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Panel on Health Services

Background brief prepared by the Legislative Council Secretariat for the meeting on 19 December 2016

Drug management of the Hospital Authority

Purpose

This paper provided background information and summarizes the concerns of members of the Panel on Health Services ("the Panel") on issues relating to drug management of the Hospital Authority ("HA").

Background

Drug Formulary of HA

2. HA has implemented the Drug Formulary ("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. Any recommendations for major changes to the Formulary will be considered during annual planning of HA.

3. At present, there are around 1 300 drugs listed on the Formulary. These drugs are classified into four categories.[1] The General Drugs and Special Drugs are provided within the standard fees and charges at public hospitals and clinics when prescribed under specified clinical conditions. General Drugs have well-established indications and cost-effectiveness, and are available for general use as indicated by patients with relevant clinical conditions. Special Drugs

[1] A drug may fall in more than one category due to different therapeutic indications or dose presentations. Existing drugs in the Formulary may be repositioned across categories in the light of latest scientific evidence under the periodic review process.

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. According to the Administration, there are 866 General Drugs and 352 Special Drugs in the Formulary. Separately, HA's expenditure on General Drugs and Special Drugs prescribed to patients at standard fees and charges in 2014-2015 and 2015-2016 was $4,333 million and $4,501 million[2] respectively.

4. Other drugs in the Formulary are self-financed items whereby patients have to purchase at their own expense.[3] 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 services. Patients who need these drugs but have financial difficulties may apply for assistance from the Samaritan Fund[4] or the Community Care Fund Medical Assistance Programme[5] ("the CCF Medical Assistance Programme") to fully or partially cover their expenses on these drugs. At present, a total of 39 self-financed drugs are covered in the scopes of the Samaritan Fund and the CCF Medical Assistance Programme.[6] Self-financed drugs without safety net include (a) drugs with preliminary medical evidence only; (b) drugs with marginal benefits over available alternatives but at significantly higher costs; and (c) lifestyle drugs (e.g. anti-obesity drugs). According to the Administration, there are currently 69 self-financed drugs without safety net. At present, HA supplies three categories of self-financed drugs at cost for purchase by patients at HA pharmacies. These include items not readily available at community pharmacies; items covered by the safety net; and items for meeting operational needs (e.g. injectable drugs).

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2 The projection in 2015-2016 was based on expenditure figure as at 31 December 2015.

3 Prescribed self-financed drugs are charged by HA at cost plus an administrative charge of $50 per drug item dispensed.

4 Established in 1950, the Samaritan Fund is a charitable fund to provide financial assistance for 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. In June 2012, the Finance Committee of the Legislative Council approved a commitment of $10 billion for a grant to support the continued operation of the Fund for the next 10 years or so.

5 The CCF Medical Assistance Programme provides financial assistance for HA patients to purchase specified self-financed cancer drugs which have not been covered by the Samaritan Fund but have been rapidly accumulating medical scientific evidence and with relatively higher efficacy.

6 Each year, HA reviews the need for expanding the safety net to cover additional self-financed drugs, relaxing the prescribing indications for existing safety net drugs, and repositioning the drugs covered by the CCF Medical Assistance Programme to be under the coverage of the Samaritan Fund.

5. According to HA, public hospitals and clinics differ in their scope of service to cater for the clinical needs of the catchment district and provide appropriate coverage within the cluster, such that certain hospitals or clinics may provide specific services only. Hence, different public hospitals and clinics stock different drugs on the Formulary according to their respective needs.

Drug procurement arrangement of HA

6. At present, the vast majority of drugs of HA have been centrally procured. Individual hospitals cannot decide on their own to purchase drugs outside the Formulary. In accordance with the mechanism put in place by HA for the procurement of drugs, HA procures drug items of high volume or in large value with market alternatives through open tenders. All tenders of the suppliers must comply with the quality requirements, such as registration with the Department of Health,[7] accreditation of Good Manufacturing Practice[8] of the manufacturing site and detailed product specific information. Tender prices will only be considered after the quality of pharmaceutical products is confirmed in order to protect the safety of patients. In 2015-2016, the annual drug expenditure for HA was $5.7 billion, accounting for around 10% of HA's total expenditure in that financial year.

7. The Drug Selection Committee of HA is responsible to review and make recommendations on procurement policy for generic pharmaceutical products; to consider and advise on acceptability of generic drug products for use in public hospitals and clinics; and to advise on monitoring of efficacy and quality of drugs selected for use in public hospitals and clinics. Separately, following the drug incidents in 2009,[9] HA has set up a Drug Quality Assurance Office under the Chief Pharmacist's Office in 2010 to monitor product quality, handle quality incident reports and manage the performance of pharmaceutical manufacturers and suppliers.

