Objective

This research aims to ascertain if Brazil’s new health technology assessment (HTA) agency—the National Commission of Incorporation of Technologies in SUS (CONITEC)—is delivering on the Ministry of Health (MoH)’s promises of transparency and assessment timelines, whilst adopting mandatory evidence requirements for new health technologies to be funded by the public Unified Healthcare System (SUS). According to legislation that created CONITEC in December 2011, the MoH has 180 days to publish a final reimbursement deliberation in the Official Gazette, from the request date, which can be extended by up to 90 days. This research focuses on biologic drugs that represent 43% of MoH’s current drug expenditure, despite accounting for 5% of purchases.

Methods

Secondary research, based on 13 CONITEC final negative and positive reimbursement recommendation reports, focused on biologic medicines published between December 2011 and 12 March 2013. Reports include deliberations from a plenary assembly of representatives (including the MoH, etc.) and a public consultation. Most reports analysed only involved evaluation of a single biologic, whilst those for psoriasis and rheumatoid arthritis (RA) included several biologics at once. Data were evaluated to determine time between the reimbursement request date and final funding decision publication in the Official Gazette, type of sponsor and rationale provided for a funding rejection, and conditions attached to a reimbursement approval recommendation.

Results

When funding request dates were published, the 180-day initial analysis phase deadline was met in most positive reimbursement cases. Amongst those evaluated were 3 already SUS funded medicines not part of a reimbursement request. But an extension period was used in some negative recommendations. CONITEC has delivered on transparency with publication of the rationale behind deliberations. Out of 13 final reports analysed, 6 corresponded to funding rejections involving 9 drugs. These negative recommendations included a multiple appraisal of 4 biologics for psoriasis and evaluations of golimumab for 2 indications. Most sponsors issued with negative recommendations were manufacturers. All rejected biologics were monoclonal antibodies (mAbs) for chronic conditions, except pegvisomant. CONITEC’s rejections centred on inadequate data submitted by manufacturers, ranging from clinical safety and efficacy to the economic analysis models. CONITEC wanted safety and efficacy studies with longer duration and including greater patient numbers, preferably with SUS comparators. The agency also questioned the choice of economic models submitted.

Out of 13 final reports analysed, 7 corresponded to positive recommendations involving 14 biologics. These included: trastuzumab, evaluated in 2 indications, and a multiple appraisal of 8 biologics for RA (including the 3 already funded aforementioned biologics). Sponsors of positively recommended drugs were mostly from MoH’s Secretariats, except trastuzumab for early breast cancer and the RA multiple appraisal. A judicial request for palivizumab also secured a positive deliberation. Funding recommendations of mAbs and the fusion protein (etanercept) were conditional on a price reduction and to prescription in line with MoH Clinical Protocols and Therapeutic Guidelines (PCDT).

Conclusion

There is an apparent mismatch between CONITEC expectations and the manufacturers’ ability to adjust to evidence requirements needed in supporting funding applications of biologics. Showing superior efficacy and safety is proving difficult, particularly compared to the outdated SUS gold standard. Lack of objective clinical evaluation criteria from CONITEC on what is more efficacious or safe is a problem. For economic evaluations, manufacturers’ use of complex models is not likely to be well received due to lack of awareness and experience from the HTA agency. Absence of clear parameters for the analysis of cost effectiveness, including the lack of a range for this threshold, is also a controversial point. There is greater transparency in CONITEC’S HTA phase, but it is absent after a positive recommendation, when the MoH ascertains how the medicine will be offered by SUS. From the biologics analysed, only trastuzumab is available to patients. A funding request requiring a complementary factor (like a diagnostic test, etc.) should consider Brazil’s regional disparities in technological infrastructure. Nonetheless, this entire process is a major advance compared to when decisions were not made public and there were no clear timelines.