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|  **HA Drug Formulary Committee (DFC)**  |

New Drug Submission Form

New drug entity (i.e. drug currently not listed in HADF) listed in the following drug categories A to J and new presentation or strength of an existing drug in the HADF satisfying category K should be submitted to the Drug Formulary Committee (DFC) for assessment.

(tick as appropriate)

|  |  |
| --- | --- |
| 1. [ ]  Antidotes and drugs used for emergency response
2. [ ]  Antiseptics and disinfectants
3. [ ]  Blood products (excluding recombinant preparations)
4. [ ]  Diagnostic agents including radiopharmaceuticals, etc.
5. [ ]  Fluids and electrolytes
 | 1. [ ]  Intravenous and oral nutrition
2. [ ]  Medical gases
3. [ ]  Peritoneal and haemodialysis fluids
4. [ ]  Vaccines
5. [ ]  Vitamins and mineral supplements
6. [ ]  New presentation or strength of an existing drug in the HADF for the same indication and without price premium
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Please complete ALL sections, attach relevant supporting documents and submit by email at **dfcapp@ha.org.hk** in order to facilitate the evaluation. **Incomplete or inaccurate application will not be considered.**

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| **contact of corresponding drug company** |  | **For submission made by HA physician** : |
|  | 1st contact point | 2nd contact point |  | Applicant’s Name |  |
| Name |  |  |  | Position & Institution |  |
| Position |  |  |  | Email |  |
| Company  |  |  |  | Telephone |  |
| Email |  |  |  | Applicant’s Signature |  |
| Telephone |  |  |  | Name of COS |  |
| Signature |  |  |  | COS’s Signature |  |
| Date |  |  |  | Date |  |

1. **General Information**

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| * 1. **Generic name of Drug (English)**
 |  | **(Chinese)** |  |
| * 1. **Proprietary name (English)**
 |  | **(Chinese)** |  |
| * 1. **Proposed HA Drug Formulary Indication(s) for this new drug**

*(Please list out proposed indication wordings, each indication should be within 300 characters including punctuation marks and spacing)* |
| [ ]  SFI  | e.g. Short-term treatment of moderate to severe atopic dermatitis in non-immunocompromised patients unresponsive to other topical treatments or when those treatment are not advisable (total 177 characters) |
| [ ]  Safety Net |  |
| [ ]  Special |  |
| * 1. **Proposed authorisation for prescribing this new drug for this indication (which specialty)**
 |
| [ ]  SFI  | e.g. Specialists: Card/ Endocrinology/ Geri/ GI Liver/ Haem/ Neurology/ Renal/ Resp/ Rheum/ A&E/ Anae/ Derm/ ENT/ FM/ ID/ HIV/ ICU/ Microbiology/ O&G/ O&T/ Onco/ Oph/ Paed/ PICU/ PID/ Psy/ Surg/ Transplant |
| [ ]  Safety Net |  |
| [ ]  Special |  |
| * 1. **Proposed HA Drug Formulary status** *(🗸where appropriate)*
 |
| Current Formulary Status of this drug: | Proposed Formulary Status (for drug categories A to J): |
| [ ]  Non-Formulary use - SFI[ ]  Non-Formulary use - Hospital-funded[ ]  Sample use | [ ]  SFI [ ]  Special[ ]  General |

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| * 1. **Type of application** *(🗸where appropriate)*
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| [ ]  New application  [ ]  Resubmission. Date of last submission: . |
| * 1. **Date of approval from Drug Office, Department of Health, Hong Kong (HK)** *(🗸where appropriate)*
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| [ ]  Newly registered drug:  Date of registration: . or Date of positive opinion letter:  |
| * 1. **Drug company and suppliers involved**
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| * + 1. Name of Drug company
 |  |
| * + 1. Name of Manufacturer
 |  |
| * + 1. Name of Supplier / Dealer
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| * 1. **Strength & form**
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| **1.10 Proposed Cost (HK$ per unit)** |
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| 1. **Proposed place in therapy if introduced into HADF**
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| * 1. **Licensed indication(s) of this new drug in Hong Kong (specific for this submission)**

*[the indication(s) should be the latest and already in effect in Hong Kong, except newly registered drug with positive opinion letter]* |
| English: |  |
| Chinese: |  |
| **2.2 Worldwide registration status for this indication**  |

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| **Region** | **Indication**  | **Approval Date** |
| Hong Kong | Erosive Esophagitis | Drug registration by “1+” mechanism: *(🗸where appropriate)* [ ]  Yes [ ]  No Nov 2010 |
| Australia  | Erosive Esophagitis~~Maintenance of healed EE~~~~Symptomatic non-erosive GERD~~(no need to list these indications which are unlicensed in HK/not relevant for this application) | Jan 2009 ~~May 2005~~ ~~May 2005~~ |
| Mainland China  |  |  |
| European Union  |  |  |
| Singapore  |  |  |
| UK |  |  |
| USA |  |  |
| **2.3 Existing treatment alternatives with dose regimens for this disease in HA** |
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| **2.4 Summary of benefits of this new drug over existing options listed in section 2.3** |
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**3. DECLARATION OF CONFLICT OF INTEREST BY HA PHYSICIAN** (if applicable)

