), in which the clinical benefit, innovation and position in therapy of a drug, for which reimbursement is sought, will be evaluated. The IPT, which was presented at a recent conference in Madrid organised by the Fundación para la Investigación en Salud (Fuinsa) will be a key tool in reimbursement and pricing decision-making by the Comisión Interministerial de Precios (CIP).

An IPT report is to be elaborated for all new licensed drugs by the AEMPS (Agencia Española del Medicamento) in collaboration with the autonomous regions. Each report is to be elaborated within 3 months of a positive opinion from the CHMP (at EMA level) or the CMH (Comité de Medicamentos de Uso Humano of the AEMPS) being obtained and are expected to be consensus documents.

Economic criteria will not be included in the IPTs, but it is expected that incidence, prevalence and potential target population data will be, and that these will be used as the basis of budget impact studies and reimbursement and pricing decisions. It is intended that the autonomous regions will follow the recommendations of the CIP.

Another new feature of the process will be the inclusion of the views of professional scientific societies, the pharmaceutical industry and patient groups in the assessment. It is also intended that continuous evaluations of drugs be carried based on real world prescription and patient data obtained since approval, to evaluate the real benefit of drugs. Re-evaluations are mooted to occur every 1-3 years and will guide decisions to continue or discontinue reimbursement of a drug and pricing decisions.

The first IPTs are due at the end of April for the drugs which obtained a positive opinion in the CHMP meeting on the 14-17 January, bosutinib (Pfizer Ltd) and ocriplasmin (ThromboGenics NV).

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