For information
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LEGISLATIVE COUNCIL PANEL ON HEALTH SERVICES

Updates on Hospital Authority Drug Formulary and the Samaritan Fund

PURPOSE

This paper provides an update on Drug Formulary (the Formulary) of the Hospital Authority (HA) and the Samaritan Fund (SF) since 2011.

BACKGROUND

2. HA implemented the Formulary in July 2005 with a view to ensuring equitable access by patients to cost effective drugs of proven safety and efficacy through standardization of drug policy and utilization in all public hospitals and clinics. Its development was underpinned by core values including evidence-based medical practice, rational use of public resources, targeted subsidy, opportunity cost considerations and facilitation of patients' choice. The Formulary evolves with regular appraisal of new drugs and review of the prevailing drug list under an established mechanism. The review process follows an evidence-based approach, having regard to the principles of efficacy, safety and cost-effectiveness and taking 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 patient groups.

3. HA has been expanding the coverage of the Formulary under relevant and established review mechanism. By the end of 2010, HA had introduced a

total of 81 new drugs to the Formulary, including nine General drugs, 41 Special drugs and 31 self-financed drugs without SF coverage. In 2010-11, the Government provided additional resources for HA to include six new drugs and reposition two self-financed drugs (including one with and one without SF coverage) as Special drugs and to expand the clinical applications of nine therapeutic groups of Special drugs in the Formulary in order to benefit more patients from using safe and efficacious drugs at standard fees and charges in public hospitals and clinics. HA's total drug consumption expenditure also increased from $2,408 million in 2008-09 to $2,986 million in 2010-11.

4. It has been the Government's public healthcare policy to ensure that no one is prevented from obtaining adequate medical treatment through lack of means. On this front, HA provides a safety net through the SF to subsidize the drug expenses of needy patients who require self-financed drugs which are not covered by the standard fees and charges in public hospitals and clinics. In recent years, HA has proactively relaxed the financial assessment criteria for applying for SF drug subsidies (including redefining the basis for calculating disposable income and allowable deductions) and expanded the coverage of SF in order to benefit more patients. Between 2007-08 and 2010-11, 12 self-financed drugs were put under SF coverage and seven indications of drugs under SF coverage were extended in phases. Besides, the Government has made several one-off injections, amounting to $1.5 billion in total by 2010-2011, in order to meet the rising demand for SF assistance. The amount of SF drug subsidies granted also increased from $73.6 million in 2008-09 to $150.5 million in 2010-11.

PROGRESS UPDATES SINCE 2011

5. Since 2011, the Formulary and the SF have evolved progressively as set out in the ensuing paragraphs.

Enhancement of Governance in Formulary Management

6. In 2013, HA set up a high-level Drug Management Committee (DMC) to replace the former Drug Utilization Review Committee to oversee the overall drug management. DMC takes charge of the Formulary management at the

strategic and policy level and oversees the two functional committees, i.e. Drug Advisory Committee (DAC) and Drug Formulary Committee (DFC), which are responsible for regular appraisal of new drugs and review of the prevailing drug list of the Formulary respectively. The two functional committees are supported by multiple expert panels which provide professional views for the review of drugs in related specialty areas. The governance in Formulary management has hence been enhanced.

Enhanced Operational Transparency of Formulary Management

7. HA maintains regular communication with both internal and external stakeholders on Formulary management and employs different means to channel relevant information to targeted parties. To enhance the operational transparency, improve the accessibility of information and strengthen confidence of stakeholders and the public in HA's Formulary management, the following measures have been taken since 2011:

(i) The composition of DAC has been uploaded to HA's internet website;

(ii) The list of new drugs to be reviewed at each DAC meeting is uploaded to both HA's internet and intranet websites;

(iii) The agenda of DAC meetings is sent to the Alliance for Patients' Mutual Help Organizations for further dissemination to its members; and

(iv) The outcome of each individual drug applications for inclusion in the Formulary, together with a list of references that have been taken into account in the process of considering each drug application, are uploaded to both HA's internet and intranet websites after each DAC meeting.

