ISPOR Global Health Care Systems Road Maps (ISPOR roadmaps) provide useful information on country-specific decision-making processes for regulatory approval, pricing and reimbursement for pharmaceuticals, medical devices and diagnostics. These roadmaps are created and updated by voluntary contributors, as a result some have not been updated since 2008. Our objective was to update specific country roadmaps for pharmaceutical products for 2016.

Methods

Belgium, England, France, Germany, Italy, Poland, Sweden and the Netherlands were selected because they were the countries with the fewest contributors to their ISPOR roadmaps and they had not had their roadmaps updated since 2010. Targeted literature reviews of published and grey literature (including agency websites) relating to country-specific, regulatory approval, pricing and reimbursement/health technology assessment (HTA) processes were performed in March 2016.

Results

Most countries (five out of eight) do not have process flow diagrams available on the ISPOR roadmaps webpage, and the three exceptions had limited information.1 We offer process flow diagrams based on the information from our review (Figures 1-8).

Significant changes relative to the earlier ISPOR roadmaps were observed for the majority of the countries, of which changes in HTA processes were most common:

In England, Primary Care Trusts were replaced by Clinical Commissioning Groups.3 Also, the National Institute of Health and Care Excellence (NICE) HTA processes have been updated.4

In France, products with an improvement of medical benefit (ASMR) rating of 1-3 have required an economic evaluation since 2013; the Commission on Environmental, Economic and Social Policy (CEESP) was introduced in the same year, and is responsible for quality assessment of the evidence/methodology of the economic impact of the drug.5 In addition, we found information regarding the temporary authorisation for use (ATU) process.12

In Germany, the Act for Restructuring the Pharmaceutical Market in Statutory Health Insurance (AMNOG) was introduced in 2014.17,18,19 In the Netherlands, the national health care institute (ZINL, formerly CVZ) carries out HTA and manages the basic health insurance package.20 Publicly held HTA agency (ACTM) became a formal government department in 2009.21

The Swedish HTA roadmap appeared to be the most up-to-date. However, additional information regarding the decision-making process between the national HTA agency (TLV), county councils and financing body is now available.

For Italy, it was difficult to observe any national level updates due to a lack of accessible information.

Discussion

At the time of our desk-based research, both the level of detail in the existing ISPOR roadmaps and the availability of information from the country’s HTA, pricing and reimbursement websites varied widely by country. The existing ISPOR roadmaps are out-dated, and while this study raises awareness of the current processes and policies, it also highlights that the processes themselves frequently change. A key limitation of this study is that, due to a lack of detailed information from some countries websites and issues with translation, some elements of the processes could not be clarified, suggesting that transparency is still very much an issue to be addressed.

Conclusions

ISPOR roadmaps are a valuable information source for researchers and manufacturers, but they need frequent updating. We recommend that ISPOR publish annual updates via the Journal Value in Health. The study reported here could form an initial step in that process.

References