PROSTHESES LIST – PROCESS TO TERMINATE LONG TERM INACTIVE APPLICATIONS

Purpose
This Circular informs stakeholders of the process to terminate applications to list prostheses on the Prostheses List that have been long outstanding and inactive.

Background
The Prostheses List Advisory Committee (PLAC) agreed at its meeting of 12 November 2014 that it is appropriate to terminate applications that have been inactive for over 12 months and where there is no prospect of them being finalised in the near future, subject to appropriate consultation with the applicant.

Inactive applications in scope are those where:

- the PLAC has recommended granting but the Prostheses Secretariat has not received advice that the prosthesis has been included on the Australian Register or Therapeutic Goods (ARTG) within 12 months of the PLAC making the recommendation; or
- the applicant has asked that consideration of the application be deferred to enable further evidence or information to be submitted, and this evidence or information has not been submitted within a period of twelve months.

The agreed process
The Prostheses Secretariat will phone the applicant to advise that the application is being considered for termination as there has been no progress for over 12 months:

- If the applicant advises that further evidence/information is available, the secretariat will negotiate a timeframe for it to be forwarded; or
- If the applicant advises that further evidence/information is not available, or there is no prospect of the product being included on the Prostheses List within the next two months, the secretariat will advise that the application will be terminated and a letter will be sent to confirm.
A letter will be sent to the applicant to advise that the application will be terminated as there has been no progress for over 12 months:

- The letter will provide the applicant with the opportunity to respond; and
- The letter will specify the date by which the applicant must respond or the application will be terminated. The end date for response will be three weeks from the date of the letter.

Please note that there will be no refund of application fees offered or given.

Any queries about this matter should be directed to Prostheses@health.gov.au or (02) 6289 9463.