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Panel on Health Services

Background brief prepared by the Legislative Council Secretariat for the meeting on 14 February 2011

Drug Formulary of the Hospital Authority

Purpose

This paper gives an account of the past discussions by the Panel on Health Services ("the Panel") on the Drug Formulary ("the Formulary") of the Hospital Authority ("HA").

Background

2. An HA Formulary was implemented 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 standardization of drug policy and utilization in all public hospitals and clinics. The Drug Utilisation Review Committee ("DURC") of HA conducts periodic reviews on existing drugs in the Formulary, whilst the Drug Advisory Committee ("DAC") of HA systematically appraises new drugs for inclusion in the Formulary every three months.

3. At present, there are about 1 300 standard drugs in the Formulary. These drugs are provided within the standard fees and charges at public hospitals and clinics when prescribed under specified clinical conditions. Standard drugs can be classified into two categories, namely General Drugs and Special Drugs. General Drugs refer to drugs having well-established indications and effectiveness which are available for general use as indicated by the patients' clinical conditions. These drugs constitute around 80% of the standard drugs. The remaining 20% of standard drugs are Special Drugs. These drugs have to be used under specified clinical conditions with

specific specialist authorization. For patients who do not meet the specified clinical conditions but choose to use Special Drugs in the Formulary, they will have to pay for the drugs as self-financed items ("SFI").

4. For those drugs which are not standard drugs in the Formulary, patients have to purchase these SFI at their own expenses. There are four types of these drugs, namely (a) drugs proven to be of significant benefits but extremely expensive for HA to provide as part of its subsidized service; (b) drugs which have preliminary medical evidence only; (c) drugs with marginal benefits over available alternatives but at significantly higher costs; and (d) life-style related drugs which are not medically necessary. For drugs of type (a) above, partial or full subsidy can be provided through the safety net of the Samaritan Fund to needy patients to cover their expenses on these drugs. There are a total of 14 SFI drugs covered in the scope of the Samaritan Fund, among which 10 are for treatment of cancer.

5. Not all SFI drugs can be purchased from HA. The following three categories of SFI drugs are supplied by HA at cost for purchase by patients -

(a) items not easily accessible in the community (e.g. dangerous drugs as defined under the Dangerous Drugs Ordinance (Cap. 134); certain psychiatric drugs, oncology drugs and immunosuppressives);

(b) items covered by the Samaritan Fund; and

(c) items that need to be supplied for operational convenience (e.g. drugs needed by in-patients and day-patients, and drugs to be administered by injection).

For other SFI drugs falling outside the above three categories, patients will need to purchase the drugs from the market.

Deliberations of the Panel

6. The Panel held 11 meetings between January 2005 and June 2009 to discuss issues relating to the Formulary and received the views of deputations at three meetings. The deliberations and concerns of members on the Formulary are summarized below.

Introduction of new drugs in the Formulary

7. Following the introduction of the Formulary by phases between July and October 2005, the Administration briefed the Panel on the results of its review on the Formulary on 10 July 2006, which proposed, inter alia, the drawing up of a set of more explicit evaluation criteria for the introduction of new drugs into the Formulary. The criteria included (a) efficacy versus alternatives; (b) efficacy versus placebo; (c) efficacy (no comparator); (d) safety; (e) drug cost versus alternatives; (f) cost impact to HA; (g) overseas reimbursement status; and (h) other considerations (e.g. patient compliance and cost effectiveness studies).

8. Noting that two of the evaluation criteria were related to cost, concern was raised as to whether HA would compromise patients' interests to save money.

9. HA responded that public resources should be utilized with maximal effect of healthcare and all patients should be provided with equitable access to cost effective drugs. Hence, apart from cost, HA would also consider other core values such as evidence-based medical practice, rational use of public resources, targeted subsidy and opportunity cost considerations, as well as facilitation of patient's choice in developing the Formulary.

Engagement with patient groups

10. Members were advised that HA had established a formal consultation mechanism with patient groups on the Formulary. Under the mechanism, annual consultation meetings would be held to inform patients of the latest developments of the Formulary, understand their major concerns, and solicit their views and suggestions on introduction of new drug items and review of existing drugs in the Formulary. Patient groups would also be given two months' time after the annual consultation meetings to submit their views to HA. Members were advised that the first annual consultation meeting on the Formulary had started in May 2009.