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[7] According to the Pharmacy and Poison Ordinance (Cap. 138), all drugs in Hong Kong must be registered and conformed to the standards on safety, efficacy and quality. Unless there are exceptional circumstances in the supply of drugs, HA only purchases drugs registered with the Department of Health.

[8] Good Manufacturing Practice is a quality assurance approach used by the drug manufacturing industry worldwide to ensure that products are consistently produced and controlled throughout the manufacturing process.

[9] In early 2009, a number of incidents concerning pharmaceutical products in Hong Kong had caused wide public concerns on drug safety. A Review Committee on the Regulation of Pharmaceutical Products in Hong Kong was set up in March 2009. The Review Committee has made a total of 75 recommendations, covering, among others, procurement and supply of pharmaceutical products in HA.

Deliberations of the Panel

8. The Panel held a number of meetings between 2005 and 2015 to discuss issues relating to the drug management of HA and received the views of deputations at four meetings. The deliberations and concerns of members are summarized in the following paragraphs.

Management of the Formulary

9. Members noted that HA had revamped the governance structure for managing the Formulary in 2013. A high-level Drug Management Committee ("DMC") was set up to replace the former Drug Utilization Review Committee. DMC would report to and seek policy direction from the Directors' Meeting, which in turn was accountable to the Medical Services Development Committee which oversaw the development of clinical services at the HA Board level. Members were concerned about the overall drug management and governance in the Formulary.

10. HA advised that DMC took charge of the Formulary management at the policy level and oversaw, among others, the Drug Advisory Committee ("DAC") and the Drug Formulary Committee ("DFC"). DAC was responsible for regular appraisal of new drugs and new indications for listing on the Formulary every three months in January, April, July and October each year. All new drug applications had to be initiated by HA clinicians and submitted to DAC for consideration via the Cluster Drug and Therapeutics Committees or Hospital Drug and Therapeutics Committees. DFC was tasked to review the prevailing drug list of the Formulary every 24 months to remove obsolete drugs and modify the clinical indications of individual Special Drugs as appropriate. In discharging their functions, DAC and DFC were supported by multiple expert panels which provided professional views for the review of drugs in related specialty areas.

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

11. Members noted that the evaluation of new drugs and review of existing drugs followed an evidence-based approach, having regard to the principles of efficacy, safety and cost-effectiveness[10] and taking into account various factors,

[10] In terms of a new drug, DAC would compare its efficacy with that of other existing treatment alternatives in the Formulary for the same disease condition where appropriate; evaluate its safety profile by weighting its clinical benefits against its risks, and compare the adverse effect profile between the new drug and its alternatives; and evaluate its cost-effectiveness by assessing its total cost impacts and making reference to related overseas pharmacoeconomic evaluation studies.

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. 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 in evaluating the new or existing drugs.

12. HA advised that public resources should be utilized with maximal effect of healthcare to ensure equitable access by patients to cost-effective drugs. This notwithstanding, the evaluation of drugs would foremost be based on the latest scientific evidence on the safety and efficacy of drugs. The factor of cost-effectiveness would only come into play when a drug was proved to be of benefits to patients. In general, HA made reference to the incremental cost-effectiveness ratio suggested by the National Institute for Health and Care Excellence of the United Kingdom[11] for consideration of the cost-effectiveness of some self-financed drugs under review.

13. There was a view that the appraisals of new drugs by DAC on quarterly basis might not be able to catch up with the rapid development of new drugs. Concern was also raised about the relatively low number of new drugs introduced in the Formulary when compared with other developed countries. There was a question as to whether the share of the total recurrent funding from the Government to HA accounted by drugs was on par with that of the public healthcare sectors in overseas countries. According to HA, it was appropriate for DAC to meet every three months for evaluation of new drugs. As the public healthcare system and the drug procurement policies varied across countries, it was not appropriate to make a direct comparison of the use of drugs by HA with the practice of other places.

14. Some members considered that the Formulary should be patient-oriented and HA should accord a higher priority to drugs with same efficacy but fewer side effects. More new psychiatric drugs and target therapy drugs for treating cancers, which were commonly used in the private healthcare sector, should also be included in the Formulary as General Drugs and Special Drugs. There was also a call for HA to reposition more Special Drugs for chronic diseases in the Formulary as General Drugs. The Administration advised that HA had introduced a number of new drugs to the Formulary, repositioned self-financed drugs as Special Drugs and expanded the clinical applications of Special Drugs

[11] Incremental cost-effectiveness ratio was calculated by dividing the difference in costs by the difference in quality-adjusted life years. A lower ratio indicated a more favourable cost-effectiveness of a drug.

in the Formulary in recent years. In 2015-2016, HA further introduced five new drug classes to the Formulary for treatment of cancer, chronic Hepatitis C and Crohn's disease, and widen the clinical application of a Special Drug for treatment of multiple sclerosis.

