**Guidance Notes on New Drug submission
to** **the Drug Advisory Committee (DAC) and the Drug Formulary Committee (DFC)**

**Preface**

1. This guidance notes apply to applications of New Drug listing / Repositioning of existing drugs in HA Drug Formulary (HADF).
2. The following categories of drugs fall outside the scope of DAC evaluation and require endorsement of DFC for listing on the HADF:

a) antidotes and drugs used for emergency response;

b) antiseptics and disinfectants;

c) blood products (excluding recombinant preparations);

d) diagnostic agents (including radiopharmaceuticals);

e) fluids and electrolytes;

f) intravenous and oral nutrition;

g) medical gases;

h) peritoneal and haemodialysis fluids;

i) vaccines;

j) vitamins and mineral supplements; and

k) new presentation or strength of an existing drug in the HA Drug Formulary for the same indication and without price premium.

1. Please refer to HADF website (<https://www.ha.org.hk/hadf/>) for further information, including the procedure of introduction of new drugs, DAC meeting date/agenda/outcome, and DAC/DFC Application Forms.

**How to apply for New Drug?**

1. An application can be submitted for consideration of listing in the HADF if the concerned drug entity or indication fulfills the following criteria:
2. It is indicated for prevention or treatment of conditions which are not covered by drugs in the existing HADF;
3. It has an advantage in terms of efficacy and adverse effects over agents in the existing HADF for the same indication;
4. It is equivalent in terms of safety and efficacy as compared to agents in the existing HADF for the same indication and of lower treatment costs.
5. For application of New Drug listing, please submit the completed New Drug Submission Form and related documents (including Appendix A for application of SN drug listing) by email, including signed submission form(s) in scanned format (e.g. PDF), to the DAC Secretariat (dacapp@ha.org.hk) before 17:00 HKT on submission deadline.
6. For categories of drugs mentioned in Paragraph 2, please submit the completed New Drug Submission Form and related documents to the DFC Secretariat (dfcapp@ha.org.hk) before 17:00 HKT on submission deadline.
7. New drug submission is only allowed from pharmaceutical companies or HA physicians. Submission from patient/ patient group would not be accepted.

**Notes on Applications**

1. Please complete ALL sections and attach relevant supporting documents in order to facilitate the evaluation. Incomplete or inaccurate application would not be considered. Incomplete applications would be returned to applicants.
2. Only electronic version of completed DAC form would be accepted. Original form or other electronic means (e.g. USB disks) would not be accepted.
3. Each applying indication for the same drug would be treated as a separate application.
4. Re-submission which is already listed on existing round of DAC meeting agenda would not be accepted.
5. Resubmission of unsuccessful DAC application(s) without additional information that address concerns from DAC would not be considered.
6. Request for deferral of submitted application to next meeting would not be accepted. Applicant could either withdraw or continue the application.
7. DAC would not consider re-submission of withdrawn application after the deadline for a period of FOUR months from the date of the concerned DAC meeting.
8. Update of submitted form after submission deadline would not be accepted. Supplementary information (e.g. update price proposal, new study and / or recommendation) could be submitted before DAC/DFC meeting.

Chief Pharmacist’s Office

Hospital Authority

November 2024