March 27, 2019

Consultation: Whether the TGA should publish that a prescription medicine is under evaluation

As a Pharmaceutical Policy Network whose membership is actively involved in research and publishing about transparency in the regulation of medicines, we are responding to the TGA consultation on whether it should publish that a prescription medicine is under evaluation.

With respect to the four options offered by the TGA we strongly support Option 2, to list all applications accepted for evaluation, but with the inclusion of additional information. We take this position for three reasons:

1. Transparency of information about medicines is an essential aspect of public health and as such overrides any consideration of commercial confidentiality;
2. The publication of the names of medicines under review would allow the public, clinicians and researchers to determine if the TGA is considering marketing authorization and to follow TGA decisions to authorisation or refusal;
3. Knowledge that a medicine is under review would allow consumers, patients and clinicians to plan for the possible eventual availability of the medicine and to start to decide whether it should form part of the therapy that they would prescribe/use.
4. The current system is inconsistent since information for some medicine applications is available through other mechanisms (e.g., PBAC agendas), making it difficult for consumers and the public to know where to go for information and potentially resulting in confusion and distrust of the TGA.

Suggested modifications
In addition to the information that the TGA proposes to release under Option 2 we also recommend that the notification include the following:

1. The **name of the company** filing the marketing application (contrary to the table in the consultation document, Health Canada has been publicly listing the name of the company since October 2018). Including the name of the company would allow any interested parties to see if the company was engaging in disease awareness activities or funding patient groups active in the disease area prior to approval of the drug;
2. The **indication(s)** that the company is applying for;
3. Whether the application is for **initial market approval or for extensions of indications**;
4. In the event of a **negative decision, publishing the date of this decision** would ensure greater transparency on TGA decision making. Currently this information is published for registered drugs (https://www.tga.gov.au/prescription-medicines-new-registrations). It is also published for negative decisions in the AUSPAR but at a much later date, hence there is a gap in information for such decisions.

Further, all regulatory information about a single drug entity should be accessible from a single location. Examples of this type of accessible information include Health Canada's Drug Product Database or the EMA website.

We do not support Options 1, 3 or 4, because they provide limited transparency and potential confusion to consumers, clinicians and others.

Sincerely

Joel Lexchin MD
Professor Emeritus, Faculty of Health
York University
Toronto, Canada

Alice Bhasale
PhD Candidate
Charles Perkins Centre
University of Sydney

Alice Fabbri MD, PhD
Postdoctoral Research Fellow
School of Pharmacy and Faculty of Medicine and Health
Charles Perkins Centre
University of Sydney

Quinn Grundy PhD
Assistant Professor
Faculty of Nursing
University of Toronto
Toronto, Canada

Emily Karanges PhD
School of Pharmacy and Faculty of Medicine and Health
Charles Perkins Centre
The University of Sydney

Barbara Mintzes PhD
Associate Professor
School of Pharmacy and Faculty of Medicine and Health
Charles Perkins Centre
University of Sydney

Lisa Bero PhD
Professor
Chair of Medicines Use and Health Outcomes
School of Pharmacy and Faculty of Medicine and Health
Charles Perkins Centre
University of Sydney

Marc-André Gagnon PhD
Associate Professor, School of Public Policy and Administration
Carleton University
Ottawa, Canada

Janice E. Graham PhD
University Research Professor
Dalhousie University
Halifax, Canada

David Henry MB ChB
Professor
Faculty of Health Sciences and Medicine
Bond University

Eliza McEwin BPharm, GradDipHospPharm, MPH, MBEth
Research Assistant
School of Pharmacy and Faculty of Medicine and Health
Charles Perkins Centre
University of Sydney

Ray Moynihan PhD
Assistant Professor and NHMRC Early Career Fellow,
Centre for Research in Evidence-Based Practice
Bond University

Lisa Parker MBBS, PhD
Postdoctoral Research Fellow
School of Pharmacy and Faculty of Medicine and Health
Charles Perkins Centre
University of Sydney

Jonathan Penm BPharm (Hons), PhD
Lecturer
School of Pharmacy and Faculty of Medicine and Health
University of Sydney

Agnes Vitry PhD
Senior Lecturer
School of Pharmacy and Medical Sciences
University of South Australia

Lynn Weekes PhD
Director, Health Strategy and Sciences
Adjunct Professor
University of Queensland