立法會
Legislative Council

LC Paper No. CB(4)973/20-21(06)

Ref : CB4/PL/HS

Panel on Health Services

Meeting on 14 May 2021

Updated background brief on Drug Formulary of the Hospital Authority and drug subsidies

Purpose

This paper provides updated background information and summarizes the major views and concerns expressed by members of the Panel on Health Services ("the Panel") and the Subcommittee on Issues Relating to the Support for Cancer Patients ("the Subcommittee") appointed by the Panel in the Sixth Legislative Council ("LegCo") on issues relating to the Drug Formulary ("the Formulary") of the Hospital Authority ("HA") and drug subsidies.

Background

Drug Formulary of Hospital Authority

2. 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 has an established mechanism with the support of 21 expert panels to regularly evaluate new drugs and review the existing drugs in the Formulary. Under the existing mechanism, HA's Drug Advisory Committee ("DAC") would review all new drug applications every three months. In addition, the Drug Formulary Committee, with the support of multiple expert panels, conducts biennial comprehensive review of the drugs listed on the Formulary which at present has approximately 1 400 drugs for treatment of various diseases.

3. Drugs in the Formulary fall into four categories[1] (viz. General drugs, Special drugs, Self-financed Items with safety net coverage and Self-financed Items without safety net coverage). The General Drugs are with well-established indications and cost-effectiveness which are available for general use as indicated by patients with relevant clinical indications and provided at standard fees and charges in public hospitals and clinics, while Special Drugs are provided at standard fees and charges in public hospitals and clinics when prescribed under specified clinical conditions.[2] There are 886 General Drugs and 415 Special Drugs in the Formulary as at January 2021. Separately, HA's expenditure on General Drugs and Special Drugs prescribed to patients at standard fees and charges in 2019-2020 and 2020-2021 was $6,223 million and $6,431 million[3] respectively.

4. Other drugs in the Formulary are self-financed items whereby patients have to purchase at their own expense. There are currently 67 self-financed items as at January 2021. These self-financed items are categorized into those with safety net coverage and those without safety net coverage. Self-financed items with safety net coverage are drugs which are proven to be of significant benefits but extremely expensive for HA to provide as part of its subsidized services. A safety net, like the Samaritan Fund ("the Fund") and the Community Care Fund Medical Assistance Programme ("Medical Assistance Programme"), is provided to subsidize the drug expenses of patients who have financial difficulties. Self-financed items without safety net coverage include drugs with preliminary medical evidence only, drugs with marginal benefits over available alternatives but at significantly higher costs, and lifestyle drugs (e.g. anti-obesity drugs). These drugs are not provided as part of HA's standard services nor covered by the standard fees and charges in public hospitals and clinics. Patients who choose to use these drugs must purchase them at their own expense.

5. Patients should in general purchase self-financed drugs from any of the registered community pharmacies, however three categories of self-financed drugs are available for purchase by patients at HA pharmacies, including drugs covered by the safety net, very specialised drugs not readily available at community pharmacies and drugs for meeting operational needs (e.g. injections). Prescribed self-financed drugs are charged by HA at cost plus an administrative charge of $105 per drug item dispensed.

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[1] A drug may fall in more than one category in the Formulary due to different therapeutic indications or dose presentations.

[2] Patients who do not meet the specified clinical conditions but choose to use Special drugs are required to pay for the drugs.

[3] The projection in 2020-2021 was based on expenditure figure as at 31 December 2020.

Drug subsidies

6. Patients who need drugs categorized as self-financed items with safety net coverage but have financial difficulties may apply for assistance from the Fund or the Medical Assistance Programme to fully or partially cover their expenses on these drugs.

Samaritan Fund

7. Established in 1950, the 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 ("FC") 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. The annual balance of the Fund as at 31 March 2020 was 10,431 million. As at January 2021, a total of 51 self-financed drugs are covered by the Fund.

Community Care Fund Medical Assistance Programme

8. To provide cancer patients with more support, the Administration launched the Medical Assistance Programme (First Phase Programme) in August 2011 to offer patients financial assistance to purchase specified self-financed cancer drugs which have not yet been brought into the Fund's safety net but have been rapidly accumulating medical scientific evidence and have relatively higher efficacy. The Administration further rolled out in August 2017 a Medical Assistance Programme, namely Subsidy for Eligible Patients to Purchase Ultra-expensive Drugs (Including Those for Treating Uncommon Disorders) ("the Ultra-expensive Drugs Programme"). The scope of the First Phase Programme and the Ultra-expensive Drugs Programme has been expanding under established mechanisms with a view to including more suitable new drugs for patients in need. As at January 2021, the Medical Assistance Programmes covers 37 drugs.

