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Tygerfalls, 7530

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	
Principle mode of action	
Registered dose and frequency	
Total daily dose	
Duration of therapy	
Important warnings	
Is the medicine listed on EML or DoH Provincial Formularies? If so, indicate which formulary and which provinces	
List of medicines already on the ICON formulary for the same indication(s)	
Advantages of the medicine being evaluated over listed alternatives	
List of medicines to be replaced by the requested medicines	

CLINICAL EVALUATION

EVIDENCE

	Parameter value	**Main reference**
Effect size		
Risk difference (95% CI)		
Relative risk or harzard ratio		
NNT		

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.	
Target population	
Characteristics of subjects	
Inclusion criteria	
Exclusion criteria	
Sample size / Number of patients enrolled	
Is this an intention-to-treat analsyis?	

Number of drop-outs	
Reason for drop-outs	
Number of participants lost to follow-up	
Was the trial design a cross-over?	
Where was the trial conducted?	
Comparability of study subjects with patients likely to receive the medicine.	
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	
Quality of life measures	
Adverse drug reactions	
Drug interactions	
Description of possibility of confounding/bias	
Method of randomization	
Blinding	
Results	
Methodological comments	
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-administerd therapies			

COMPARISON OF CLINICAL OUTCOMES OF MEDICINE BEING EVALUATED AND ITS COMPARATORS

Medicine	Citation	mean PFS (months)	Median PFS (months)	Mean OS	Median OS	Absolute difference in PFS	Absolute difference in OS
Medicine evaluated:							
Comparator medicines:							

MOTIVATION FOR THERAPEUTIC VALUE OF MEDICINE

State reasons why this medicine should be re-imbursed:

SAFETY (If not already mentioned in the key trial information)

Major adverse events	
Significant medicine interactions	
Precautions and contraindications	

Motivation for the safety claims of the medicine.

Post marketing surveillance report

State any particular experiences with the medicine since registration:

PHARMACO-ECONOMIC (PE) EVALUATION

Prescribed Dose /m^2	Quantity administered per cycle	Number of cycles	Cycle length (weeks)	Cost per cycle	Cost for duration of treatment	Cost per patient	Cost per benefit year

GUIDELINES

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

Guideline	Date published	Organization 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	
	A MCC approved package insert	
	A clear and adequate index	
	Have page numbers throughout	
	Full published copies of the key clinical trials	