

# 立法會 *Legislative Council*

LC Paper No. CB(2)2003/10-11(01)

Ref : CB2/PL/HS

## **Panel on Health Services**

**Updated background brief prepared by the Legislative Council Secretariat  
for the meeting on 14 June 2011**

## **Drug Formulary of the Hospital Authority**

### **Purpose**

This paper summarizes the concerns of the Panel on Health Services ("the Panel") on issues relating to the Drug Formulary ("the Formulary") of the Hospital Authority ("HA").

### **Background**

2. HA has implemented the Formulary since 2005 with a view to ensuring equitable access to cost effective drugs of proven efficacy and safety by standardizing the drug policy and drug utilization in all public hospitals and clinics. Existing drugs in the Formulary are reviewed by the Drug Utilisation Review Committee ("DURC") of HA, whilst new drugs for inclusion in the Formulary are appraised by the Drug Advisory Committee ("DAC") of HA.

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% 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 12 meetings between January 2005 and February 2011 to discuss issues relating to the Formulary and received the views of deputations at three meetings. The major concerns of members are summarized below.

#### Introduction of new drugs and review of existing 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.

10. Members expressed dissatisfaction at the low transparency of HA in relation to its decisions on the introduction of new drugs and review of existing drugs. They sought information on the composition of DAC and DURC, and the mechanism for evaluating new or existing drugs in the Formulary.

11. HA advised that DAC, which comprised specialists, pharmacists, clinical pharmacologists and academics, was tasked with recommending new drugs taking into account a number of considerations such as scientific evidence, safety, cost-effectiveness, international practices and comparison with available drugs in the Formulary. DURC assisted HA in reviewing the prevailing drug classes in the Formulary and guidelines of drug treatment. Its composition included the Chairmen of the drug committees of the seven hospital clusters and specialists. Nineteen specialty panels had also been set up under DAC and DURC to provide professional advice on related issues.

12. Members remained of the view that HA should enhance transparency of the Formulary. They urged the Administration to provide more information to the public such as meeting papers of DAC and DURC, summaries of the decisions of the two committees and the reasons for the decisions on the introduction of new drugs and review of existing drugs in the Formulary.

#### Engagement with patient groups

13. 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. Two annual consultation meetings on the Formulary had been held in May 2009 and June 2010 respectively.

14. Concern was raised as to whether HA would invite 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.

15. 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

16. 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.

17. 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. There was also a suggestion that patients' expenditure on SFI should be tax deductible.

18. The Administration stressed that it was its long-standing policy that no patients would be denied adequate medical treatment due to a lack of means. Needy patients could apply for assistance from the Samaritan Fund to meet expenses on these drugs. Apart from the Samaritan 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. The Administration further advised that the Medical Subcommittee under the Community Care Fund was actively considering measures to provide assistance to people facing financial difficulties, in particular those who fell outside the safety net.

19. Members remained of the view that drugs which were proven to be of significant benefits should be covered by the standard fees and charges in public hospitals and clinics, rather than being classified as SFI with safety net.

#### Use of drugs in life threatening emergency situations

20. 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.

21. Members expressed grave concern about the unawareness of frontline doctors of HA 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.

22. 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 had revised its policy and operational guidelines on the use of drugs in immediate life threatening emergency situations. Under the revised policy, a drug given under an immediate life threatening emergency situation deemed necessary by the clinician should not be charged outside the standard

fees and charges. The policy would 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

23. Members were advised of 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.

24. The Panel held a series of meetings to discuss HA's proposal and received the views of deputations. The Consumer Council and patient groups generally 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, such as 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.

25. Concern 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.

26. 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.

## Procurement of drugs for public hospitals

27. There was a view that frequent change of the suppliers of drugs for public hospitals should be avoided in order to minimize dispensing errors. HA responded that its drug procurement mechanism followed the requirements of the World Trade Organization. Patent drugs would be procured through single tender whilst off-patent generic drugs would be procured through open tender. Due regard would be given to the quality and price of the drugs when assessing the submissions in an open tender.

## **Recent developments**

28. Subsequent to the meeting on 14 February 2011, the Administration advised the Panel in writing on 21 April 2011 that in response to members' request to enhance the transparency of the Formulary, HA proposed to implement the following measures in phases, starting from the second quarter of 2011-

- (a) posting information in relation to the professional composition of DAC and the various expert panels for individual specialties to HA's website for public information, but names of individual members serving on DAC and the relevant expert panels would not be disclosed to minimize unwarranted pressure on the committee members and to ensure their impartiality;
- (b) uploading regularly the list of new drugs to be reviewed by DAC to HA's website;
- (c) uploading the full drug list for review of DAC to HA's Intranet website for staff's information to strengthen internal communication;
- (d) uploading to HA's Intranet and Internet websites the decisions of DAC on individual applications for new drug evaluation, together with a list of reference that had been taken into account in the process of consideration of the applications;
- (e) meeting with patient representatives by the Chief Executive of HA to receive their views on patient services through a platform established in early 2011; and

- (f) developing a search engine for the Formulary available at HA's website to improve accessibility to information on individual drugs and adding a hyperlink of the most up-to-date version of the Formulary to HA's "Smart Patient" website which provides comprehensive patient-related and disease-based information to make the Formulary more accessible to patients.

### **Relevant papers**

29. A list of the relevant papers on the Legislative Council website is in the **Appendix**.

Council Business Division 2  
Legislative Council Secretariat  
8 June 2011

## Appendix

### Relevant papers on the Drug Formulary of the Hospital Authority

Committee	Date of meeting	Paper
Panel on Health Services	31.1.2005 (Item I)	<a href="#">Agenda</a> <a href="#">Minutes</a> CB(2)1049/04-05(01) ( <i>Chinese version only</i> )
Panel on Health Services	8.3.2005 (Item I)	<a href="#">Agenda</a> <a href="#">Minutes</a>
Panel on Health Services	13.6.2005 (Item V)	<a href="#">Agenda</a> <a href="#">Minutes</a> <a href="#">CB(2)2705/04-05(01)</a>
Panel on Health Services	10.7.2006 (Item IV)	<a href="#">Agenda</a> <a href="#">Minutes</a> <a href="#">CB(2)3090/05-06(01)</a> <a href="#">CB(2)747/06-07(01)</a>
Panel on Health Services	25.9.2006 (Item I)	<a href="#">Agenda</a> <a href="#">Minutes</a>
Panel on Health Services	23.1.2007 (Item I)	<a href="#">Agenda</a> <a href="#">Minutes</a> <a href="#">CB(2)1894/06-07(01)</a>
Panel on Health Services	12.2.2007 (Item III)	<a href="#">Agenda</a> <a href="#">Minutes</a>
Panel on Health Services	24.6.2008 (Item I)	<a href="#">Agenda</a> <a href="#">Minutes</a> <a href="#">CB(2)23/08-09(01)</a>
Panel on Health Services	10.11.2008 (Item IV)	<a href="#">Agenda</a> <a href="#">Minutes</a>

<b>Committee</b>	<b>Date of meeting</b>	<b>Paper</b>
Panel on Health Services	8.6.2009 (Item VI)	<a href="#">Agenda</a> <a href="#">Minutes</a>
Panel on Health Services	19.6.2009 (Item I)	<a href="#">Agenda</a> <a href="#">Minutes</a>
Panel on Health Services	14.2.2011 (Item VI)	<a href="#">Agenda</a> <a href="#">Minutes</a>

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