For information
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Legislative Council Panel on Health Services

Update on the Drug Formulary of the Hospital Authority

PURPOSE

This paper briefs Members on the latest developments of the Hospital Authority (HA) Drug Formulary (the Formulary).

BACKGROUND

2. The World Health Organization has all along been actively promoting the concept of "essential medicines". It recommends that health authorities around the world establish their own mechanisms for systematic selection of drugs to promote the availability, accessibility, affordability, quality and rational use of medicines. In keeping with international developments, HA has formulated its own Formulary under the guiding principles that public resources should be utilized with maximal effect of healthcare, and have equitable access by all patients. The development of the Formulary was also underpinned by other core values including evidence-based medical practice, rational use of public resources, targeted subsidy, opportunity cost considerations and facilitation of patients' choice.

3. HA has implemented 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. The Formulary is developed with evaluation of new drugs and review of the prevailing list of drugs by relevant experts on a regular basis. The review process is based on the scientific and clinical evidence on the safety, efficacy and cost-effectiveness of the drugs, having regard also to the views of patient groups.

PRESENT POSITION

Drug Categories in the Formulary

4. At present, there are around 1,300 drugs in the Formulary, which consists of the following four categories:

(a) General Drugs – drugs with well-established indications and cost-effectiveness which are available for general use as indicated by patients with relevant clinical conditions. These drugs constitute around 76% of the drugs in the Formulary and are provided at standard fees and charges in public hospitals and clinics;

(b) Special Drugs – drugs which are used under specific clinical conditions with specific specialist authorization. These drugs constitute around 24% of the drugs in the Formulary and are provided at standard fees and charges in public hospitals and clinics when prescribed under specific conditions. For patients who do not meet the specified clinical conditions but choose to use special drugs, they have to pay for the drugs;

(c) Self-financed Item (SFI) with safety net – drugs which are proven to be of significant benefits but extremely expensive for HA to provide as part of its standard services. These drugs are not covered by the standard fees and charges in public hospitals and clinics. Patients who need these drugs and can afford the costs have to purchase the drugs at their own expense. However, a safety net is provided through the Samaritan Fund to subsidize the drug expenses of patients who need the drugs but have financial difficulties. Currently, there are 14 SFI with safety net; and

(d) SFI without safety net – drugs with preliminary medical evidence only, drugs with marginal benefits over available alternatives but at significantly higher costs, and lifestyle drugs (e.g. weight-loss drugs). These drugs are not provided at standard fees and charges and patients have to purchase these drugs at their own expense. Currently, there are 84 SFI without safety net.

Review Mechanism for the Formulary

5. The drug list in the Formulary is regularly reviewed under an established mechanism. The HA Drug Advisory Committee (DAC), comprising doctors, clinical pharmacologists and pharmacists, systematically appraises new drugs every three months. On the other hand, the HA Drug Utilization Review Committee (DURC) conducts periodic review on existing drugs in the Formulary.

6. DAC and DURC are supported by expert panels which provide specialist views on the selection of drugs for individual specialties. The review

process follows an evidence-based approach and adopts specific evaluation criteria. In reviewing individual drugs, the committees and expert panels have regard to the principles of efficacy, safety and cost-effectiveness and 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.

7. New drugs meeting the assessment criteria will be included in the Formulary as general drugs, special drugs or SFI as appropriate. Meanwhile, general drugs that have become obsolete or are no longer used or required will be removed from the Formulary, while the clinical indications of individual special drugs may be modified as appropriate. Existing drugs in the Formulary may also be repositioned across categories in the light of the latest evidence on clinical efficacy, safety and cost-effectiveness. For example, special drugs may be repositioned as general drugs; SFI previously not covered by the safety net may be included in the scope of the safety net or repositioned as special drugs in the Formulary; and SFI with safety net coverage may be repositioned as special drugs in the Formulary.

8. Any recommendation for major changes to the Formulary will be considered in the HA Annual Planning process. Any recommendation of DURC for including include drugs as SFI under the safety net coverage will be considered by the HA Samaritan Fund Management Committee, which in turn will make recommendations to the Medical Services Development Committee under the HA Board for endorsement.

Engagement with patient groups

9. Since the implementation of the Formulary in 2005, HA has maintained close communications with patient groups on the Formulary and the Samaritan Fund through its established liaison channels. As part of the continuous efforts to enhance its accountability and partnership with the community, HA established in 2009 a formal consultation mechanism under which annual consultation meetings will be convened to inform patient groups of the latest developments of the Formulary and the Samaritan Fund, gather their major concerns and solicit their feedback on the introduction of new drugs and review of existing drugs in the Formulary or covered by the Samaritan Fund. After the meeting, patient groups will be invited to submit their views and propose any changes to the Formulary and the Samaritan Fund. Their views and suggestions will then be presented to the relevant committees for consideration.

Since the establishment of the mechanism, annual consultation meetings were held in May 2009 and June 2010 with wide patient group participation. Besides, another meeting was held in December 2009 to update the patient groups on the latest development of the Samaritan Fund.