Relaxation of the means tests of the Fund and the Medical Assistance Programmes

9. Since early 2019, the Administration have relaxed the means test mechanism for the Fund and the Medical Assistance Programmes, including modifying the calculation of annual disposable financial resources ("ADFR") in a drug subsidy application by counting only 50% of the patients' household net

assets, thereby offering asset protection to their families; and refining the definition of "household" adopted in financial assessment to cover only core family members living under the same roof and having direct financial connection with the patient concerned. Measures will also be taken to ease the financial burden of patients requiring long-term medication after reviewing the effectiveness of the measures, including: (a) modifying the calculation of the ADFR for recurrent applications, including deducting the drug expenses paid by the patient for the last treatment course[4] and calculating only 80% of the patient's household disposable income; (b) including more allowable deduction items in the calculation of the ADFR (including school fees on tertiary education for full-time students aged 25 or below, and maintenance payments), and adjusting the calculation of income[5] for all applications; and (c) extending the validity period of the financial assessment of recurrent applicants[6]. The amount of subsidies approved under the Fund and the Medical Assistance Programmes could reach up to $2.1 billion in 2020-21 and $3.1 billion in 2021-22.

Drug procurement arrangement of HA

10. 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

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4 The expenses at public hospitals/clinics on the drug under application of the last 12 months.

5 Double pay, year-end payment, bonus and gratuity, as well as monthly payout amount of reverse mortgage / policy reverse mortgage will be excluded from the calculation of income.

6 The validity period of the financial assessment of the first application will be extended from 12 months to 18 months on the condition that the patient contribution is not more than $2,000. In addition, HA will waive the requirement to submit financial documents if the patient has been referred second application within one to two months after the first application.

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.

in order to protect the safety of patients. In 2020-2021, the annual drug expenditure for HA was $8.62 billion, accounting for around 10.6% of HA's total expenditure in that financial year. 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.

Discussion of the Panel and the Subcommittee

11. At the Panel meeting held on 19 December 2016, members were briefed on the drug management system of HA. The Subcommittee received views from deputations on expensive drugs, cancer strategy and the means test mechanism for the Fund and the Medical Assistance Programmes at its meeting on 16 December 2019. The Administration briefed the Panel on the review on the measures to enhance the means test mechanism for the Fund and the Medical Assistance Programmes at its meeting on 8 January 2021.

The Formulary

12. Members called on HA to comprehensively review the Formulary which had been put in place since 2005. In particular, they requested HA to engage patient groups and relevant professionals outside HA in managing the Formulary. Referring to the criticisms of the Director of Audit[9] on various areas of drug management of HA, members expressed concern that many drugs of proven clinical benefits were not listed as General drugs, Special drugs or self-financed drugs with safety net, members urged HA to conduct a review of the principles underlying the development of the Formulary.

13. The Administration advised that the drug management system of HA and the Formulary had been constantly reviewed. The development of the Formulary was underpinned by the core values of evidence-based medical practice, rational use of public resources, targeted subsidy, opportunity cost consideration and facilitation of patients' choice. To enhance the transparency

[9] Findings of the value-for-money audit on HA's drug management as set out in Chapter 5 of Report No. 67 of the Director of Audit ("the Audit Report"), details of which were set out in the Administration's paper (LC Paper No. CB(2)386/16-17(03)). The Public Accounts Committee ("PAC") did not hold any public hearing on this subject but asked for written responses to its questions raised on the subject. Details of PAC's deliberations thereon were set out in Chapter 5 of the Director of Audit's Report No. 67 – "Hospital Authority's drug management".

of the Formulary, HA had published a Hospital Authority Drug Formulary Management Manual in 2015[10] to give an account of the governance structure as well as the principles and operational procedures for managing the Formulary. In response to the recommendations put forth in the Audit Report, HA had drawn up an action plan for implementation in phases within a year. The Administration assured members that views of external stakeholders, including patient groups and relevant professionals, had been and would continuously be collected in managing the Formulary.

14. Some members noted that HA's expenditure on drugs, which was about 10% of HA's total expenditure, was low when compared to that of other developed countries. They opined that the cost and budget control measures adopted by individual public hospitals had affected doctors' prescription decisions in some cases. Members asked whether HA had set a prescribed proportion of its total expenditure for expenditure on drugs. Some other members also expressed concern as to whether the difference in the resources allocated to individual public hospitals would affect the selection of drugs for listing on the hospital drug formularies.

