PHAA submission on Review of Medicines and Medical Devices

Public Health Association of Australia

Submission on Review of Medicines and Medical Devices

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Introduction

The Public Health Association of Australia Incorporated (PHAA) is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles. The PHAA has a vision for a healthy region, a healthy nation and healthy people living in a healthy society and a sustaining environment while improving and promoting health for all.

Public Health

Public health includes, but goes beyond the treatment of individuals to encompass health promotion, prevention of disease and disability, recovery and rehabilitation, and disability support. This framework, together with attention to the social, economic and environmental determinants of health, provides particular relevance to, and expertly informs the Association’s role.

The Public Health Association of Australia

PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups concerned with the promotion of health at a population level.

Key roles of the organisation include the development of policy, capacity building and advocacy. Core to our work is an evidence base drawn from a wide range of members working in public health practice, research, administration and related fields who volunteer their time to inform policy, support advocacy and assist in capacity building within the sector. PHAA supports a preventive approach for better population health outcomes by championing appropriate policies and providing strong support for Australian governments and bodies such as the National Health and Medical Research Council in their efforts to develop and strengthen research and actions in public health.

The PHAA is an active participant in a range of population health alliances including the Australian Health Care Reform Alliance, the Social Determinants of Health Alliance, the National Complex Needs Alliance and the National Alliance for Action on Alcohol.

PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and public events and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a providing a close involvement in the development of policies. In addition to these groups the PHAA’s Australian and New Zealand Journal of Public Health (ANZJPH) draws on individuals from within PHAA who provide editorial advice, and review and edit the Journal.

Advocacy and capacity building

In recent years PHAA has further developed its role in advocacy to achieve the best possible health outcomes for the community, both through working with all levels of governments and agencies, and promoting key policies and advocacy goals through the media, public events and other means.
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Response to “Review of Medicines and Medical Devices Regulation discussion paper”

The PHAA has made a number of submissions on the TGA since March 2009 (Draft Guideline for Levels and Kinds of Evidence for Listed Medicines with Indications and Claims for Weight Loss) including July 2010 (Position Paper on the Promotion of Therapeutic Goods) and and February 2011 on Transparency of the TGA.

The PHAA appreciates the important role that the TGA has generally made in ensuring the safety of medicines and medical devices. Although we have been critical in the past with regard to some issues around breast implants and vaccine safety, we believe these are the exceptions and the TGA has played a key role in protecting community health.

We appreciate this opportunity to make some very brief comments on a couple of important aspects with regard to the discussion paper:

1. Retaining the TGA is important not only from the perspective of Australians but also from a regional and Pacific perspective as it assists in capacity building within the region.

2. The TGA also functions as the reference Regulator for a number of smaller regulators in the region and, as an example, is the reference regulator (ie the country of first licensure globally) for an important public health vaccine eg The Japanese Encephalitis vaccine Imojev a monovalent, live attenuated viral vaccine. produced by Sanofi Pasteur.

3. In the review document reference is made to other regulators as being of comparable technical standard but no mention is made of the WHO and its processes of pre-qualifying medicines and also of the WHO essential medicines list.

This is unfortunate for Australian public health as a number of WHO essential medicines are not licenced in Australia (eg anti-Tuberculosis medicines) but may be useful in certain circumstances. If WHO pre-qualification was recognised for the essential medicines that are unlicensed in Australia, for example to manage infectious disease risk, the routine use of the Special Access Scheme (SAS scheme), which is associated with significant difficulties in importation may not be necessary.

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1 http://www.phaa.net.au/documents/120109 Breast implants and the TGA as printed in The Age pdf

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