10. In recent years, a number of changes to the Formulary and scope of the Samaritan Fund have been made in response to the views and suggestions of patient groups. Some examples are set out below:

(a) in 2008-09, Deferasirox, an oral iron chelating drug for thalassaemia, has been repositioned from SFI without safety net to special drug;

(b) in 2008-09, HA has revised the prescription guideline for psychiatric drugs to enable early use of new drugs by patients;

(c) since April 2010, the clinical application of Clopidogrel, a special drug for cardiovascular diseases, has been expanded to provide an extended duration of treatment;

(d) since April 2010, drugs for enzyme replacement therapy for the treatment of rare metabolic diseases have been repositioned from SFI without safety net to special drugs; and

(e) since June 2010, Pemetrexed, formerly a SFI without safety net, has been included into the scope of the Samaritan Fund for the treatment of mesothelioma.

RECENT DEVELOPMENTS

11. In recent years, HA has been expanding the coverage of the Formulary under the relevant review mechanism. Recently in 2009-10 and 2010-11, HA has incorporated six drugs for treatment of rare metabolic diseases and two drugs for treatment of cancer in the special drug category of the Formulary, and expanded the clinical applications of 12 drug classes for the treatment of cardiovascular diseases, osteoporotic fracture, hepatitis B/C, diabetes mellitus, hypertension, breast cancer, wet aged-related macular degeneration and mental illness. Since the implementation of the Formulary in July 2005, HA has introduced a total of 81 new drugs to the Formulary, including nine general drugs, 41 special drugs and 31 SFI without safety net coverage. Also, the Government has been providing additional resources for HA to meet the growth in drug expenses. HA's total drug expenditure increased

from $2.28 billion in 2007-08 to $2.68 billion in 2009-10.

12. At the same time, HA has in recent years expanded the coverage of the safety net under the Samaritan Fund to benefit more patients. Since 2007, HA has introduced a total of 12 drugs into the scope of the Samaritan Fund in phases for the treatment of oncology, rheumatology and haematology diseases. The clinical applications of five self-financed drugs already with safety net coverage have also been expanded in phases since 2008. At present, a total of 14 self-financed drugs are included in the scope of the Samaritan Fund (see **Annex**). As a result of the above expansions, the subsidies granted by the Samaritan Fund on drugs increased substantially from $17.3 million in 2004-05 to $84.2 million in 2009-10. To meet the rising demand for assistance, the Government injected $1 billion to the Samaritan Fund in 2008-09.

13. Meanwhile, the following SFI with safety net have been repositioned as special drugs in the Formulary, and are now provided to patients with specific clinical indications at standard fees and charges –

(a) Liposomal Amphotericin B for treating fungal infection for cancer patients (repositioned since October 2005);

(b) Pacilitaxel for metastatic breast cancer (repositioned since April 2007);

(c) Irinotecan for advanced colorectal cancer (repositioned since April 2010); and

(d) Interferon for hepatitis C (repositioned since April 2010)

Proposed expansion of the Formulary in 2011-12

14. In the light of the latest scientific evidence and advances in medical technologies, HA is planning to further expand the coverage of the Formulary in 2011-12 to benefit more patients. The proposed expansion covers the widening of clinical applications and inclusion of new drug to enhance the treatment of a range of diseases, including diabetes mellitus, pulmonary and cardiovascular diseases, hepatitis B, renal anaemia, glaucoma, thalassaemia major, colorectal cancer and mental illness. In formulating the proposals, HA has considered the latest evidence on safety, efficacy and cost-effectiveness of the concerned drugs, technological advances in treatment options, actual experience in the use of the drugs, as well as the views of professionals and patient groups, to ensure that public resources will be used in an equitable and effective manner for provision

of appropriate treatment to patients. HA will continue to keep its Formulary under review having regard to the principles of effective use of limited public resources and maximizing health benefits to more patients.

ADVICE SOUGHT

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

Food and Health Bureau
Hospital Authority
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Annex

Self-financed Items covered by safety net through Samaritan Fund (as at January 2011)

1. Adalimumab for rheumatoid arthritis / ankylosing spondylitis / psoriatic arthritis (introduced in June 2010)
2. Bortezomib for multiple myeloma (introduced in June 2010)
3. Cetuximab for initial treatment of locally advanced squamous cell carcinoma of head and neck (introduced in December 2009)
4. Dasatinib for Imatinib-resistent chronic myeloid leukaemia (introduced in June 2010)
5. Etanercept for rheumatoid arthritis / ankylosing spondylitis / juvenile idiopathic arthritis (introduced in April 2007) / psoriatic arthritis (introduced in December 2009)
6. Infiximab for rheumatoid arthritis / ankylosing spondylitis (introduced in April 2007) / psoriatic arthritis (introduced in December 2009) / Crohn's Disease (introduced in October 2008)
7. Imatinib for chronic myeloid leukaemia / gastrointestinal stromal tumour (introduced in January 2005) / acute lymphoblastic leukaemia (introduced in October 2008)
8. Nilotinib for Imatinib-resistent chronic myeloid leukaemia (introduced in June 2010)
9. Oxaliplatin for adjuvant resected colon cancer (introduced in December 2009)
10. Pemetrexed for malignant pleural mesothelioma (introduced in June 2010)
11. Trastuzumab for HER 2 over-expressed metastatic breast cancer (introduced in April 2007) / HER 2 positive early breast cancer (introduced in December 2009)
12. Rituximab for malignant lymphoma (introduced in October 2008) / maintenance therapy for relapsed follicular lymphoma (introduced in June 2010) / refractory rheumatoid arthritis (introduced in December 2009)
13. Growth Hormone
14. Interferon