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Panel on Health Services

Background brief prepared by the Legislative Council Secretariat for the meeting on 17 March 2014

Drug Formulary of the Hospital Authority and the Samaritan Fund

Purpose

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

Background

The Formulary

2. The Hospital Authority ("HA") has implemented the Formulary since 2005 with a view to ensuring equitable access by patients to cost-effective drugs of proven safety and efficacy by standardizing the drug policy and drug utilization in all public hospitals and clinics. HA appraises new drugs and reviews the prevailing drug list in the Formulary regularly through an established mechanism.

3. At present, there are more than 1 200 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 which have well-established indications and cost-effectiveness, and are available for general use by doctors of public hospitals and clinics; and Special Drugs which 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, they will have to pay for the drugs.

4. For those drugs which are not standard drugs in the Formulary, patients have to purchase these drugs at their own expense. These self-financed items are categorized into those with safety net and those without safety net. The former are drugs which are proven to be of significant benefits but extremely expensive for HA to provide as part of its subsidized service. Patients who need these drugs but have financial difficulties can receive subsidy from the Fund to fully or partially cover their expenses on these drugs. At present, 20 self-financed drugs are covered in the scope of the Fund. Self-financed drugs without safety net include (a) drugs which have preliminary medical evidence only; (b) drugs with marginal benefits over available alternatives but at significantly higher costs; and (c) lifestyle drugs (e.g. weight loss drugs).

5. At present, HA supplies three categories of self-financed drugs at cost for purchase by patients. These include items not easily accessible in the community; items covered by the safety net of the Fund; and items that need to be supplied for operational convenience (e.g. injection drugs). A summary of the number of patients who purchased self-financed drugs through HA and the total expenditure incurred by these patients during the period of 2008-2009 to 2012-2013 is in **Appendix I**.

The Fund

6. The Fund is a charitable fund established by resolution of the Legislative Council ("LegCo") in 1950. Its objective is to provide financial assistance to needy patients to meet expenses on designated privately purchased medical items (including drugs) or new technologies required in the course of medical treatment which are not covered by hospital maintenance or outpatient consultation fees in public hospitals and clinics. The Fund is administered by HA. It is mainly financed by donations and Government grant. HA reviews annually the income and expenditure accounts of the Fund and estimates the overall expenditure of the Fund for the next few years, and will seek additional funding from the Government if necessary. The Finance Committee of LegCo last approved in June 2012 a commitment of $10 billion for a grant to support the continued operation of the Fund for the next 10 years or so.

7. Patients who meet the specified clinical criteria for the relevant items supported by the Fund and can pass the financial assessment conducted by the Medical Social Workers will be given a full or partial subsidy for meeting the expenses on the items. Financial assessment for applications for non-drug items is based on the income and assets of the patient and his/her household members living under the same roof. If the patient's household income is below the corresponding Median Monthly Domestic Household Income and the household assets not exceeding three times of the item cost, the patient would generally receive assistance from the Fund.

8. For application for drug items, financial assistance will be granted if the estimated cost of the drug is above the patients' maximum annual contribution payable, the calculation of which is based on the applicants' annual disposable household financial resources ("ADFR"), i.e. the sum of the patient's annual household disposable income and disposable capital. The annual household disposable income is the annual household gross income less the allowable deductions, ranging from $5,720 to $23,520 (depending on the number of household members), during the period. With the relaxation of the financial assessment criteria since 1 September 2012, a deductible allowance, ranging from $212,000 to $698,000 (depending on the number of household members), is also provided when calculating the value of disposable capital of the patient's household. The tiers of patient's contribution ratio for drug expenses are also simplified from the past 12 bandings to the present seven bandings. Separately, the Second Phase of the Community Care Fund ("CCF") Medical Assistance Programme[1] was incorporated into the Fund on 1 September 2012 by reducing the patients' maximum contribution ratio from 30% to 20% of their ADFR.

9. A summary of the number of patients granted with subsidy under the Fund from 2008-2009 to 2012-2013 and the total amount of subsidies granted to cover expenses on self-financed drugs during the corresponding period is in **Appendix I**.

Deliberations of the Panel

10. The Panel held a number of meetings between 2005 and 2012 to discuss issues relating to the Formulary and the Fund. The deliberations and concerns of members are summarized below.