Expansion of Formulary and SF Coverage

8. HA regularly appraises new drugs and reviews the prevailing drug list in the Formulary under established mechanism. Between 2011 and 2013, HA has further introduced 44 new drugs to the Formulary, including six General drugs, 25 Special drugs and 13 self-financed drugs without SF coverage.

Besides, with additional recurrent allocation of over $500 million in total by the Government from 2011-12 to 2013-14, HA has repositioned six self-financed drugs (including four with and two without SF coverage) as Special drugs and expanded the clinical applications of 19 therapeutic groups of Special drugs in the Formulary in phases. With additional funding support from the Government, HA's total drug consumption expenditure has increased from $2,986 million in 2010-11 to the projected sum of $4,028 million in 2013-14, representing an average increase of about 9% per annum.

9. At present, there are around 1 300 drugs in the Formulary, as set out in the following table -

Drug Category	**Number**
a) General drugs	891
b) Special drugs	331
c) Self-financed drugs covered by safety net through Samaritan Fund	20
d) Self-financed drugs covered by Community Care Fund (CCF) Medical Assistance Programme	9
e) Self-financed drugs not covered by Samaritan Fund nor CCF Medical Assistance Programme	65

10. Similarly for the SF, HA has been reviewing its coverage to benefit more patients. During the period from 2011-12 to 2013-14, HA has introduced a total of 9 new drugs under the coverage of the SF and has extended 12 indications of drugs under SF coverage.

11. We have reported to the Panel in April 2012 via LC Paper No. CB(2)1640/11-12(03) the relaxation of financial assessment criteria (RFAC) for SF drug applications. The RFAC was implemented on 1 September 2012. With the relaxation, a deductible allowance[1] for calculating the total value of applicant's disposable capital was introduced thereby enabling more patients

[1] The current amount of deductible allowance ranges from $212,000 to $698,000 depending on the patient's household size. The allowance is subjected to annual review.

who have to rely on self-financed drugs to meet the financial test under SF and become eligible for the SF subsidy. The tiers of patient's contribution ratio for drug expenses were also simplified and the patients' maximum contribution ratio was reduced from 30% to 20% of their annual disposable financial resources (ADFR)[2].

12. HA has preliminarily reviewed the effect of the RFAC by assessing the number of patients benefited from the relaxation and the amount of additional subsidies granted. About 50% of the newly approved cases between 1 September 2012 (i.e. RFAC effective date) and 31 December 2013 have benefitted from the relaxation. A summary of the preliminary review of RFAC is at **Annex A**. Since RFAC has only been implemented for slightly more than a year, its full impact has yet to be accumulated and is subject to further evaluation.

13. In 2012-13, the Government provided a one-off grant of $10 billion to support the continued operation of the SF and to give more headroom for HA to increase the types of subsidized drugs in accordance with clinical protocols and scientific evidence with a view to benefiting more needy patients. At present, SF is supporting 20 self-financed drugs (see **Annex B**). Moreover, since 2011, five self-financed drugs originally subsidized by the SF had been repositioned as Special Drugs in the Formulary, with four of them being supported by additional recurrent allocation from the Government as explained in paragraph 8 (see **Annex C** for a complete chronology on repositioning of self-financed drugs). The amount of SF drug subsidies granted has increased from $150.5 million in 2010-11 to $206.6 million in 2013-14 (up to 31 December 2013).

Community Care Fund

14. In addition to the SF safety net, the Community Care Fund (CCF) offers financial assistance to HA patients on self-financed drugs. Two medical assistance programmes (the First Phase and Second Phase Programmes) were implemented.

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[2] Annual disposable financial resources (ADFR) are taken as the annual household disposable income (annual household gross income less allowable deductions during the period) plus the disposable capital.

