FACT SHEET

Drug Formulary of the Hospital Authority

1. Introduction

1.1 The Hospital Authority ("HA") has implemented the Drug Formulary ("the Formulary") since July 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 HA. There are four categories of drugs in the Formulary, namely:

(a) General Drugs[1] which are provided to patients at standard fees and charges in public hospitals and clinics;

(b) Special Drugs[2] which are provided at standard fees and charges when prescribed under specific conditions;

(c) Self-financed Items ("SFI") with safety net[3] which can be purchased by patients at their own expense or with subsidy provided under the Samaritan Fund[4]; and

(d) SFI without safety net[5] which can be purchased by patients at their own expense.

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1 General Drugs are drugs with well-established indications and effectiveness. These drugs are available for general use as indicated by the patients' clinical conditions.

2 Special Drugs are drugs which are used under specified clinical conditions with specific specialist authorization. Patients who do not meet the specified clinical conditions but choose to use these drugs have to pay for the drugs at their own expense.

3 SFI with safety net are drugs which are proven to be of significant benefits but extremely expensive for HA to provide as part of its standard services.

4 The Samaritan Fund is a charitable fund established with the objective to provide financial assistance to needy patients who meet the specified clinical criteria and pass the means test to meet expenses on privately purchased medical items or self-financed drugs required in the course of medical treatment. It is under the management of HA and financed by donations, reimbursement by the Government for persons under Comprehensive Social Security Assistance and government grant.

5 SFI without safety net include drugs with preliminary medical evidence only, drugs with marginal benefits over available alternatives but at significantly higher costs, and lifestyle drugs such as weight-loss drugs.

1.2 HA reviews the drug list in the Formulary regularly and may include new drugs in and remove existing drugs from the Formulary. Members had expressed concern about the low transparency of the decision-making process for evaluation of new drugs and review of existing drugs in the Formulary on several occasions, including the meetings of the Panel on Health Services on 14 February, 14 June and 14 November 2011. At the Panel meeting on 14 June 2011, a member had queried whether there was any bias in favour of individual pharmaceutical companies in selecting new drugs for inclusion in the Formulary.

1.3 At its meeting on 14 June 2011, the Panel on Health Services requested for a fact sheet to provide information on the changes made to the Formulary, and the pharmaceutical companies involved in supplying new drugs included in the Formulary since July 2005. This was to facilitate members' further discussion on the issues related to the selection of new drugs for inclusion in the Formulary.

2. Changes made to the Drug Formulary

2.1 Applications for inclusion of new drugs in the Formulary and the review of the Formulary are not initiated by the pharmaceutical companies. Under the established review mechanism, the Drug Advisory Committee ("DAC") of HA[6] is tasked with appraising new drugs upon applications submitted by the Drug and Therapeutic Committees[7] of individual clusters or hospitals on a quarterly basis, whereas the Drug Utilization Review Committee ("DURC") of HA[8] is responsible for reviewing the existing drugs in the Formulary periodically. DAC and DURC are supported by expert panels which provide specialist views on the selection of drugs for individual specialties.

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6 The website of HA only contains information on the composition of DAC without showing the names of individual members except that of the Chairman of DAC. According to the website, DAC is chaired by Dr Cheung Wai Lun, Director (Cluster Services) of HA and comprises (a) Chief Pharmacist of HA; (b) representatives from the Department of Medicine of the University of Hong Kong and the Chinese University of Hong Kong; and (c) specialists from the specialties of Medicine, Orthopaedic, Paediatric, Surgery, Psychiatry, and Clinical Oncology.

7 The Drug and Therapeutic Committees are responsible for the oversight and management of the Formulary at individual clusters or hospitals level.

8 DURC comprises the chairmen of the drug committees of the seven hospital clusters of HA and specialists.

2.2 In reviewing individual drugs, DAC, DURC and the expert panels supporting them will consider the principles of efficacy, safety and cost-effectiveness. They will also take 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. If required, the pharmaceutical companies of the new drugs being appraised will be invited to submit relevant information for consideration by DAC.

2.3 Between July 2005 and March 2011, DAC had considered 221 applications of new drugs for inclusion in the Formulary, with each application involving a new indication of a drug[9]. According to HA, the new drugs are classified into the relevant drug categories, mainly General Drugs, Special Drugs or SFI without safety net in the Formulary after their applications are accepted. New SFI with safety net are included in the Formulary through repositioning of drugs from the SFI without safety net category under the review process for existing drugs.

2.4 Among the 107 successful applications (48% of all applications), 11 were accepted as General Drugs, 46 as Special Drugs and 50 as SFI without safety net. As a result, 89 new distinct drugs were included in the Formulary between July 2005 and March 2011, including 11 General Drugs, 44 Special Drugs and 36 SFI without safety net.

2.5 The number of new drug applications submitted for inclusion in the Formulary and results of the applications between 2005-2006 and 2010-2011 are shown in **Table 1**.

[9] An indication of a drug refers to the specific medical condition under which the drug is used. A drug in the Formulary may have more than one indication and it may have more than one formulary status for different indications.

Table 1 — New drug applications submitted for inclusion in the Drug Formulary between 2005-2006 and 2010-2011[(1)]

Financial year	Number of applications rejected	Number of successful applications[(2)]			Total number of applications
		General Drugs	Special Drugs	Self-financed Items without safety net	
2005-2006[(3)]	11	2	6	7	26
2006-2007	16	0	4	8	28
2007-2008	18	1	10	4	33
2008-2009	30	3	11	13	57
2009-2010	21	2	12	11	46
2010-2011	18	3	3	7	31
Total	**114**	**11**	**46**	**50**	**221**

Notes: (1) The figures refer to applications submitted between July 2005 and March 2011. Each application involved a new indication of a drug. Applications involving a new indication of an existing drug or re-submission of applications that were rejected previously are counted as separate applications.

