

NEW PRODUCT SUBMISSION FORM

APPLICANT INFORMATION

Date of submission	
Name of applicant	
Physical address	
Postal Address	

First contact:	
Name	
Position	
Telephone number	
Email address	
Second contact:	
Name	
Position	
Telephone number	
Email address	

Is this a re-submission: Yes No ?

If this application is a re-submission, then provide new information only that was not provided in the previous application.

New information	Comment

PRODUCT INFORMATION

Brand name of product	
Active ingredient	
Therapeutic classification (ATC)	
Therapeutic class	
MCC Registration number	
Date of MCC registration or anticipated date of registration	

Product strength	
Dosage form	
Pack size	
SEP (incl VAT)	

SEP unit price	
NAPPI code	

Registered indications	
Registered dose and frequency	
Recommended duration of therapy	
Important warnings	
Is the medicine listed on EML or DoH Provincial Formularies? If so, indicate which formulary and which provinces	

CLINICAL EVALUATION

EVIDENCE

	Trial Group	Comparator Group
Median OS months		
Median PFS/iDFS months		
Median duration of treatment (months and cycles)		
GR5 Adverse Events %		
GR3-4 Adverse Events %		
GR1-2 Adverse Events %		

For each **key article** used in the clinical evaluation of the product, provide brief summary of the article according to the following criteria:

Criteria	Summary of key points
Citation/authors	
Title of article	
Journal of Publication	
Year of publication	
Level of evidence (SORT)	
Description of trial including phase of trial	
Study design	
Is this a randomized clinical trial? If not, state study design. Also specify the method of randomisation.	
Blinding	
Description of possibility of confounding/bias	
Patient eligibility criteria	

Sample size / Number of patients enrolled	
Was the trial design a cross-over?	
Where was the trial conducted (List countries)?	
Is the dose administered different to that in the package insert?	
Median and range duration of follow-up of trial	
Primary outcomes measured	
Secondary outcomes measured	
Drug interactions	
Are there any other significant endpoints that may influence HTA outcome that is not specified	
Limitation of studies	
General comments	

COMPARATOR MEDICINE FOR SAME INDICATION			
Comparator drug	Strength and formulation	Comparative dose with medicine evaluated	Reference (if available)
Non medicine comparators			

What are the typical co-administered therapies	
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MOTIVATION FOR THERAPEUTIC VALUE OF MEDICINE

State reasons why this medicine should be re-imbursed:
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Motivation for the safety claims of the medicine.

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Post marketing surveillance report

State any particular experiences with the medicine since registration:
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GUIDELINES

Are there any prescribing guidelines for the medicine being evaluated? Please attach.

Guideline	Date published	Organisation Endorsed by	Comments

PLACE IN THERAPY FOR THE DISEASE

State whether first-line or second line therapy, etc. Provide the associated reference:

POLICY CHANGES

Should policy or practice change as a result of the evidence contained in the clinical and pharmacoeconomic evaluation? If yes, motivate why?

Checklist

	A signed covering letter for submission	
	A signed 'new product submission' application form	
	An executive summary of the submission (1 page maximum)	
	A MCC approved package insert	
	A clear and adequate index	
	Have page numbers throughout	
	Full published copies of the key clinical trials	