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Proposal to change the format of Section H

The Researched Medicines Industry (|RMI) has concerns about the some of the changes to Section H proposed in your letter of 12 October 2009.

Deletion of Part III of Section H – Assessed Pharmaceuticals

The information contained in Part III of Section H is not widely "available from other sources including PHARMAC's website" as suggested in your consultation letter. This information is generally only available to District Health Board (DHB) staff, who can access it via the Hospital Pharmaceutical Assessment Database (HPAD). Therefore, with the exception of limited information that can be requested under the Official Information Act (OIA), Part III of Section H is currently the only source of information about PHARMAC's cost-utility analyses (CUA) available to other stakeholders. Furthermore, it is the only source of PHARMAC's fiscal estimates of cost-effectiveness available to these stakeholders, since the results of CUA are almost always redacted from information released under the OIA.

The RMI therefore does not support the removal of this sub-section of Section H without the provision of an alternative source of information about CUA for stakeholders other than those employed by a DHB.

However, we note that this issue could be overcome by opening up access to HPAD for all stakeholders. It is acknowledged that it may be necessary to modify some of the reports contained in that database due to the commercial sensitivity of information included in them to date. Therefore, it may be preferable for PHARMAC to, instead, publish suitably edited versions of its future CUA reports or summaries thereof on its website.

We note from previous discussions with PHARMAC on this issue that some of the stated reasons why PHARMAC has not been more open about its CUA in the past are:

- Disclosure of the assumptions and/or results of its CUA before or during negotiations may negatively impact on price from PHARMAC's viewpoint.
- The final results may be commercially sensitive where pharmaceuticals are ultimately listed under confidential rebates.
- It would be too much work.

The RMI does not consider these issues to be insurmountable and suggests that release of CUA reports or summaries thereof would greatly enhance transparency around PHARMAC's prioritization and funding processes.

The RMI considers that, in the interests of transparency, once a CUA has been prepared, it should be published on the PHARMAC website or at least sent to the applicant involved as a matter of course. The CUA forms part of the decision making process (as do PTAC deliberations and recommendations) and is relevant to both parties during negotiations. However, if PHARMAC insists on maintaining the significant/ultimate commercial leverage it currently holds as the gatekeeper to the Pharmaceutical Schedule, it could adopt a policy of publishing reports or summaries only after a drug is funded (either by DHBs or listed on the Pharmaceutical Schedule).

Where confidential rebates are utilized to reduce the price of the pharmaceutical, the published CUA results could be based on list prices with a caveat that the true cost per QALY is lower due to risk-share arrangement. This would at least allow stakeholders to understand the assumptions behind the result and how the results are impacted by changes to these assumptions. Withholding all financial results (as PHARMAC currently does under the OIA) makes the latter impossible.

We refute the assertion that the release of PHARMAC's reports or summaries of them would be too onerous. PHARMAC generally makes less than 20 new investments (i.e. new listings or increased access) per year. CUA reports are presumably included in each relevant board paper. The additional work required to edit each report in order to ensure that commercially sensitive information was not released would not be significant.

We also trust that the cessation of publication of CUA results for hospital pharmaceuticals does not signal a reduction in the amount of resource allocated to assessing hospital pharmaceuticals. The RMI considers that, in the face of growing and significant equity issues between DHB Hospitals in terms of pharmaceutical access, now is the time for greater alignment between DHB hospitals and the community in terms of pharmaceutical funding. We would in fact support a single assessment process and budget for all pharmaceuticals, regardless of whether they are used in hospitals or the community.

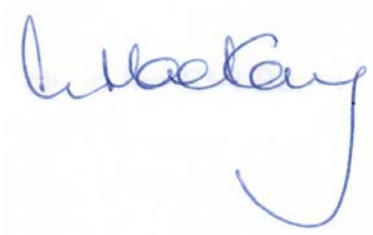
Removal of DV Pharmaceuticals

While the process for including these items in the Pharmaceutical Schedule may not be ideal, the RMI considers that the lists of DV Pharmaceuticals are at least of some assistance in ensuring DHB Hospital compliance with Hospital Supply Status (HSS) contracts.

PHARMAC has already reduced its obligations to monitor compliance with DV Limits from those under which HSS was introduced. This proposal potentially represents further dilution of the rights of suppliers who bid for HSS contracts.

We therefore seek assurance that PHARMAC will monitor the effect of removing the lists of DV Pharmaceuticals on compliance with HSS contracts, and reinstate them if it is found that compliance suffers after their removal.

Yours sincerely



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