15. The First Phase Programme, implemented on 1 August 2011, provides financial assistance to eligible HA patients to purchase specified self-financed cancer drugs which have not yet been brought under SF coverage but have been rapidly accumulating medical scientific evidence and with relatively higher efficacy. In April 2013, two drugs previously covered by the Programme were repositioned to SF safety net. It currently covers nine drugs for seven types of cancers. The Second Phase Programme was implemented on 16 January 2012. Under this programme, patients' maximum contribution to drug expenses has been reduced from 30% to 20% of their ADFR. This Second Phase Programme has been regularized into the SF on 1 September 2012 as explained in paragraph 11 above. As at 31 January 2014, 2 445 cases had been approved under the two CCF programmes with a total subsidy amounting to $201 million.

Engagement of External Stakeholders

16. HA has all long been maintaining close communication with patient groups on the Formulary and the SF through established liaison channels. Stakeholder engagement and communication channels have been formalized to ensure proper consultations and appropriate participation of stakeholders and service partners. To enhance accountability and partnership with the community, HA convenes two consultation meetings with the patient groups every year to keep them abreast of the latest developments of the Formulary and the SF, gather their views on the introduction of new drugs and review the existing drug list in the Formulary and drugs covered by the SF. Patient groups are invited to attend meetings and submit their views or proposals to HA for reference and consideration by the relevant drug committees. In early 2011, the Patient Advisory Committee was set up and the HA Chief Executive would regularly meet with patient representatives to collect their views on various areas of patient services, including matters related to the Formulary and the SF. Ad hoc meetings would also be convened with individual patient groups to discuss specific issues of concerns where necessary.

17. Furthermore, HA maintains open and on-going dialogues with drug companies, which is one of its key service partners. Apart from communications on Formulary development and drug review mechanism, HA also invites drug companies to provide relevant information on new drugs for consideration of inclusion in the Formulary. Moreover, HA maintains close communication with individual drug companies on the implementation of

special drug programmes and drug subsidy schemes in order to benefit more needy patients who require the use of self-financed drugs.

SUPPORT FOR PATIENTS WITH UNCOMMON DISORDERS

18. There is no common definition of rare diseases available worldwide, and the interpretation varies among countries with different characteristics of the respective health systems and situations. Being the major public healthcare service provider of Hong Kong supported by public funding, HA places high importance in providing optimal care for all patients and ensuring optimal and rational use of resources. On the basis of this established philosophy and framework and with due regard to the limitations of evaluating drug treatment for uncommon disorders, HA has been managing uncommon disorders by putting in place an independent expert panel to evaluate the benefits of individualized treatments and enlisting additional recurrent funding from the Government to support the drug treatments for uncommon disorders. Besides, HA provides various treatments, including rehabilitative care, pain alleviation, surgical treatment and bone marrow transplant, for patients concerned, irrespective of the number of patients with such uncommon disorders.

19. At present, there are a number of patients suffering from lysosomal storage disorders such as Pompe, Gaucher, Fabry and Mucopolysaccharidosis (MPS) Types I, II and VI. These disorders affect patients' metabolic system and progressively cause malfunctioning of their organs. Enzyme Replacement Therapy (ERT), which provides patient with the enzyme that is deficient or defective in their bodies, is one of the treatments for these diseases.

20. Given that the efficacy of ERT varies among patients under different clinical conditions and ERT is extremely expensive, HA has since December 2007 put in place a mechanism to assess, through an expert panel, the suitability of individual patients to receive ERT and the efficacy of such treatment. The assessment is conducted in accordance with established treatment guidelines formulated for the diseases concerned, having regard to the patients' clinical conditions and making reference to overseas treatment guidelines and the latest available clinical evidence. In 2008-09 and 2010-11, the Government allocated additional recurrent funding of $10 million and $35 million

respectively for HA to provide ERT for patients with lysosomal storage disorders. Currently, there are six ERT drugs listed as Special Drugs in the Formulary. HA would provide ERT to individual patients at standard fees and charges if the treatment is proved to be of significant clinical benefits to them.