(2) The drug category refers to the one that the drug was categorized into when the application was accepted. New drugs are mainly accepted as General Drugs, Special Drugs or Self-financed Items without safety net. New Self-financed Items with safety net are included in the Drug Formulary through repositioning of drugs from the Self-financed Items without safety net category under the review process for existing drugs.

(3) The Drug Formulary was first implemented in July 2005.

Source: Food and Health Bureau.

2.6 While HA had included 89 new drugs in the Formulary between 2005-2006 and 2010-2011, it had removed some drugs that had become obsolete or were no longer used from the Formulary, and repositioned some drugs across categories. As a result, the total number of drugs in the Formulary decreased from 1 370 as at July 2005 to 1 306 as at April 2011. According to HA, information on the movement of drugs related to formulary status is not captured in its system and is not readily available. Hence, HA cannot provide the information on the number of drugs that had been removed from and drugs that had been repositioned in the Formulary by drug categories as at publication of this fact sheet. Net changes in the number of drugs in the Formulary between 2005-2006 and 2010-2011 are summarized in **Table 2**.

Table 2 — Number of drugs in the Drug Formulary

Drug category	Number of drugs as at July 2005(1)	Number of drugs as at April 2011	Net changes
General Drugs	1 063	930	– 133
Special Drugs	236	293	+ 57
Self-financed Items with safety net	4	14	+ 10
Self-financed Items without safety net	67	69	+ 2
Total number of drugs	1 370	1 306	– 64

Note: (1) The Drug Formulary was first implemented in July 2005.
Source: Food and Health Bureau.

3. Pharmaceutical companies supplying new drugs in the Drug Formulary

3.1 The established mechanism of HA on the procurement of drugs follows the requirements of the World Trade Organization. HA would procure drugs, including existing and new drugs in Formulary, that are of high volume or large value through open tenders. The specific drug items and amount of the items to be ordered, and whether a new drug in the Formulary will be ordered is determined by individual hospital clusters[10].

[10] Individual hospital clusters may stock part of the drugs listed in the Formulary according to their service provision and targeted patients.

3.2 Under the established drug procurement mechanism, all products to be supplied to HA must comply with mandatory quality requirements, including: (a) pharmaceutical product registration with the Department of Health; (b) Good Manufacturing Practices[11] of the manufacturing site; and (c) detailed product specific information[12] for evaluation of product quality, safety and efficacy. A product supplier would be considered for selection based on its offered price only if all the quality requirements of the product concerned are met.

3.3 According to HA, a total of 38 pharmaceutical companies were involved in the supply of new drugs that were included in the Formulary between 2005-2006 and 2010-2011. Among these 38 pharmaceutical companies[13], 10 had supplied General Drugs, 25 had supplied Special Drugs and 19 had supplied SFI, including items with safety net and those without safety net which are available for purchase by patients at pharmacies in public hospitals[14]. The total spending on procurement of the new drugs between 2005-2006 and 2010-2011 was about HK$1.9 billion, with 2% being spent on General Drugs, 12% on Special Drugs and 86% on SFI.[15]

3.4 The total spending of HA on procuring new drugs included in the Formulary between 2005-2006 and 2010-2011, and the share of spending by the pharmaceutical companies involved in supplying the drugs are shown in **Table 3**.

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11 Good Manufacturing Practices is a system for ensuring that products are consistently produced and controlled according to quality standards appropriate to their intended use and as required by the product specification.

12 The required product specific information includes product master formula, finished product specifications and stability data, and bioequivalence data for generic drugs demonstrating comparable efficacy as the proprietary drugs.

13 Some pharmaceutical companies had supplied more than one new drug to HA between 2005-2006 and 2010-2011.

14 HA may supply some SFI that are very specialized and not readily available at community pharmacies for purchase by patients at pharmacies in public hospitals. These drugs include drugs with safety net, oncology drugs and dangerous drugs.

15 Information provided by the Food and Health Bureau.

Table 3 — Total spending on procuring new drugs included in the Drug Formulary between 2005-2006 and 2010-2011

	New drugs included in the Drug Formulary between 2005-2006 and 2010-2011			
	General Drugs	**Special Drugs**	**Self-financed Items with and without safety net(1)**	**Total**
Total spending (HK$ million)(2)	36.9	232.3	1,667.5	1,936.7
Number of pharmaceutical companies supplying the new drugs	10	25	19	38(3)
Share of spending among pharmaceutical companies supplying the new drugs	Ranges from less than 1% to 57% of total spending	Ranges from less than 1% to 26% of total spending	Ranges from less than 1% to 32% of total spending	Ranges from less than 1% to 27% of total spending

Notes: (1) The Hospital Authority may supply some Self-financed Items that are very specialized and not readily available at community pharmacies for purchase by patients at pharmacies in public hospitals. These drugs include drugs with safety net, oncology drugs and dangerous drugs. The information covers those Self-financed Items with safety net that had been repositioned from new Self-financed Items without safety net between 2005-2006 and 2010-2011.

(2) The figures refer to total spending on all the new drugs included in the respective drug categories between 2005-2006 and 2010-2011. For new drugs that have been repositioned to other drug categories during the period, spending on those drugs will be included in the final repositioned drug categories as at the end of each financial year.

(3) Some pharmaceutical companies had supplied more than one new drug to the Hospital Authority between 2005-2006 and 2010-2011.

Source: Food and Health Bureau.

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