RECOMMENDATION BY HOSPITAL AUTHORITY'S OFFICE FOR PRIORITY REIVEW OF NEW DRUG APPLICATION UNDER "1+" MECHANISM

HA

1

IDENTIFY PRODUCT

- Hospital Authority (HA) identifies drugs for cancer treatment (initial phase) for priority review, with priority given to:
  - local unmet medical need
  - cost-effectiveness, particularly for those evidenced by Health Technology Assessment (HTA) in HK
  - completed, ongoing or planned clinical trials within the Greater Bay Area(preferred)/local data available

HA

2

CONNECT POTENTIAL APPLICANT

- HA connects with potential applicant for New Drug Application (NDA)
- Refer them to request for pre-NDA meeting with Department of Health (DH)
- Obtain its consent to notify DH

DH

3

CONFIRM CRITERIA AND REGISTRATION REQUIREMENTS

- DH assesses regulatory criteria upon notification, based on:
  - "1+" mechanism eligibility criteria*
  - pre-NDA meeting request
  - application status outside Hong Kong

HA

4

DECIDE TO RECOMMEND PRODUCT

- Upon DH confirmation of eligibility, HA determines priority review recommendations
- If recommended, HA submits recommendation letter to DH

DH

5

PRIORITY REVIEW

- DH screens application & HA's recommendation letter
- Evaluates accepted application with target cumulative time of **100 working days.**
- Applicant also has its target response time (see diagram of "Stop-clock Mechanism")

Evaluation time Expedited to within **100 working days#**

Important: Recommendation for priority review is only accepted before evaluation begins

DH

6

APPROVE BY REGISTRATION COMMITTEE

- Registration Committee** approves application based of safety, efficacy and quality
- DH marks approved products as "Priority Review" on Drug Database for Pharmacy and Poisons Board

HA

7

ENLIST IN HA FORMULARY

- Once pricing and other requirements are resolved, recommendation will be submitted within 120 calendar days for Drug Advisory Committee (DAC) review
- If recommended by DAC, enlistment will follow prevailing procedures and timelines

* Refer to Table 2 of <Guidance Notes on Registration of Pharmaceutical Products: New Drug Applications>

** Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee

Regular cumulative processing time for "1+" applications : within 150 working days.