PUBLIC Submission to the Public Consultation on the draft revised Pharmaceutical Benefits Advisory Committee (PBAC) Guidelines (Draft Version 5.0)

Merck is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions.

Founded in 1668, Merck is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

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Merck welcomes the opportunity to provide commentary on the draft PBAC Guidelines v5.0. We support the recommendations made by the submission from our industry

Merck
Merck Serono Australia Pty Ltd
ABN: 72 006 900 830
Un t 3-4
25 Frenchs Forest Road East
Frenchs Forest NSW 2086
Tel: +61 (2) 8977 4100
Fax: +61 (2) 9975 1516
www.merckserono.com.au

association, Medicines Australia (both the shorter public submission and the longer technical submission).

Merck is providing its own submission to complement that by Medicines Australia, due to our fundamental concern about the new proposed onerous requirements - should the revised Guidelines adapt the proposal to change the 'choice of comparator' section from Version 4.4. In 2015, Medicines Australia released its "Compare" Report. This report showed that Australia was ranked the 3rd lowest (out of 20) 'like countries' for access to 'first in class' medicines. This has a direct impact on patient care, and Merck is concerned that the draft Guidelines v5.0 may further impede access to innovative medicines for patients.

Recommendation 1:

Considering the fundamental concerns that the draft Guidelines raise (the significant increase in complexity proposed), we caution the Department against rushing the implementation of these revised Guidelines. The Department must ensure that appropriate feedback is debated/considered and put out for final review later in 2016.

Recommendation 2:

That the Guidelines v.5.0 keep the 'choice of comparator' section as is in v.4.4 and encourage the PBAC to act in accordance with the intent of this section in v4.4. This would keep the Guidelines in keeping with world best practice[1] and significantly reduce the burden on evidentiary requirements, which would reduce uncertainty for the PBAC, and benefit patients by speeding access to reimbursed medicines compared to what is proposed in v5.0 regarding 'choice of comparator'.

Government's RED TAPE reduction Strategy:

The Guidelines Review Steering Committee (GRSC) would be aware of the Government's red tape reduction strategy,

"The government is committed to reducing regulatory burden and red tape through the delivery of effective regulation and programmes. In delivering the regulatory reform

[1] http://www.eunethta.eu/sites/5026.fedimbo.belgium.be/files/Choice_of_comparator.pdf

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agenda, Health will consult with a range of stakeholders to ensure that a broad variety of views are considered."[2]

Merck contends that version 5.0 of the Guidelines may do the exact opposite to what is intended by the Government's own strategy. The draft guidelines lends itself to greater complexity which increases administrative burden, for both the sponsor and the Department of Health. The GRSC must consider how a number of logical recommendations in the revised Guidelines can be implemented without increasing complexity and thus uncertainty. Indeed, data shows that when the last major changes to the PBAC Guidelines were introduced (v4.0), the level of uncertainty for the PBAC increased significantly[3]

National Medicines Policy

The National Medicines Policy aims to improve positive health outcomes for all Australians through their access to and wise use of medicines. The National Medicines Policy has four central pillars based on active and respectful partnerships, taking into account elements of social and economic policy.

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry

Two pillars are of note in this submission; timely access and maintaining a viable medicines industry. With respect to Access, the Policy states, "*access processes are made as simple and streamlined as possible, so that subsidisation of medicines is timely, mechanisms are understood, and unnecessary administrative barriers and expenses are avoided*". Further, "*all partners take adequate responsibility for achieving value for money*".

Merck contends that the draft Guidelines v5.0 conflict with the National Medicines Policy by increasing administrative barriers (in submission preparation and submission evaluation) and undermining value for innovation. The PBAC Guidelines are the most public route through which medicines demonstrate their innovation value. As complexity increases, uncertainty increases, which, rather than facilitating the demonstration of

[2] http://www.health.gov.au/internet/main/publishing.nsf/Content/opportunities-to-reduce-regulation-and-red-tape

[3] Chollet, M et al (2010). Complexity increases uncertainty: The impact of PBAC Guidelines (version 4) on PBAC decision making. HTAI Conference Abstract, Dublin, Ireland

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value, does the opposite and undermines value of innovation. This directly impacts on Australian patients, by delaying or preventing access to new medicines.

With respect to Maintaining a viable medicines industry, the Policy states, "*It is essential that industry policy and health policy be coordinated, providing a consistent and supportive environment for the industry, and appropriate returns for the research and development, manufacture, and supply of medicines. International competitiveness will only be achieved if Australian industry can operate in a global environment. …. and medical research and innovation [should be] supported"*

Merck contends that the draft Guidelines v5.0 conflict with the National Medicines Policy by not providing a supportive environment nor supporting innovation for access to new medicines. We also have supplied separately a confidential product example to demonstrate our concern.

Is the definition of 'choice of comparator" a concern in the current Guidelines v4.4?

Of the 25 submissions lodged to discuss the items to be included in the review, none recommend that the comparator should be changed to become the least expensive alternative - not New Zealand's PHARMAC, International Health Technology Associations (HTAi), Medical Oncology Group of Australia (MOGA), Society of Hospital Pharmacists Australia (SHPA), Medicines Australia, nor the remaining consumer groups or pharmaceutical companies.

Indeed, one of the toughest reimbursement markets in the world is New Zealand. However, NZ's PHARMAC in its submission to the PBAC Guideline review (dated 8/09/2015), does not suggest that the comparator should be the least expensive alternative.

Thus, if none of the interested parties felt that the cheapest comparator should be an item to be included, Merck is unsure why the revised draft PBAC Guidelines v5.0 propose this alternative.

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