21. Up to December 2013, 22 HA patients with lysosomal storage disorders have been provided with ERT. Currently, 17 patients are still undergoing ERT with breakdown as follows:

Diseases	**Number of patients undergoing ERT**
Pompe	8
Gaucher	2
Fabry	3
Mucopolysaccharidosis Type I	2
Mucopolysaccharidosis Type II	0
Mucopolysaccharidosis Type VI	2
Total	**17**

WAY FORWARD

22. HA will continue to regularly appraise new drugs and review the drug list in the Formulary and drugs covered by the SF and the CCF Medical Assistance Programme through established mechanisms. Changes will be made as appropriate to provide suitable treatment for patients while ensuring equitable and effective use of public resources. Any recommendation for major changes to the Formulary will be considered during HA Annual Planning.

23. In 2014-15, the Government will allocate additional recurrent funding of $37 million for HA to extend the therapeutic applications of Special Drugs for treating pyschosis, dementia and prostate cancer to enhance treatment for patients concerned. Separately, an additional recurrent funding of $167 million will be provided for HA to cope with the projected increased in expenditure for drug-related activities, which includes an additional $10 million recurrent funding for managing the increasing demand for and sustaining the provision of ERT.

24. HA will also continue to maintain regular communication with both internal and external stakeholders to enhance patients' understanding of the Formulary and its consultative mechanism in engaging stakeholders, as well as to enhance frontline doctor's understanding of the governance structure of the Formulary and the procedure for new drug inclusion. A HA Drug Formulary Manual will be compiled to outline the enhanced governance structure in Formulary management, drug review process and considerations, delineated roles and responsibilities of service partners, operational guidelines as well as procedures for drug applications. This will improve the transparency of Formulary management in HA and enable its service partners to execute their functions smoothly in different platforms of collaboration. HA will promulgate the manual to all internal and external stakeholders through different communication channels and established liaison mechanisms.

25. Furthermore, the website of the Formulary will be revamped to enhance easy access to information and facilitate effective conveyance of information to targeted stakeholders and service partners. Public education and stakeholder training will also be strengthened in order to ensure appropriate interpretation of information related to the Formulary management.

ADVICE SOUGHT

26. Members are invited to note the content of this paper.

Food and Health Bureau
Hospital Authority
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Annex A

Effect of Relaxation of Financial Assessment Criteria (RFAC)
for Samaritan Fund Drug Applications

Newly approved cases between 1 September 2012 (RFAC effective date) and 31 December 2013

	Number of cases	**Percentage (%)**	**Average Amount of Additional Subsidy per case ($)**
Patient who were eligible for full subsidy regardless of RFAC (including CSSA recipients)	1 278	49.1	Not applicable
Patients who had been highly subsidized with entitled subsidy being unaffected after RFAC	39	1.5	Not applicable
Patients who had been partially subsidized but received a higher amount of subsidy, or the partially subsidized drug costs had become fully subsidized	1 237	47.6	29 522
Patients who became newly eligible for SF subsidy	47	1.8	47 496
Total	**2 601**	**100**	

Annex B

Drugs Supported by the Samaritan Fund

In alphabetical order
(Drugs in italics were introduced in 2013)