11. Question was raised as to whether HA would consider inviting patient groups to join DAC to appraise new drugs. The Administration advised that when considering whether to introduce new drugs into the Formulary, DAC would take into account the scientific evidence on safety and efficacy, cost effectiveness, technology advances in treatment options and service scope in public hospitals. This would require professional knowledge on the part of doctors, clinical pharmacologists and pharmacists. Nonetheless, HA would take into account views collected under the newly established consultation

mechanism with patient groups when considering the introduction of new drugs and the review of existing drugs in the Formulary.

12. On the suggestion that an independent mechanism should be set up to review the Formulary and to receive complaints from patients concerning the use of drugs at public hospitals and clinics, the Administration advised that more time should be given for HA to implement the newly established consultation mechanism with patient groups and to assess its effectiveness.

Safety net for SFI drugs

13. In the context of discussing the Administration's proposal for a one-off grant of $1 billion to the Samaritan Fund to meet the Fund's projected funding requirements up to 2012, members expressed concern over the existing arrangements of deciding which drugs should be categorized as SFI drugs with safety net. Members noted that at present, DURC would advise the Samaritan Fund at the beginning of each year on the potential list of SFI drugs to be supported by the Fund. The recommendations of DURC would be considered by the Samaritan Fund Management Committee, which in turn would make recommendations to the Medical Services Development Committee of HA Board.

14. Members were also concerned about the financial burden imposed by the extremely expensive SFI, such as cancer drug Imatinib (Glivec) and drugs for treatment of Mucopolysaccharidoses which would cost about $200,000 and at least $1 million per year respectively, on middle-class families. Question was raised on whether consideration would be given to putting a cap of, say, $100,000, on the expenses borne by each patient for purchasing SFI each year and the amount exceeding the cap to be covered by HA as part of its subsidized services.

15. The Administration advised that for patients who had difficulties in meeting the drug expenses, financial support had all along been available to them via the Samaritan Fund, which covered eight SFI drugs as at June 2009. Needy patients could apply for assistance from the Fund to meet expenses on these drugs. Apart from the Fund, needy patients might seek fee waiver from HA. Under the fee waiver mechanism, a patient might be provided with a one-off full or partial waiver for hospital fees and charges.

16. On the medical needs of patients with rare genetic lysosomal diseases, HA advised that it currently sought to alleviate patients' discomfort and treat the complications arising from the disease through the collaboration of healthcare staff from various specialties, such as orthopaedics,

otorhinolaryngology, ophthalmology and respiratory medicine, along with genetic counseling, as well as the provision of appropriate drugs, surgery and rehabilitation programme. These services were covered by the standard fees of HA. An Expert Panel on Rare Metabolic Diseases was also set up in 2007 to formulate the assessment criteria for the use of drugs on patients with rare genetic lysosomal diseases, including Mucopolysaccharidoses patients. However, there was no solid scientific data to prove the efficacy of drug therapies to improve the lung function of Mucopolysaccharidoses patients.

Iron chelating therapy for Thalassaemia patients

17. Members noted that there were three iron chelating agents available in HA, namely Desferrioxamine ("DFO"), Deferiprone and Deferasirox (Exjade). DFO was used as the first-line treatment for Thalassaemia patients in public hospitals while Deferiprone was a second-line treatment for patients for whom DFO therapy was contraindicated, intolerant or non-compliant. Exjade was currently available in HA as a SFI.

18. Concern was raised about the serious side effects of DFO and Deferiprone on some Thalassaemia patients. While Exjade offered an additional choice of second-line treatment for these patients, its high cost (about $20,000 per month) had rendered it unaffordable to many patients. Members suggested including Exjade in the Formulary as a second-line treatment for cases where the patients' clinical indications had been assessed by the attending doctors under clear clinical protocols.

19. HA advised that when considering the inclusion of a drug into the Formulary, HA was guided by the principles of clinical efficacy, safety, cost-effectiveness, opportunity cost as well as facilitation of patients' choice. As Exjade was put to market only in November 2005, it was a relatively new drug of preliminary medical evidence and marginal benefits and there were reports of possible severe side effects and fatal complications in post market surveillance. HA would continue to monitor the therapeutic effectiveness and safety of Exjade before reviewing its categorization in the Formulary.

20. HA further advised that in case DFO failed to achieve adequate chelation and the use of Deferiprone had caused serious complications, the use of Exjade would be considered as an exceptional alternative. An expert panel in HA was tasked to evaluate the risks and benefits of the medication and define the target patient group that could be prescribed with Exjade under the standard subsidized public services. The target was to have the relevant clinical guidelines updated for dissemination to doctors in all clusters at the end of 2008.