15. On the question about whether DAC's decisions on new drug applications could be reviewed, HA advised that there was no limit on the number of applications. Unsuccessful applicants could re-submit their applications providing further information of the reviewed drugs for re-consideration of DAC. To enhance operational transparency, the outcome of each individual drug applications for inclusion in the Formulary, together with a list of references that had been taken into account in the process of considering each drug application, were uploaded to HA's internet and intranet websites after each DAC meeting.

Provision of drugs at individual cluster or hospital of HA

16. 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.

17. According to the Administration and HA, given that not all public hospitals provided exactly the same range of clinical services, mechanisms were in place for public hospitals to formulate their local drug formulary by selecting suitable drugs from the Formulary in light of service needs. HA clinicians would prescribe suitable treatments having regard to patients' clinical needs and established clinical guidelines. The financial position of hospital clusters would not affect the prescription of appropriate treatment for patients.

Engagement with patient groups in the development of the Formulary

18. Members noted that HA had established a formal consultation mechanism with patient groups on the Formulary, under which two consultation meetings would be held every year 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 consultation meetings to submit their views to HA. Some members were of the view that the membership of DMC and other drug committees of HA should comprise representatives from patients groups.

19. 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. In addition, the Chief Executive of HA would regularly meet with patient representatives to collect their views on various areas of patient services, including matters related to the Formulary, through the Patient Advisory Committee set up in 2011. Ad hoc meetings would also be convened with individual patients groups to discuss specific issues of concerns where necessary. While not ruling out the possibility to include patient representatives in the relevant drug committees, HA advised that there had been concerns that doing so might give rise to the issue of conflicts of interest in discussion and might affect the core value of evidence-based practice.

20. There was a 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.

Financial assistance for purchasing self-financed drugs

21. Members were concerned about the financial burden imposed by the extremely expensive self-financed drugs on patients, especially those suffering from cancers and chronic diseases. 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.

22. 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 self-financed drugs or seek fee waiver from HA. The CCF Medical Assistance Programme also provided 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 Samaritan Fund but had been rapidly accumulating medical scientific evidence and with relatively high efficacy.

23. 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. Given 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 Samaritan Fund, they considered that the Samaritan 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. To ensure an efficient use of the $10 billion grant to the Samaritan 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.

Drugs for patients with rare diseases

24. Concern was raised over the drug treatments for rare diseases. Some members considered that the Administration should provide a clear definition and policy on rare diseases to support patients suffering from these diseases. There was also a suggestion of developing a territory-wide database for rare diseases to provide a profile of the common types of rare diseases in Hong Kong, so as to foster scientific research and facilitate support for patients with rare diseases.

25. According to the Administration, there was no common definition of rare diseases worldwide. The definition of rare diseases in different countries varied depending on their healthcare systems and situations. HA managed uncommon disorders by putting in place an independent expert panel to assess the suitability of individual patients for receiving enzyme replacement therapy ("ERT") and the efficacy of such treatment for six types of lysosomal storage disorders[12]. The assessment by the expert panel was based on the established treatment guidelines specifically formulated for the diseases, having regard to the patients' clinical conditions and making reference to overseas treatment guidelines and the latest available clinical evidence. These ERT drugs had been positioned as Special Drugs in the Formulary. From 2008-2009 to 2014-2015, the Administration allocated in stages a total of $55 million recurrent expenditure to subsidize the expenses of the above six types of patients on the expensive drugs. For applications approved by the expert panel, HA would provide ERT for the patients concerned at standard fees and charges. In addition to drug therapy, HA also provided rehabilitation care, pain alleviate and surgical treatment for patients with uncommon disorders.

Procurement of drugs for public hospitals and clinics

26. 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 advised that its drug procurement mechanism followed the requirements of the World Trade Organization. Patent drugs would be procured through single tender whereas off-patent generic drugs would be procured through open tender.

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[12] The six lysosomal storage disorders included Pompe disease, Fabry disease, Gaucher disease and Mucopolysaccharidosis Type I/Type II/Type VI.

Due regard would be given to the quality and prices of the drugs when assessing the submissions in an open tender.

