

**For discussion
on 31 January 2005**

Legislative Council Panel on Health Services

Introduction of a Standard Drug Formulary in Hospital Authority

PURPOSE

This paper seeks Members' views on the introduction of a Standard Hospital Authority Drug Formulary (醫管局標準藥物名冊) ("Standard Drug Formulary") in the public hospital system.

BACKGROUND

2. Drug therapy is a key and essential element in patient treatment. It is an integral part of medical services provided by public hospitals and clinics, where patients are provided with the necessary drugs in accordance with their clinical needs and available treatment guidelines in the Hospital Authority ("HA") at highly subsidised rates¹. The drug consumption of HA was \$ 1.9 Billion in 2003-04, accounting for 6.7% of HA's overall expenditure².

3. Rapid advances in medical technology have brought in many new drugs into the pharmaceutical market every year. These available drugs are huge in number and vary widely in terms of cost, evidential support for their clinical efficacy, therapeutic effectiveness and side effects. It is a responsibility of every healthcare organisation to

¹ For inpatients at public hospitals and outpatients at General Outpatient Clinics, the provision of drugs is covered by the basic fee charged by the HA. For outpatients at Specialist Outpatient Clinics, the drug charge is \$10 per drug item. The income from drug charges was \$65.4 million in 2003-04 (drug charging was introduced for 11 months). There is in place a waiving mechanism for patients on CSSA or with financial difficulty. In 2003-04, \$25.2 million in drug charges was waived.

² The overall expenditure did not include the expenditure for combating SARS and the ex-gratia payment of \$626 Mn for staff who joined the HA Voluntary Early Retirement Scheme in 2003-2004

establish and constantly review its drug formulary to ensure good standard of medical practice, delivery of effective treatment to patients and rational use of resources. As a publicly funded medical healthcare organisation, the HA has to ensure rational use of public resources and deliver a scope of service that best serves the interest of the public. Drug utilisation should be underpinned by the principle objectives of ensuring safety, efficacy and cost effectiveness as guided by the best available scientific evidence. Against this background, the HA has set up its Drug Advisory Committee since 1996 to scrutinize the introduction of new drugs into public hospitals. In addition, HA issues and reviews guidelines on clinical practices to ensure that drug utilisation in the organisation is rational and evidence-based.

4. However, it remains the current practice that individual hospitals / hospital clusters may maintain their own drug formularies, and there are existing variations in practice across HA hospitals in terms of clinical use of certain new drugs and situations under which patients should purchase drugs at their own cost. Consequently, patients with similar clinical conditions could receive different drug therapy at different hospitals or could be required to pay for the cost of a drug in one hospital but not be required to do so at another. The introduction of a standard drug formulary will further standardise drug utilisation across public hospitals and clinics and ensure patients in similar clinical conditions would have similar access to drug therapy.

STANDARD DRUG FORMULARY

Objective

5 The main objective of developing an HA-wide Standard Drug Formulary is to ensure equitable access to cost effective drugs of proven efficacy and safety, through standardisation of drug policy and utilisation in all HA hospitals and clinics. After the introduction of the HA Standard Drug Formulary, the drug policy as well as the range, choice, classification and indication for the use of drugs will be clearly defined to ensure uniformity and equity across all HA hospitals and clinics. The number of drugs in our drug list would largely be the same

as the present number, and there would not be an anticipated reduction in drug expenditure.

Advice of World Health Organisation and International Practice

6. The development of the Standard Drug Formulary by the HA is also in line with international developments. The World Health Organisation (WHO) has been actively promoting the concept of “essential medicines”. It recommends health authorities around the world to establish their own mechanism for the systematic selection of drugs, which meet the healthcare priorities of their community, for public supply or reimbursement. The objective of such national programmes is to promote the availability, accessibility, affordability, quality and rational use of medicines. Over the past ten years, over 100 countries have followed WHO’s advice and developed their national list of essential medicines, taking into account their disease prevalence, available evidence on efficacy and safety, and comparative cost effectiveness.

