For Information
on 19 June 2009

Legislative Council Panel on Health Services

Policy on use of drugs in life threatening emergency situations

PURPOSE

This paper briefs Members on the policy on the use of drugs in public hospitals under the Hospital Authority (HA) in immediate life threatening emergency situations.

EXISTING POLICY

2. It is the Government's long established policy that no one should be denied adequate healthcare through lack of means. Saving life is always the first priority of HA, regardless of a person's financial position. The guiding principle of HA in charging fees is that no person should be charged beyond the standard fees and charges for needed drugs in immediate life threatening emergency situations.

3. The Hospital Authority Drug Formulary (the Formulary) was implemented in public hospitals and clinics by phases between July and October 2005. The objective of the Formulary is to ensure equitable access to cost effective drugs of proven efficacy and safety, through standardisation of drug

policy and drug utilisation in all public hospitals and clinics operated by HA.

4. In designing the Formulary, HA was guided by the principle that public healthcare resources should be utilised with maximal effect of healthcare and provide equitable access by all patients. Special considerations have been given during the development of the Formulary to ensure that drugs used in immediate life threatening emergency situations are included in the Formulary as general drugs or special drugs and are covered by standard fees and charges. This fundamental principle has been upheld since the Formulary was put in place.

5. HA's Drug Utilisation Review Committee (DURC) conducts periodic review on existing drugs in the Formulary and drugs categorized as Self-financed items (SFI), which are not covered by HA's standard fees and charges. In March 2006, DURC has reviewed the policy on the use of drugs in immediate life threatening emergency situations and reaffirmed the fundamental principle in paragraph 4 above. In addition, DURC considered that in case of emergency situations, if the use of a SFI or a special drug outside its indications specified in the Formulary is considered necessary based on clinician's professional judgment, and no other alternatives are available, the drug should not be charged as SFI. This arrangement has in general been followed by the hospital clusters.

THE QUEEN ELIZABETH HOSPITAL INCIDENT

6 On 13 June 2009, a trauma patient injured at a traffic accident was sent to the Queen Elizabeth Hospital (QEH) for treatment. The clinical teams of QEH have provided all necessary care to the patient, including resuscitation, initial stabilisation, investigations and immediate emergency operations.

Subsequent to the provision of all the appropriate treatment, with a view to improving the patient's blood coagulation status, the attending doctor has made special consideration on the potential use of a drug called Novo Seven beyond the drug's registered indications, bearing in mind that while the drug could be of potential benefit to the patient, the safety and efficacy of the drug for this use is still uncertain.

7. Novo Seven is classified as a special drug in the Formulary. Its clinical indications specified in the Formulary are in line with the indications specified by its manufacturer during the registration of the drug, i.e., for use on control of bleeding in haemophilia patients or on patients with Factor VII deficiency only. When the drug is used within the indications specified in the Formulary, it will be prescribed to the patients at the rate of standard fees and charges.

8. As HA understands it, the manufacturer of Novo Seven does not recommend using the drug outside its registered indications. There is also no scientific data from the manufacturer supporting the use of the drug outside its registered indications based on safety and efficacy. Therefore, in the QEH incident, the drug was used under an extraordinary condition and beyond its registered indications, after thorough discussion with the patient's relatives. The use of the drug in such circumstances is not part of HA's routine clinical practice. On subsequent review of the patient's overall condition and the potential benefit of the drug on the patient, the hospital management of QEH had taken the decision on the same day (13 June) to arrange full refund of the amount charged for using the drug on the patient. We are very concerned about this incident and HA has sent apologies to the patient and her family for the confusion caused.

SYSTEM ENHANCEMENT

9. HA has already re-circulated the principle on the use of drug in immediate life threatening emergency situations to all clusters. HA will also promulgate a more explicit guideline to all hospitals to reiterate this policy, with a view to clarifying all uncertainties and potential grey areas, and devising a mechanism to facilitate clinicians' professional judgments about the best treatment based on clinical evidence or experience.

10. Meanwhile, HA will set up an expert panel to review and evaluate the scientific evidence of Novo Seven in terms of its safety and efficacy for use in immediate life threatening emergency situations beyond its licensed indications for haemophilia patients. The panel will also make recommendations to standardize the practices among all public hospitals.

ADVICE SOUGHT

11. Members are invited to note the content of this paper.

Food and Health Bureau
Hospital Authority
June 2009