

# NOTIFICATION OF PROPOSAL TO SUBMIT SUPPLEMENTARY DATA

Submission number:

Sponsor's name:

Generic name:

Trade/Proprietary name:

Dose form/s:

DSEB Admin file number:

DSEB Clin/Tox file number:

In response to receipt of the Module <4/5> evaluation report for this submission,  
..... wishes to submit supplementary data comprising:  
<name of sponsor>

Data type: (clinical or non-clinical data /title of studies etc)      Volumes:      Pages:

Brief description of data and its relevance

Expected date of data delivery:      /      /

The following declaration is to be completed by the sponsor.

In notifying a proposal to submit supplementary data, .....  
<name of sponsor>

agrees to a clock stop for a maximum of 60 working days to allow for submission of the data and recognises that this may delay the application being finalised by the TGA.

Signature: ..... Date:      /      /

Name: .....

Position: .....

# SUBMISSION OF SUPPLEMENTARY DATA

Submission number:

Sponsor's name:

Generic name:

Trade/Proprietary name:

Dose form/s:

DSEB Admin file number:

DSEB Clin/Tox file number:

Further to the notification dated ..... in response to receipt of the  
Module <4/5> evaluation report for this submission, .....  
now submit supplementary data comprising:

<date>

<name of sponsor>

Data type: (clinical or non-clinical data /title of studies etc)      Volumes:      Pages:

The following declaration is to be completed by the sponsor:

In submitting these supplementary data, and pursuant to Regulation 16A(2)(c) of the *Therapeutic Goods Act 1989* (the Act), ..... agrees to a clock stop for a  
maximum of 135 working days to allow for evaluation of the data and recognise that this will delay the submission being finalised. This 135 days does not include allowance for additional time for questions to be asked under Section 31 of the Act.

<name of sponsor>

Signature: ..... Date: / /

Name: .....

Position: .....