Guiding Policy, Values and Review Mechanism

7. The HA embarked on the development of its Standard Drug Formulary in the fall of 2003. In the process, the HA is guided by the principle that public resources should be utilised with maximal effect of healthcare, and have equitable access by all patients. Other core values include evidence-based medical practice, rational use of public resources, targeted subsidy and opportunity cost considerations, and facilitation of patient’s choice. These are wholly considered in formulating the framework of the Standard Drug Formulary. Expert Panels, comprising specialist clinicians, pharmacists and academics in pharmacology have been established to deliberate on the usage and screening of drugs for each clinical specialty. Patient groups are consulted in the process and reference made to overseas practices.

Content of the Standard Drug Formulary

8. The Standard Drug Formulary will contain two categories of drug, namely General Drugs (通用藥物) and Special Drugs (專用藥物).

9. General Drugs refer to drugs with well-established indications and effectiveness which are available for general use as indicated by the patients' clinical conditions. This group comprises around 85% of the drugs within the Formulary. This category of drug is provided within the standard fees and charges at public hospitals and clinics.

10. Special Drugs refer to drugs which are to be used under specified clinical conditions with specific specialist authorisation. This group comprises less than 15% of the drugs within the Formulary. Generally speaking, drugs within this group are newer, more expensive, and with variable existing practices at the HA. An example is the use of specific anti-psychotics. Standard treatment for psychosis is with first-line drugs (General Drugs) of well-established clinical efficacy and safety. In case the first-line drugs are contraindicated, not tolerated, or having poor response, second-line drugs (Special Drugs) are to be used. Provided that the drug usage is within the specific indications, these second-line drugs are provided within the standard fees and charges.

11. In considering whether a drug falls under the category of special drugs, the HA is guided by the principles of evidence-based medical practice, rational use of public resources and facilitation of patient's choice.

12. The Standard Drug Formulary will be periodically reviewed in a systematic manner taking into account changes in scientific evidence, cost effectiveness, technology advances in treatment options, and changes in service provisions with addition, deletion and modification of guidelines in the use of drugs. Some drugs which were non-standard provisions in the past, for example, the third line anti-fungal treatment which could be hundred times more expensive than the first line treatment, would be considered to be introduced as a special drug under selective conditions in the Standard Drug Formulary.

DRUGS OUTSIDE THE STANDARD DRUG FORMULARY

Types of Drugs

13. Generally speaking, four main types of drugs have not been included in the draft Standard Drug Formulary, guided by the principles of evidence-based medical practice, targeted subsidy and opportunity costs considerations. Most of these drugs are already self-financed by patients at present. These include –

- (a) Drugs proven to be of significant benefits but extremely expensive for the HA to provide as part of its subsidised service

Drugs within this group are new and usually only indicated in advanced stages of diseases and beyond currently available standard modalities of treatment. An example of this type of drug is Imatinib (Glivec) for the treatment of Gastrointestinal Stromal Tumour (GIST). The existing standard treatment is surgery and supportive care. For patients with unresectable GIST, the prognosis is poor with few patients, if any, surviving beyond 5 years. For patients who have been put on Glivec, the overall survival estimates will be around 70% at 2 years, as compared with 20% for patients under conventional treatment³. The annual cost of this drug for one patient is \$180,000 to \$270,000.

- (b) Drugs which have preliminary medical evidence only

One of the examples of drugs with limited therapeutic evidence is Gefitinib (Iressa) in the treatment of lung cancer where efficacy is only supported by a small number of clinical trials and considered questionable by the Food and Drug Administration of the United States.

3. Jaap Verweig et al. Progression-free survival in gastrointestinal stromal tumours with high-dose imatinib: randomised trial. *Lancet* 2004; 364: 1127-1134.

- (c) Drugs with marginal benefits over available alternatives but at significantly higher costs

Examples of drugs with high cost but only marginal benefits are the COX II inhibitors. The daily cost of these drugs is ten times higher than the usual daily cost for the class of conventional non-steroidal anti-inflammatory drugs, and the claimed benefits of COX II inhibitors are only marginal.

- (d) Life style drugs

Examples of life style drugs include erectile dysfunction drugs (e.g. Sildenafil (Viagra)); hair growth drugs (e.g. Finasteride (Propecia)); and anti-obesity drugs (e.g. Orlistat (Xenical)).

14. The above drugs will be non-standard provisions in the HA and patients will have to purchase these drugs at their own expenses.