1. Abatacept for rheumatoid arthritis
2. *Adalimumab* for rheumatoid arthritis / ankylosing spondylitis / psoriatic arthritis / Crohn's Disease / *severe psoriasis*
3. Bortezomib for multiple myeloma / frontline induction therapy of transplant-eligible, younger multiple myeloma patients
4. *Dasatinib for* Imatinib-resistant chronic myeloid leukaemia / newly diagnosed chronic myeloid leukaemia in chronic phase / *acute lymphoblastic leukaemia*
5. Erlotinib for EGFR mutation-positive non-small cell lung cancer (second line)
6. *Etanercept* for rheumatoid arthritis / ankylosing spondylitis / juvenile idiopathic arthritis / psoriatic arthritis / *severe psoriasis*
7. *Fingolimod for refractory relapsing-remitting multiple sclerosis (RRMS)*
8. Gefitinib for EGFR mutation-positive non-small cell lung cancer (second line)
9. Golimumab for rheumatoid arthritis / ankylosing spondylitis / psoriatic arthritis
10. Growth Hormone
11. Imatinib for chronic myeloid leukaemia / gastrointestinal stromal tumour / acute lymphoblastic leukaemia
12. *Infliximab* for rheumatoid arthritis / ankylosing spondylitis / psoriatic arthritis / Crohn's Disease / *severe psoriasis*
13. Interferon gamma for chronic granulomatous disease
14. *Lenalidomide for multiple myeloma (MM)*
15. Nilotinib for Imatinib-resistant chronic myeloid leukaemia / newly diagnosed chronic myeloid leukaemia in chronic phase
16. *Rituximab* for malignant lymphoma / maintenance therapy for relapsed follicular lymphoma / refractory rheumatoid arthritis / *previously-untreated and relapsed / refractory chronic lymphocytic leukaemia*
17. *Temozolomide for Glioblastoma Multiforme (used together with radiotherapy)* / therapy for recurrent high grade glioma, following standard therapy
18. *Tocilizumab* for rheumatoid arthritis / *systemic juvenile idiopathic arthritis*
19. Trastuzumab for HER 2 over-expressed metastatic breast cancer / HER 2 positive early breast cancer
20. *Ustekinumab for severe psoriasis*

Annex B

Drugs Supported by the Samaritan Fund

Grouped by disease type		
Disease type	**Indications**	**Drugs**
Gastroenterology	Crohn's Disease	Adalimumab, Infliximab
Haematology	Acute lymphoblastic leukaemia	Dasatinib, Imatinib
	Chronic myeloid leukaemia	Dasatinib, Imatinib, Nilotinib
	Multiple myeloma	Bortezomib, Lenalidomide
	Relapsed follicular lymphoma	Rituximab
	Chronic lymphocytic leukaemia	Rituximab
Rheumatology	Rheumatoid arthritis	Abatacept, Adalimumab, Etanercept, Golimumab, Infliximab, Tocilizumab
	Ankylosing spondylitis	Adalimumab, Etanercept, Golimumab, Infliximab
	Psoriatic arthritis	Adalimumab, Etanercept, Golimumab, Infliximab
	Juvenile idiopathic arthritis	Etanercept
	Active systemic juvenile idiopathic arthritis	Tocilizumab
	Refractory rheumatoid arthritis	Rituximab
Neurology	Refractory relapsing-remitting Multiple Sclerosis	Fingolimod
Oncology	Gastrointestinal stromal tumour	Imatinib
	Malignant lymphoma	Rituximab
	Glioblastoma multiforme	Temozolomide
	Lung cancer	Erlotinib (For Second line treatment)
		Gefitinib (For Second line treatment)
	Breast cancer	Trastuzumab
Endocrinology	Dwarfism	Growth Hormone
Dermatology	Severe psoriasis	Adalimumab, Etanercept, Infliximab, Ustekinumab
Others	Chronic granulomatous disease	Interferon

Annex C

Chronology of drugs originally under Samaritan Fund coverage and were repositioned as Special Drugs in the HA Drug Formulary

	Drugs	Effective date
Drugs	**Up to 31 Dec 2010**	
	Liposomal Amphotericin B for treating Fungal Infection for cancer patients #	October 2005
	Paclitaxel for Metastatic Breast Cancer #	April 2007
	Peg-Interferon for Hepatitis C #	April 2010
	Irinotecan for Advanced Colorectal Cancer	April 2010
	From 1 Jan 2011 Onwards	
	Interferon for Chronic Myeloid Leukaemia #	April 2011
	Interferon for Multiple Sclerosis	April 2012
	Oxaliplatin for Adjuvant Resected Colon Cancer	April 2012
	Cetuximab for initial treatment of Locally Advanced Squamous Cell Carcinoma of Head and Neck	April 2013
	Pemetrexed for Malignant Pleural Mesothelioma	April 2013

Drug repositioned by using existing resources of HA.