15. The Administration advised that HA would ensure that doctors would have adequate drug options for the same indication under the Formulary. If there were a number of agents with similar efficacy for the same indication, doctors would give due regard to, among others, the cost-effectiveness of the drugs in prescribing drug treatments for patients according to their clinical conditions. Drugs having significant budget impacts on HA would be addressed through the annual planning process with a view to soliciting additional funding allocation from the Government to list the new drugs on the Formulary.

16. Some members pointed out that the drug formularies of the medium-sized public hospitals were different from that of the leading hospitals. Some other members also expressed concern that the drug formularies of public hospitals were different from that of public outpatient clinics.

17. The Administration advised that public hospitals and outpatient clinics differed in their scope of service to cater for the clinical needs of the catchment district. Hence, different hospitals and outpatient clinics would stock different drugs on the Formulary according to their respective service needs. For instance, the local drug formularies of those public hospitals which provided tertiary and quaternary level services comprised 1 000-plus drugs, whereas those

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[10] The Manual was further updated in 2018. (https://www.ha.org.hk/hadf/Portals/0/Docs/HADF_manual_Eng_2018.pdf)

of the medium-sized public hospitals and the outpatients clinics comprised around 800 and 400 drugs respectively.

18. The Subcommittee recommended that the Administration should streamline the procedures for introducing new drugs into the Formulary; set up a fast-track mechanism for evaluating new cancer drugs for inclusion into the Formulary; increase the transparency of the drug inclusion mechanism; and further increase the frequency of reviewing drug proposals for inclusion into the safety net.

Expensive drugs

19. Members called on HA to include more target therapy drugs for treating cancers and drugs for treating rare diseases, which were usually very expensive, in the Formulary. Some members also expressed concern about the financial burden brought about by the self-financed target therapy drugs without safety net on cancer patients and the drug treatment for other patients. A member considered that HA should provide financial assistance for those patients who could meet part but not all of the drug expenses.

20. The Administration explained that drug treatments for uncommon disorders could be extremely expensive. HA had been actively liaising with the drug suppliers with a view to formulating a sustainable financial arrangement to support the patients concerned. A mechanism was in place for HA to provide the ultra-expensive drug treatments for individual patients at standard fees and charges in emergency situations. The Administration further advised that cancer drugs which had proven to be of significant clinical benefits but were extremely expensive for HA to provide as part of its standard services would be positioned as self-financed drugs with the safety net of the Fund, which provided financial assistance to needy patients who met the specified clinical criteria and passed the means test to meet the drug expenses. This apart, the Medical Assistance Programme currently provided financial assistance for HA patients to purchase specified self-financed cancer drugs which had not yet been brought into the Fund but had been rapidly accumulating medical scientific evidence with relatively higher efficacy.

21. Some members remarked that the number of self-financed drugs covered under the Fund and the Medical Assistance Programme was far from adequate to meet the needs of patients in need of expensive drug treatments. Members asked whether HA had conducted any analysis on the types of diseases which required expensive drug treatments not being covered by the Fund. Some other members expressed concern that there was currently no control on the price setting by drug suppliers on ultra-expensive drugs.

22. The Administration advised that the coverage of the Formulary was driven by service needs. Hence, all applications for new drug listing would be initiated by HA clinicians and submitted to DAC for consideration via the Cluster or Hospital Drug and Therapeutics Committee. Drugs which had proven to be of significant clinical benefits but were extremely expensive for HA to provide as part of its standard services would be positioned as self-financed drugs with safety net. For those ultra-expensive drugs for uncommon disorders, HA would liaise with the drug suppliers with a view to mapping out the way forward for providing sustainable drug treatments for patients with these diseases.

23. Noting that HA had conducted sample checks on some approved financial assistance cases for purchasing self-financed drugs under the Fund and the Medical Assistance Programme, some members were concerned that cases had been found on under-reporting of income and/or assets.

24. The Administration advised that for cases involving overpayment of subsidy, HA would take actions to recover the overpaid amounts and report suspected fraud cases to the police for investigation. HA had enhanced patient education in this regard in order to safeguard proper use of public funds.

25. The Subcommittee requested the Administration to further relax the threshold for the means test mechanism of the two safety nets and consider providing tax deduction for cancer drug expenses.

Use of drugs not listed on the Formulary

26. Noting that HA had incurred a certain amount of expenditure on non-Formulary drugs, members asked whether and, if so, when these drugs would be incorporated into the Formulary.

27. The Administration explained that the use of non-Formulary drugs was to cater for the clinical needs of individual patients in exceptional situations. It should be noted that some of these drugs were not registered in Hong Kong but were required for use on certain named patients as recommended by the prescribing doctors concerned on a case-by-case basis.