Introduction of new drugs and review of existing drugs in the Formulary

11. Noting that the Drug Advisory Committee ("DAC") and the Drug Utilization Review Committee ("DURC") of HA were responsible for appraising new drugs for inclusion in the Formulary and reviewing the existing drugs in the Formulary respectively, members expressed dissatisfaction with the lack of transparency on the membership and the operation of the two committees. Some members considered that HA should accord a higher priority to drugs with same efficacy but fewer side effects. More target therapy drugs for treating cancers should also be included in the Formulary as general drugs or special drugs.

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[1] The Steering Committee on CCF launched two Medical Assistance Programmes (the First Phase and Second Phase Programmes), which adopts the same mode of operation as that for the Fund, in August 2011 and January 2012 respectively. The First Phase Programme aims to subsidize HA patients to use nine specified self-financed cancer drugs which have not been brought into the safety net of the Fund but have been rapidly accumulating medical scientific evidence and with relatively high efficacy. The Second Phase Programme provides subsidy to HA patients who could not benefit from the Fund or the First Phase Programme, with the contribution ratio of patients being reduced from the maximum of 30% to 20% of their ADFR.

12. HA advised that DAC, which comprised doctors, clinical pharmacologists and pharmacists, systematically appraised new drugs every three months. DURC conducted periodic review on existing drugs in the Formulary. Its composition included the Chairmen of the drug committees of the seven hospital clusters and specialists. DAC and DURC were supported by expert panels which provided specialist views on the selection of drugs for individual specialties. In reviewing individual drugs, the committees and expert panels had had regard to the principles of efficacy, safety and cost-effectiveness and taken into account various factors, including international recommendations and practices, changes in technology, pharmacological class, disease state, patient compliance, quality of life, actual experience in the use of drugs, comparison with available alternatives, impacts on healthcare costs and views of professionals and patients groups.

13. In response to members' repeated calls for enhancing transparency of the Formulary, HA had uploaded to its website the decisions of DAC on individual applications for new drug evaluation submitted by the Drug and Therapeutic Committees of individual clusters or hospitals, together with a list of reference that had been taken into account in the process of consideration of the applications. HA had also disclosed on its website the professional composition of DAC and the individual specialties of the relevant expert panels. However, the names of individual members serving on DAC and the relevant expert panels were not disclosed. The rationale put forth by HA was that this could minimize unwarranted pressure on the committee members and ensure the impartiality of expert opinions in the discussion process. Some members did not subscribe to HA's explanation. They considered that members of DAC and the relevant expert panels should be subject to public monitoring.

14. Noting that cost-effectiveness was one of the principles for assessing the drugs, members were concerned about whether HA would compromise patients' interests to save money. Question was also raised about the weighting of the factors of efficacy, safety and cost effectiveness adopted by HA when evaluating the new or existing drugs. HA advised that public resources should be utilized with maximal effect of healthcare in order to ensure equitable access by patients to cost-effective drugs. This notwithstanding, efficacy and safety were the most important considerations in evaluating the drugs. The factor of cost-effectiveness would only come into play in the context of deciding whether a drug should be positioned as a general drug, special drug and self-financed drug with or without safety net.

<u>Provision of drugs at individual cluster or hospital of HA</u>

15. Members expressed grave concern about the variation in the provision of drugs across different clusters due to the difference in their size of budget for purchasing drugs; as well as the time lag between the inclusion of a new drug in

the Formulary and the date the drug was included in the drug list of a cluster or hospital. There was a view that the prevailing arrangement to allow each cluster or hospital to decide on their own the drugs to be included in its drug list was at variance with the objective of introducing the Formulary.

16. According to the Administration and HA, individual cluster would stock part of the drugs listed in the Formulary according to their service provision and targeted patients. Given that it was common that there were 30 to 40 drugs with similar efficacy available in a drug class, a hospital would systemically select the drugs to be included in its drug list in order to adopt a more unified approach of treatment by its frontline doctors. The use of new drug included in the Formulary by a cluster depended on the knowledge and experience of the doctors of each cluster in using the drug concerned. However, there would not be a great difference in the available drugs for the treatment of common types of disease across different clusters.

Engagement with patient groups in the development of the Formulary

17. Members noted that HA had established a formal consultation mechanism with patient groups on the Formulary, under which 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 drugs and review of existing drugs in the Formulary. The patient groups would be given two months' time after the annual consultation meetings to submit their views to HA. Question was raised as to whether HA would invite representatives of the patient groups to become members of DAC. HA advised that the views and suggestions submitted by patient groups under the consultation mechanism would be presented to the relevant drug committees for consideration.