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| ***As recommended by the ICAC Corruption Prevention Department in relation to HA’s drug procurement practices (2 May 2007):******The applicant doctors (for new drugs to be added to the hospital drug list), should be required to report to the approving committee any conflict of interest (e.g. sponsorship from the drug manufacturer) they or their family members may have in relation to any companies whose commercial interests may be affected by the committee within a specified period.******There are also guidelines, as per*** [***Human Resources Circular No. 6/2008***](https://ha.home/circular2/Hr-2008-06.pdf) ***regarding Acceptance of Advantages, Entertainment and Sponsorship, in place to minimise the potential conflicts of interest risks in the process of new drug introduction, for example instructing staff to be delinked from the decision-making process for a reasonable period of time which is normally 6 months in cases of sponsorship (such as conference attendance) from a drug manufacturer.*** |
| *A conflict of interest is a situation in which the interests of the HA compete or conflict with the private interests of the applicant. “Private interests” include the financial and other interests of the applicant and that of the following -*1. *his/her family members and relatives;*
2. *his/her close personal friends*

*(e.g. friends who know each other for a long time and have frequent social relationships);*1. *any person to whom the officer owes a favour or is obligated in any way.*

*In order to uphold and protect HA’s and your reputation, you should avoid over-socialising with any potential company/ manufacturer concerned during any stage of the procurement process and avoid obligations to business associates resulting from advantages, gifts or entertainment received in, or due to your official capacity which could compromise your position in any way. As a personal responsibility, you should declare any potential conflict of interest and abstain from engaging in situations that may lead to perceived bias in the business decision-making process. Should you be asked to express any opinion, owing to your professionalism and expertise, in relation to the business enterprise or any matter concerning the company/manufacturer, you will do so impartially and without regard to your interest.**There are several situations that could give rise to a conflict of interest. The most common ones are investment, shareholding, direct or indirect interest in the business enterprise, business and close social or family relationships with the company/manufacturer, participation in a conference sponsored by the company/manufacturer for the past six months or use of loaned equipment for research or other purposes. A potential conflict of interest exists for applicant who makes decisions in carrying out his/her duties that would allow him/her to give advantages, preferences or favours to a business enterprise in exchange for anything of personal benefit or advantages to himself/herself or any of (a) to (c) above. Any applicant with these potential conflicts of interest has a duty to disclose the nature of the potential conflict.* |
| **Are you or any (a) to (c) above a director, officer, sole owner, partner, employee, consultant or advisor to any business enterprise that to your knowledge or belief and at the time of making the declaration, supplies HA with any goods or services?** *(🗸where appropriate)* |
|  [ ]  No [ ]  Yes *(please provide details under below Description of interest section)* |
| **Do you or does any member of (a) to (c) above, has any direct or indirect financial interest in any business enterprise that to your knowledge or belief and at the time of making the declaration, supplies HA with any goods or services?** *(🗸where appropriate)* |
|  [ ]  No [ ]  Yes *(please provide details under below Description of interest section)* |
| **Description of interest (if any)** |
|  |
| I have thoroughly reviewed the above and the answers to the questions are to my best knowledge correct.**Requested by** |
| Signature: |  |  | Date: |  |  |
| Name: |  |  | Institution: |  |  |

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|  | **4. Supporting documents for this submission**  |
|  | **Please submit the following documents for evaluation by email to dfcapp@ha.org.hk** (Incomplete or inaccurate applications will not be considered*Ǿ*)**:** [ ]  Duly signed DFC New Drug Submission Form(in PDF format), and* Submit a separate form for each applying indication.
* For applications submitted by HA physicians, duly signed Section 3 - Declaration of Conflict of Interest form (in scanned format) should be submitted.

[ ]  Artwork or photographs of the product sample (please do **not** forward the actual sample)[ ]  Latest Prescribing information sheet with month/year of approval in Hong Kong (package insert in Hong Kong which is effective, except newly registered drug with positive opinion letter)* (for newly registered drug entity) ‘Positive opinion letter’ or Certificate of drug registration in HK issued by the Department of Health of Hong Kong (DH)

[ ]  Mandatory pharmacovigilance / Risk Management Plan for safety monitoring (if applicable)[ ]  Worldwide registration status – * month/year of registration for the indication(s) specific for this DFC submission. Do not include worldwide registration status of other indications that are not relevant for this submission.
* Registration status in Australia, Mainland China, European Union, Singapore, UK, USA must be specified.

[ ]  Clinical data relevant to the evaluation for the indication(s) specific for this DFC submission, including: * Please provide only the highest level of evidence (e.g. If head-to-head clinical trial compared with an HA alternative is available, there is no need to provide placebo-controlled trials. If phase III randomized-controlled trials are available, there is no need to provide lower evidence level trials.)
* Please provide only fully published clinical trials. Do not include abstracts or posters.
* Please provide other safety data e.g. US black box warning, post-marketing surveillance, current risk alerts.
* Relevant latest international guidelines from relevant authoritative organisations or associations (e.g. ESMO, ASCO, EULAR, AHA)
* Resubmission of unsuccessful DFC application(s) without additional information to address DFC’s concerns will not be considered.

[ ]  Formal price quotation/ proposal (in HK dollar) in company letterhead which, net of any offered bonus terms, would stand valid for at least 2 years from the date of approved listing on the HADF[ ]  Supporting references for sections 1 – 2 where applicable* List out the references under this section
* Please ensure that all supporting documents are clearly numbered and referred to
* Provide soft copy of the references (in PDF format) and the full reference list (in MS word format)

**References:**Please use the following citation format:1. Bxxxxxx A, Pxxx Jx, Gxxx A, et al. XXXX administration by pre-filled syringe: efficacy, safety and usability results from a randomized controlled trial. Br J Dermatol. 2024;15(8):4

*Remarks:Ǿ Incomplete applications will be returned to applicants.* |