Drug subsidies

28. The Panel welcomed the measures to enhance the means test mechanism for the Fund and the Medical Assistance Programmes. Members called on a further relaxation on the definition of "household" to allow patients applying the

subsidies in the name of an individual. Members also suggested further reducing the maximum patient contribution to less than 10% (or capped at $500,000) of the patient's household ADFR. Members urged the Administration to expedite the inclusion of suitable new drugs in the Self-financed items with safety net coverage of the Formulary.

29. The Administration explained that the definition of "household" was drawn up with reference to that used in other Government Funds. The enhancement measures introduced in 2019 had refined the definition of "household" adopted for financial assessment to cover only core family members living under the same roof and having direct financial connection with the patient concerned. The exercise for including self-financed drugs in the Fund and Medical Assistance Programmes had been increased to twice a year.

Referral from the Public Complaints Office

30. In January 2019, the Public Complaints Office of LegCo Secretariat referred an item to the Panel relating to inclusion of drugs for treatment of serious mental disorder in the Formulary. The deputation expressed that two drugs for treatment of serious mental disorder, which were prescribed to patients in certain public hospitals as sample drugs, had significant clinical benefits to patients. Those drugs were extremely expensive and the deputation requested HA to include those drugs in the Formulary.

31. Members expressed concern that apart from the price of the drugs, HA should also consider its efficacy and benefit to patients. Members also opined that it was unfair as only some of the hospitals were given sample drugs by pharmaceutical companies.

32. The Administration explained that one of the drugs concerned was provided for patients as a sample drug in certain hospitals. DACevaluated the application of inclusion of that drug in the Formulary and rejected its application due to insufficient proof of its effectiveness and there were other drugs in the Formulary that had similar theraputical effects. HA was subsequently informed by the relevant pharmaceutical company that the drug was no longer supplied to Hong Kong. As for another drug, it was provided by individual doctors as a sample drug. HA did not receive any application for inclusion of that drug in the Formulary.

Relevant questions raised at Council meetings and Finance Committee meetings

33. Questions related to the Formulary and drug subsidies were raised at the Council meetings of 30 January 2019, 26 June 2019 and 23 October 2019. At the special FC meetings to examine the Estimates of Expenditure 2021-2022 held on 15 April 2021, a number of members raised questions about the Formulary, the Fund and the Medical Assistance Programmes. The hyperlinks to the questions and the Administration's responses are in **Appendix**.

Relevant papers

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

Council Business Division 4
Legislative Council Secretariat
11 May 2021

Appendix

List of relevant papers

Committee	Date of meeting	Paper
Panel on Health Services	19 December 2016	Administration's paper CB(2)386/16-17(03) Background brief on Drug management of the Hospital Authority CB(2)386/16-17(04) Minutes CB(2)1226/16-17
	8 January 2021	Administration's paper CB(2)579/20-21(05) Background brief on means test mechanism for Samaritan Fund and Community Care Fund Medical Assistance Programmes prepared by the Legislative Council Secretariat CB(2)579/20-21(06)
Subcommittee on Issues Relating to the Support for Cancer Patients	16 December 2019	Administration's paper CB(2)356/19-20(01) Background brief on Mechanism for appraisal of cancer drugs for inclusion in the Hospital Authority Drug Formulary and the safety net and arrangement for the provision of sustainable and affordable drug treatment for cancer patients prepared by the Legislative Council Secretariat CB(2)356/19-20(02)

Committee	Date of meeting	Paper
		Minutes CB(2) 901/19-20
	17 July 2020 (issued date)	Report of the Subcommittee CB(2) 1367/19-20
Public Accounts Committee	15 February 2017 (tabled date)	Extract of P.A.C. Report No. 67 – Chapter 5 of Part 7 on Hospital Authority's drug management
Council Meeting	30 January 2019	Question raised by Dr Hon CHIANG Lai-wan on "Samaritan Fund and Community Care Fund Medical Assistance Programmes"
	26 June 2019	Question raised by Dr Hon CHIANG Lai-wan on "Treatment of cancers"
	23 October 2019	Question raised by Dr Hon Helena WONG on "New drugs for treating lung cancers"
Special Finance Committee	15 April 2021	Administration's replies to Members' initial written questions (Reply Serial Nos. FHB(H)028, FHB(H)069, FHB(H)076, FHB(H)102, FHB(H)108, FHB(H)110, FHB(H)120,FHB(H)142, FHB(H)179)

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