Safety Net for Drugs outside the Standard Drug Formulary

15. The opportunity cost for treating a single patient with drugs under paragraph 13 (a) will mean forgoing treatment for a much larger number of patients with other effective means. For example, the annual cost of putting one patient on Glivec is equivalent to the annual costs of treating a few hundred to a thousand patients with simple hypertension or diabetes. As there is an overriding need for rational use of finite public resources and competing needs to maximise health benefits to more, patients requiring such expensive treatment and can afford to pay should pay under the targeted subsidy principle. These non-standard drugs are therefore not covered under the standard fees and charges of public hospitals and clinics. However, it is recognised that for patients, such drugs are proven to be of significant benefits, hence support has all along been provided to patients who have difficulties in meeting the drug expenses via a safety net. Depending on their individual financial situation, patients in need may receive a partial subsidy or even full reimbursement for their expenses on these drugs.

16. Since the therapeutic objectives of drugs described in paragraph 13 (b) to (d) fall outside the scope of public medical services, patients have to purchase these drugs at their own expenses. HA doctors may prescribe these drugs at the request of patients where appropriate, having regard to the clinical condition of the patients and the safety of the drugs concerned.

MECHANISM TO PRESCRIBE DRUGS OUTSIDE THE STANDARD DRUG FORMULARY

17. The Standard Drug Formulary and the provision of a safety net for non-standard drugs under paragraph 13 (a) should be sufficient to meet the needs of patients within the scope of HA service provisions. However, HA recognizes that with increasing knowledge by patients of available alternative therapeutic options, patients may prefer to choose options outside the Standard Drug Formulary. There is an existing mechanism to allow clinicians to prescribe drugs to patients outside the drug formulary. To ensure proper medical standard, continuity of care and liability management, a system is in place to approve, monitor, record and track such prescriptions.

SUPPLY OF SPECIAL DRUGS OUTSIDE THE SPECIFIC INDICATIONS OR DRUGS OUTSIDE THE STANDARD DRUG FORMULARY

18. HA adopts an open position on the arrangement for the supply of drugs which are to be purchased by the patients at their own expenses. There are different views among patients, private medical practitioners, the pharmaceutical supplies industry and the pharmaceutical retail industry. The arrangement to be adopted should attain a balance amongst the interests of all parties. The options under consideration by the HA include –

- (a) Advising the patients to purchase the drugs from community pharmacies. The main advantage is that this would significantly simplify the systems of procurement, supply

and distribution at the HA. The retail pharmaceutical industry would benefit from increased business and welcome this option. However, the patients would most likely find it less convenient and may also have to pay variable prices for the drugs. There will also be a risk of parallel market making it more difficult for consumers to make choices. In addition, some very specialised drugs would have a limited market interest because of the small patient number.

- (b) Inviting community pharmacies to operate in hospital premises to supply, inter alia, the non-standard drugs to patients. The option is similar to (a), but with the added benefit for patients in terms of convenience.
- (c) Supplying the non-standard drugs prescribed by HA doctors at the hospital pharmacies. This option would be the most convenient for patients and should be most favoured by them. To avoid direct competition with private pharmacies, the HA could limit the availability of this drug service to patients of public hospitals and clinics. There may even be room for HA to charge slightly higher prices than cost and apply the positive balance / surplus for cross-subsidising those requiring the drugs described in paragraph 13 (a).
- (d) Other models or combinations of the above.

CONSULTATION

19. In the process of preparing the draft Standard Drug Formulary, the HA has briefed major stakeholders on the rationales and needs for the development of a Standard Drug Formulary and invited their views on the proposal. More specifically, since late 2003, the HA had arranged more than 10 consultation meetings and briefing sessions with relevant professional staff groups, patients groups as well as the pharmaceutical industry.

20. Although individual patients had expressed worries that a particular drug might not be available in HA, the patient groups consulted by HA recognised that the Standard Drug Formulary is a means to protect equity and fairness in access to treatment of proven efficacy and cost effectiveness within the finite budget of HA. Professional groups, especially doctors, welcome the move towards a more explicit policy on HA's coverage. The pharmaceutical industry expressed that HA should not restrict access to the range of pharmaceutical products available and that a clear list should facilitate the industry to plan market strategies.

21. The HA plans to launch a three months public consultation on the proposal.

ADVICE SOUGHT

22. Members are invited to comment on the proposed introduction of a Standard Drug Formulary in the public hospital system.

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