21. The Panel passed a motion at its meeting on 24 June 2008 urging HA to introduce Exjade in the Formulary. The Government should also increase its funding for HA as appropriate.

Use of drugs in life threatening emergency situations

22. At the meeting on 19 June 2009, the Panel discussed the policy on the use of drugs in public hospitals in life threatening emergency situations, and the Queen Elizabeth Hospital incident concerning the charges for the use of a Special Drug called Navo Seven beyond its registered indications for the treatment of a trauma patient injured at a traffic incident on 13 June 2009.

23. Members expressed grave concern about the fact that frontline doctors of HA were unaware of the principle that patients should not be charged for needed drugs in immediate life threatening emergency situation as well as DURC's decision made in March 2006 which stated that in case of emergency situations, if the use of a SFI or a Special Drug outside its indications specified in the Formulary was considered necessary based on clinicians' professional judgement, and no other alternatives were available, the Special Drug should not be charged as SFI.

24. HA advised that the minutes of the relevant DURC meeting had been circulated to the drug committees of all hospitals where further actions and communication would be pursued. The incident was caused by different interpretations by frontline doctors when a drug was used outside its registered indications. HA would promulgate a clear guideline for frontline staff to reiterate the policy and set out the operational guidelines on the use of drugs in immediate life threatening emergency situations.

25. Subsequent to the meeting, HA advised the Panel in November 2009 that the policy mentioned in paragraph 23 above was revised to remove any potential uncertainty. Under the revised policy, a drug given under immediate life threatening emergency situation deemed necessary by the clinician should not be charged outside the standard fees and charges. The policy should apply to all drugs, including registered and unregistered drugs; drugs under the Formulary (i.e. General and Special Drugs used within and outside the specified indications, SFIs with or without safety net) and non-Formulary drugs; in-label use (i.e. used with the registered indications) and off-label use (i.e. used outside the registered indications). Individual hospitals should develop their own operational procedures on the use of drugs in immediate life threatening emergency situations, such as the decision process, clinical guidelines to guide clinicians on the use of drugs for

immediate life saving purposes, etc. A circular on the subject was issued to all professional staff on 29 June 2009.

Mode of supply of SFI drugs

26. Members were advised about HA's proposal to expand the supply of SFI drugs at HA pharmacies to cover all SFI drugs prescribed to patients by HA doctors at the meeting on 10 July 2006. In order to minimize interference with the private market, prices for the expanded SFI drugs supplied by HA (i.e. SFI drugs not within the existing three categories mentioned in paragraph 5 above) would be set at rates which were comparable to the levels in the market so as not to restrict patients' choice from obtaining SFI drugs from other sources.

27. The Panel held a series of meetings to discuss HA's proposal and also listened to the views of deputations. Generally speaking, the Consumer Council and patient groups welcomed the supply of SFI drugs by HA, as this would provide an assurance of continuous supply of safe and quality drugs at reasonable prices and convenience. On the other hand, pharmacist groups considered that public-private collaboration in the supply of SFI drugs, say, allowing community pharmacies to be set up in HA hospitals to sell SFI drugs to HA patients, was the solution that would truly benefit patients.

28. Question was raised over the appropriateness for HA, as a public organization, going into business as a retailer of medicines and competing with the private pharmacies for the business. There was also concern over the possibility that community pharmacies in public hospitals would be monopolized by large retail pharmacy groups whose profit-driven nature would likely lead to an increase in drug prices.

29. At the meeting on 12 February 2007, the Administration was requested to report to the Panel when the HA Board had come to a view on the supply of SFI drugs before implementation.

Recent developments

30. The Chief Executive announced in his 2010-2011 Policy Address that the Government would strengthen the services for cancer patients, and add more new and effective drugs to the Formulary.

31. In response to the proposal of Hon Alan LEONG to incorporate oral chemotherapy drugs into the Formulary as subsidized drugs as set out in his

letter dated 5 November 2010, the Administration advised the Panel in writing on 12 and 16 November 2010 that HA plans to incorporate more new drugs with proven efficacy in the Formulary in 2011. The relevant expert committees of HA will evaluate and consider each individual drug in accordance with the established mechanism. The next meetings of DAC and DURC will be held within January 2011.

Relevant papers

32. Members are invited to access the Legislative Council website (http://www.legco.gov.hk) for details of the relevant papers and minutes of the meetings of the Panel held on 31 January 2005, 8 March 2005, 13 June 2005, 10 July 2006, 25 September 2006, 23 January 2007, 12 February 2007, 24 June 2008, 10 November 2008, 8 June 2009 and 19 June 2009.

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