18. 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.

Financial assistance to needy patients

19. Members were concerned about the financial burden imposed by the extremely expensive self-financed drugs, such as cancer drugs, on patients. Question was raised as to whether the expenses borne by each patient for purchasing self-financed drugs could be capped at, say, $100,000 each year, and the amount exceeding the cap would be covered by HA as part of its subsidized services. There was also a view that patients' expenditure on self-financed drugs should be tax deductible.

20. 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 Fund to meet expenses on self-financed drugs or seek fee waiver from HA. The First Phase CCF Medical Assistance Programme would also provide financial assistance to needy HA patients for the use of specified self-financed drugs which had not been brought into the safety net of the Fund but had been rapidly accumulating medical scientific evidence and with relatively high efficacy.

21. Some 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 self-financed drugs with safety net. To ensure an efficient use of the $10 billion grant to the Fund, there was a suggestion that HA should review the Formulary and expand the scope of the Fund to cover more self-financed drugs such as cancer drugs.

Role of the Fund

22. Noting that HA was responsible for determining the drugs to be introduced and categorized as self-financed drugs with safety net, as well as managing the Fund, some members doubted whether the Fund could serve its intended purpose of providing relief to needy patients. In their view, the Fund might be used as a justification by HA for excluding drugs proven to be of significant benefits but extremely expensive to provide in the Formulary. They urged the Administration to enhance the transparency of the operation of the Fund.

23. The Administration stressed that the Fund had never deviated from its objective of providing relief to needy patients. The introduction of drugs into the Formulary and the inclusion of self-financed drugs into the scope of the Fund would foremost be based on the latest scientific and clinical evidence on efficacy and safety of drugs and not their cost. Recommendations for major changes to the Formulary would be considered in the HA Annual Planning process. Recommendations of DURC for including drugs as self-financed drugs under the Fund would be considered by the Samaritan Fund Management Committee, which in turn would make recommendations to the Medical Services Development Committee for endorsement. HA pointed out that a number of measures had been implemented to enhance the transparency of the overall drug policy. A consultation mechanism with patient groups had also been put in place to gauge their views on the formulation and changes to the scope of the Formulary and the Fund.

Financial assessment for drug subsidies under the Fund

24. There was a view that income of the extended family members living with the patients should not be counted as the patients' household income when

assessing the financial condition of the applicants for the Fund. Some members went further to suggest that patients living with their family members should be allowed to apply for assistance from the Fund on an individual basis. A high-level committee should also be set up for the exercise of discretion to grant approval for subsidy to patients who fell marginally outside the safety net.

25. The Administration advised that the practice of using patients' household income in assessing the level of subsidy granted under the Fund was in line with other safety nets funded by public money, such as public housing, student loans, legal aid and the Comprehensive Social Security Assistance. This assessment criterion for public assistance was also adopted in many developed countries. The rationale was to encourage family members to support each other and to prevent the avoidance of responsibility by resorting to public assistance in the first instance. It should be noted that due regard would also be given to non-financial factors, such as medical and social grounds meriting special discretion, when vetting an application for the Fund.

26. While expressing support for the provision of a $10 billion grant to the Fund and the regularization of the Second Phase CCF Medical Assistance Programme, many members considered that the Administration should further relax the financial assessment criteria to benefit more needy patients, in particular those from the middle class families who were often required to purchase the costly self-financed drugs at their own expense. According to the Administration, it was estimated that about 3 000 patients would benefit from the regularization of the Second Phase CCF Medical Assistance Programme and the relaxation of the financial assessment criteria of the Fund. These included patients who were receiving partial subsidy and would become fully subsidized or contributed a smaller amount of the drug cost, patients who would become newly eligible for the subsidy, as well as those who were currently enjoying full subsidy from the Fund.

Long-term sustainability of the Fund

27. Noting that there would be a multifold increase in the annual expenditure for the Fund in the coming years, members urged the Administration to invest the funds which were not immediately required to generate return to sustain the operation of the Fund. The Administration advised that it was expected that the expenditure of the Fund would continue to increase in the coming years due to advancement in medical technology, and rising demand from an aging population which had resulted in an increasing number of patients suffering from cancer and other chronic diseases. To make better use of public resources and to enhance the sustainability of the Fund, a prudent investment approach was being considered with the aim of optimizing investment returns and meeting operating cash flow requirements.

