The European Medicines Agency (EMA) aims to foster and protect public health, and considers transparency a key aim in service delivery to patients and society. To this end, the EMA has two policies that govern public access to clinical trial data: Policy 043, which allows anyone to request clinical study reports (CSRs) and Policy 070, which requires clinical trial summaries, overviews, and CSRs from centrally authorized market authorization applications to be published on the EMA’s clinical data website. Policy 070 stipulates that clinical trial data should be published 60 days after the European Commission decision and publication of the European Public Assessment Report (EPAR). The policy came into effect in January 2015 for license extensions and in July 2015 for new indications. For older applications and data, or for data pertaining to non-centrally authorized products, Policy 043 applies.

To protect commercial business interests, the EMA allows commercially confidential information (CCI) to be redacted; however, the agency regards very little information to be truly confidential. In the first 5 months of the policy's enforcement, 495 documents were published, containing 13,356 pages; of these, only 10 pages had CCI redacted (for only three of the drugs). Clinical data are being accessed under Policy 070: between October 2016 and February 2017, a total of 2,326 users accessed 35,633 documents.

Methods

The EMA clinical data publication website was searched for drugs with published clinical data (to 31 March 2018) and the EPAR publication date was located using the "find medicine" search function. The websites of National Institute for Health and Care Excellence (NICE) and Scottish Medicines Consortium (SMC) were searched for assessments of these drugs; the reference lists of the appraisal documents were then checked to determine whether the clinical data had been used in the decision-making process.

Results

A total of 82 treatments had clinical data published up to the cut-off date (31 March 2018); the documents identified included 52 initial applications, 22 indication extensions, and 8 withdrawals of initial applications. When generics were excluded, there were only 59 new indications and extensions: 18 had been assessed by NICE and 22 by the SMC.

Discussion

Transparency of clinical data is considered to be vital for clinicians, payers, and the general public to have confidence in the drugs they are prescribing, buying, and taking, respectively. Some manufacturers have already taken the initiative to publish all clinical trial data (e.g., GSK, which set up a study register in 2004). Conversely, other manufacturers have resisted publication: Amicus Therapeutics has recently taken the EMA to court to prevent the publication of the pivotal CSRs for Galecta. While the role of the EMA is to assess the risks and benefits of a product, the objective of HTA agencies is to consider the value to patients and healthcare systems. They therefore consider much of the same data as regulators, from an alternative perspective, but also require access to additional data from trials. The German HTA agency, the Institute for Quality and Efficiency in Health Care (IQWiG), strongly supported Policy 070 in a document summarizing the agency’s comments on the draft policy. It stated: “There is overwhelming evidence, that so far publicly available trial data are insufficient to provide a complete and unbiased picture of a drug when healthcare intervention. HTA needs additional independent and high quality data sources.”

We were therefore surprised to find that the SMC and NICE do not appear to have used the data available from published clinical trials. When preparing HTA submissions, manufacturers should consider the impact of HTA agencies’ access to full trial data, and how they themselves can use the additional data for comparator products.

Conclusions

The EMA publication site for clinical trial data is being undersubscribed in UK HTA. This is likely to be due to delays in the publication of clinical data submitted in 2015 and 2016, and because HTA agencies have access to unpublished data. When preparing HTA submissions, manufacturers should consider the impact of HTA agencies’ access to full trial data, and how they themselves can use the additional data for comparator products.