Transparency in drug regulation: public assessment reports in Europe and Australia

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Openness and transparency are important considerations for medicines regulators, where public health is of paramount concern. As part of their commitment to transparency, the European Medicines Agency (EMA) and Therapeutic Goods Administration (TGA) in Australia publish information relating to their evaluation of medicines via public assessment reports. European Public Assessment Reports (EPARs) and Australian Public Assessment Reports (AusPARs) provide information about the considerations that led the regulator to approve or refuse the application. The reports summarise assessments by each regulator of the information provided on the quality, safety, and efficacy of the medicine under evaluation. Here, we describe the experiences of two established medicines regulators in publishing public assessment reports, and reflect on their future role in communicating medicines information.

Introduction

The TGA and EMA contribute to the protection and promotion of public health as regulatory bodies responsible for evaluating new medicines for human use in Australia and the European Union (EU), respectively. Openness and transparency are important means by which a regulator seeks to provide the public with confidence in its processes [1]. As part of their commitment to transparency, both regulators publish information on their respective websites (EMA: www.ema.europa.eu; TGA: www.tga.gov.au) about their decisions relating to medicines evaluations [2,3]. EMA publishes EPARs and TGA publishes AusPARs. Each public assessment report outlines the outcomes of the evaluation process of the regulator and provides a record of the scientific reasoning on which a decision was made to approve or refuse an application for marketing authorisation. Here, we discuss the rationale and approach for publishing EPARs and AusPARs over time and reflect on their future role in communicating information about medicines.

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Evolution of EPARs and AusPARs

In 1995, the publication of EPARs was a significant pioneering step for a regulatory body and constituted an important milestone in building a regulatory network involving national competent authorities for medicines in 31 European countries. This move was in line with the commitment to public disclosure built into EMA from its inception [4]. In a similar way, the first AusPAR was published in 2009 as part of the commitment of the TGA to the increased transparency strategy of the Australian Government.

EPARs

Following the establishment of the European medicines system in 1995 with an explicit commitment to transparency [5], EPARs were founded on Article 12 of Regulation (EEC) No. 2309/93. This legislation required the agency to make the reasons for granting authorisation available on request. The EMA went beyond this requirement and began publishing EPARs from the very first centrally authorised product in 1995. Although critics did not believe a change to greater transparency was possible because of concerns about safeguarding commercially sensitive information [6], industry gradually accepted the principles of the EPAR. The first EPARs comprise the assessment report and approved product information (PI).

http://dx.doi.org/10.1016/j.drudis.2016.06.025

The assessment report was initially updated with postmarketing changes. However, because of challenges in document layout and readability, this information on postmarketing changes was published separately from 1999 onwards. In 2004, EPAR publication was enacted into Regulation (EC) No. 726/2004, which also introduced the requirement for publication of a summary for the public. These requirements recognised the need to present information in publicly accessible language [7]. This legislation also required publication of assessment reports for those medicines when applications for marketing authorisation were withdrawn or refused. The EPARs of centrally authorised medicines are now updated to incorporate new data throughout the life of the medicine and are available on the EMA website via a dedicated page for each medicine. To the end of 2015, 1179 EPARs for individual human medicines had been published along with 565 EPAR updates for extensions of indications (Fig. 1a).

AusPARs

The first AusPAR was published on 13 November 2009 as part of the implementation by the TGA of an increased transparency

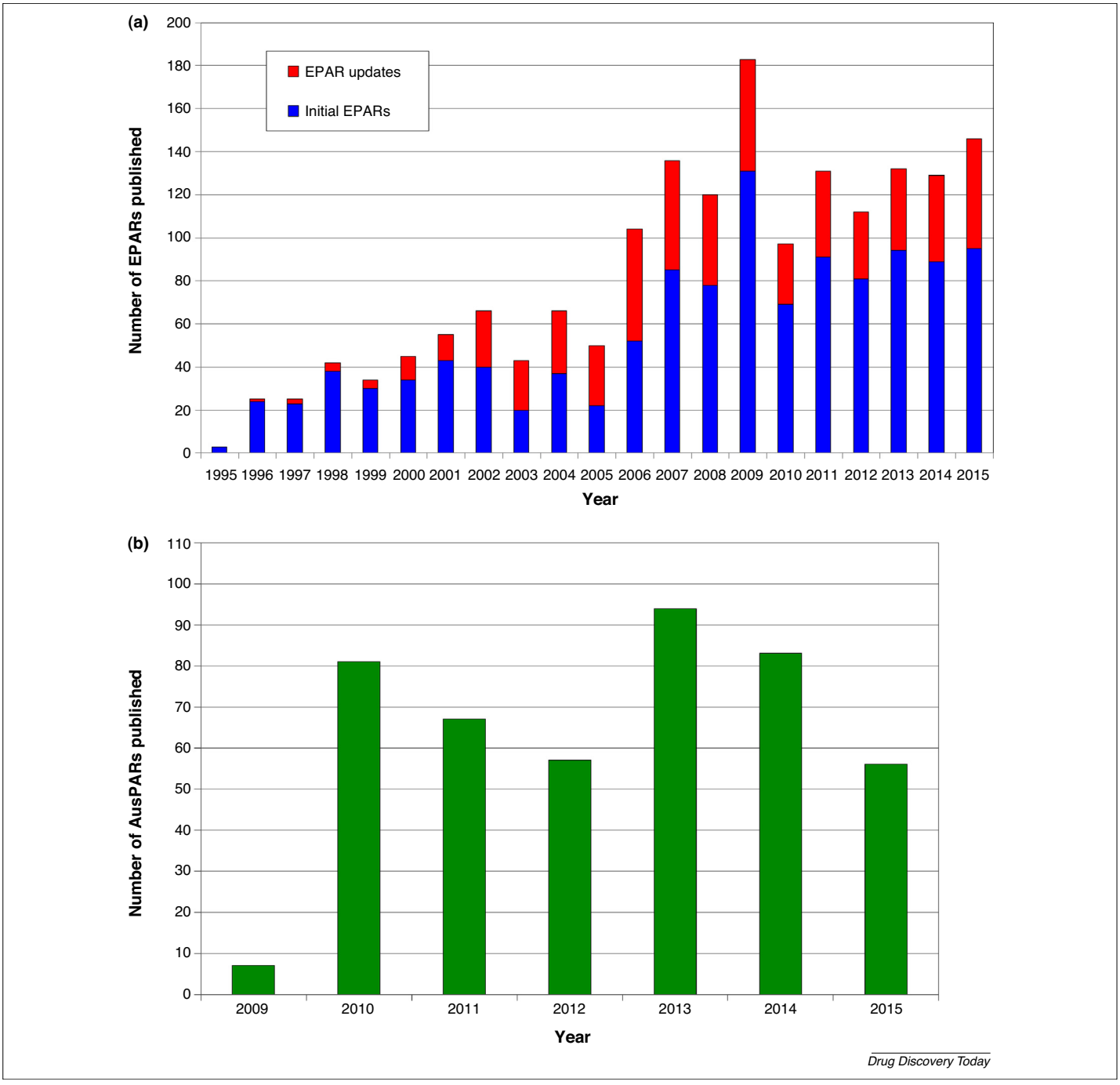

FIG. 1

Number of public assessment reports published annually to 2015. **(a)** European Public Assessment Reports (EPARs) published annually from 1995. 'EPAR updates' indicate extension of indication updates. **(b)** Australian Public Assessment Reports (AusPARs) published annually from 2009.