Recent developments

28. The Government has earmarked an additional recurrent funding of $230 million for HA to introduce three new drugs as Special Drugs in the Formulary and expand the clinical applications of nine therapeutic groups of drugs in 2012-2013. In 2013-2014, an additional $44 million was allocated to HA for inclusion in the Formulary two chemotherapeutic drugs for cancer treatment and expanded the clinical applications of two therapeutic groups of drugs for treatment of advanced Parkinson's disease and cancer. At the Panel meeting on 20 January 2014 to receive a briefing from the Secretary for Food and Health on the 2014 Policy Address in relation to health matters, members were advised, among others, that HA would continue to expand the coverage of the Formulary to cover more new drugs in 2014-2015. To enhance the governance of the Formulary, HA has set up a high-level Drug Management Committee in 2013 to replace DURC to oversee the overall drug management.

29. According to the Annual Operation Report of the Fund, the projected expenditure of the Fund is $401 million (including a $90 million expenditure on non-drug items and a $311 million expenditure on drug items) in 2013-2014, representing an increase of 38% over the $292 million in 2012-2013.

Relevant papers

30. A list of the relevant papers on the LegCo website is in **Appendix II**.

Council Business Division 2
Legislative Council Secretariat
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Appendix I

The number of patients who purchased self-financed drugs through the Hospital Authority, the total expenditure incurred by these patients and the support provided by the Samaritan Fund during the period of 2008-2009 to 2012-2013

	2008-2009	**2009-2010**	**2010-2011**	**2011-2012**	**2012-2013** (Actual figure up to 31 December 2012)
The purchase of self-financed drugs					
Number of patients purchasing self-financed drugs through the Hospital Authority	33 490	40 033	43 610	47 539	44 977
Total expenditure incurred by these patients on purchasing self-financed drugs through the Hospital Authority ($ million)	614.6	752.4	780.4	857.8	687.3
Support provided by the Samaritan Fund					
Number of patients provided with subsidy under the Samaritan Fund to cover expenses on self-financed drugs with safety net	782	1 055	1 282	1 435	1 269
Amount of subsidies granted under the Samaritan Fund to cover expenses on self-financed drugs with safety net ($ million)	73.59	84.2	150.5	174.9	182.9

Source: *The Administration's written replies to Members' initial written questions during the examination of estimates of expenditure 2013-2014*

Relevant papers on the Drug Formulary of the Hospital Authority and the Samaritan Fund

Committee	Date of meeting	Paper
Panel on Health Services	31.1.2005 (Item I)	Agenda Minutes CB(2)1049/04-05(01) *(Chinese version only)*
Panel on Health Services	8.3.2005 (Item I)	Agenda Minutes
Panel on Health Services	18.4.2005 (Item VI)	Agenda Minutes
Panel on Health Services	13.6.2005 (Item V)	Agenda Minutes CB(2)2705/04-05(01)
Panel on Health Services	10.7.2006 (Item IV)	Agenda Minutes CB(2)3090/05-06(01) CB(2)747/06-07(01)
Panel on Health Services	25.9.2006 (Item I)	Agenda Minutes
Panel on Health Services	11.12.2006 (Item IV)	Agenda Minutes CB(2)849/06-07(01)
Panel on Health Services	8.1.2007 (Item VI)	Agenda Minutes
Panel on Health Services	23.1.2007 (Item I)	Agenda Minutes CB(2)1894/06-07(01)
Panel on Health Services	12.2.2007 (Item III)	Agenda Minutes

Committee	Date of meeting	Paper
Panel on Health Services	24.6.2008 (Item I)	Agenda Minutes CB(2)23/08-09(01)
Panel on Health Services	10.11.2008 (Item IV)	Agenda Minutes
Panel on Health Services	8.6.2009 (Item VI)	Agenda Minutes
Panel on Health Services	19.6.2009 (Item I)	Agenda Minutes
Panel on Health Services	14.2.2011 (Item VI)	Agenda Minutes CB(2)1602/10-11(01)
Panel on Health Services	14.6.2011 (Item I)	Agenda Minutes
Panel on Health Services	14.11.2011 (Item VI)	Agenda Minutes CB(2)1680/11-12(01)
Panel on Health Services	16.4.2012 (Item IV)	Agenda Minutes CB(2)2087/11-12(01)
Panel on Health Services	10.7.2012 (Item II)	Agenda Minutes

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