Recent developments

27. The Audit Commission has recently conducted a review of HA's drug management, covering the management of the Formulary, procurement of drugs, dispensing and handling of drugs, monitoring the quality of drugs, as well as administrating financial assistance programmes for purchasing self-financed drugs. The recommendations made in this regard as set out in Report No. 67 of the Director of Audit ("the Audit Report") are highlighted in **Appendix I**.

28. HA advised on 23 November 2016 that it would carry out follow-up actions in response to the recommendations of the Audit Report. These included, among others, (a) formulating a comprehensive guideline on the use of non-Formulary drugs; (b) continue to increasing bulk contract arrangements for suitable drugs in line with the current drug procurement strategies; (c) rolling out the drug refill service to break down long-duration prescriptions and provide drug counselling to targeted patient groups; and (d) including appropriate new drugs under the scope of the safety net on the basis of safety, efficacy and cost-effectiveness considerations and other relevant factors.

Relevant papers

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

Council Business Division 2
Legislative Council Secretariat
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Appendix I

The Director of Audit's Report No. 67

Audit recommendations on the Hospital Authority's drug management

Management of the Drug Formulary of the Hospital Authority ("the Formulary")

(a) review what measures need to be implemented to ensure that patients attending different public hospitals and clinics have equitable access to non-Formulary drugs when they have the relevant clinical needs;

(b) consider drawing up a detailed manual for managing the use of non-Formulary drugs and ensure compliance;

(c) issue comprehensive guidelines on the charging of non-Formulary drugs covering different situations and ensure compliance;

(d) encourage and facilitate more Hospital Authority's hospitals and clinics to apply for new drug listing on the Formulary;

Procurement of drugs

(e) set up an effective mechanism for regularly analyzing hospitals' demand for drug items not covered by bulk contracts to determine whether bulk contracts should be used to achieve the best value for money;

(f) closely monitor the performance of drug suppliers in complying with delivery schedules and take effective follow-up action on delivery complaints received from hospitals;

(g) assess the risk and impact of supply disruption for commonly-used drug items to determine whether multi-source procurement should be implemented for them;

Dispensing and handling of drugs

(h) regularly assess the extent of drug wastage among patients of the Hospital Authority, and take appropriate measures to tackle the problem;

(i) conduct a comprehensive review of the handling and custody of dangerous drugs where necessary, issue guidelines on the investigation of incidents of missing dangerous drugs and ensure that such incidents are forthwith reported to the Department of Health;

Monitoring the quality of drugs

(j) formulate a strategy for sample testing of drugs and lay down clearly the sampling methodology for implementing the strategy;

(k) ensure that contractors submit reports on drug testing according to the time frame set out in the contracts;

(l) ensure that investigations of complaints about drug quality are completed as soon as possible;

Administering financial assistance programmes for purchasing self-financed drugs

(m) continue to include appropriate new self-financed drugs under the scope of the safety net; and

(n) explore expanding the scope of post-approval checks on financial assistance cases and take improvement measures on the long time taken to follow up some significant cases of under-reporting of income and/or assets.

Source: Executive summary of Chapter 5 on Hospital Authority's drug management of Report No. 67 of the Director of Audit

Appendix II

Relevant papers on drug management of the Hospital Authority

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)*
	8.3.2005 (Item I)	Agenda Minutes
	13.6.2005 (Item V)	Agenda Minutes CB(2)2705/04-05(01)
	10.7.2006 (Item IV)	Agenda Minutes CB(2)3090/05-06(01) CB(2)747/06-07(01)
	25.9.2006 (Item I)	Agenda Minutes
	8.1.2007 (Item VI)	Agenda Minutes
	23.1.2007 (Item I)	Agenda Minutes CB(2)1894/06-07(01)
	12.2.2007 (Item III)	Agenda Minutes
	24.6.2008 (Item I)	Agenda Minutes CB(2)23/08-09(01)
	31.3.2009 (Item I)	Agenda Minutes

Committee	Date of meeting	Paper
	8.6.2009 (Item VI)	Agenda Minutes
	19.6.2009 (Item I)	Agenda Minutes
	11.1.2010 (Item V)	Agenda Minutes
	14.2.2011 (Item VI)	Agenda Minutes CB(2)1602/10-11(01)
	14.6.2011 (Item I)	Agenda Minutes
	20.1.2014 (Item IV)	Agenda Minutes CB(2)1424/13-14(01)
	17.3.2014 (Item III)	Agenda Minutes CB(2)2053/13-14(01)
	15.6.2015 (Item V)	Agenda Minutes

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