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PHARMAC's Decision Criteria Proposal for Change

Thank you for the opportunity to comment on PHARMAC's consultation document *Decision Criteria Proposal for Change* (February 2014). I note that this consultation follows PHARMAC's May 2013 consultation on the decision criteria. On 4 September 2013, in response to that consultation, I noted that safety and quality was not, at that stage, one of the nine decision criteria. With reference to PHARMAC's extended responsibility in respect of medical devices, I recommended that PHARMAC amend the decision criteria to ensure that patient safety and quality is at the forefront of any decision to fund a medical device in New Zealand. I have **enclosed** a further copy of my 4 September 2013 submission for ease of reference.

PHARMAC proposes to replace the current decision criteria with a matrix that sets out "factors for consideration" to inform subsidy decisions. The matrix includes consideration of the "clinical benefits and risks of the medicine or medical device to the patient and health outcomes". The matrix is supplemented by a "Supporting Information" document, which provides additional explanations of the factors for consideration, as set out in the matrix.

Although the consultation document explains that the consideration of the clinical benefits and risks of a medicine or medical device is intended to capture considerations regarding patient safety and the clinical safety of pharmaceuticals and medical devices, this is not explicitly stated in the Supporting Information document. In particular, with regards to "clinical benefits and risks", the Supporting Information document notes that consideration of clinical benefits and risks will include assessing clinical evidence, clinical benefits, access and optimal use, supplier characteristics and wider population clinical benefits and risks. Patient safety is not listed in the Supporting Information document as a particular, independent factor for consideration in respect of clinical risks and benefits.

I acknowledge that the Supporting Information states that, in the case of pharmaceuticals and medical devices in which clinical evidence is difficult to obtain, PHARMAC will balance the lack of evidence and the risks associated with that against other relevant factors such as health need. While this could be said to encompass consideration of patient safety, I consider that it needs to be more explicit, particularly in respect of funding decisions regarding medical devices.

As stated in my 4 September 2013 submission, there is much less data available about the effectiveness and safety of medical devices than pharmaceuticals. There is a legitimate concern that the public may interpret a positive funding decision by PHARMAC in respect of a medical device as endorsement of its quality and safety.

For this reason, I recommend that patient safety and quality is explicitly listed in the Supporting Information document as a key factor for consideration in respect of "clinical benefits and risks".

Encl: HDC submission to PHARMAC, dated 4 September 2013