For information
on 14 May 2021

Legislative Council Panel on Health Services

The Hospital Authority Drug Formulary and Drug Subsidy

PURPOSE

This paper briefs Members on the mechanism of the Hospital Authority Drug Formulary (HADF) and the provision of drug subsidy to patients through the Samaritan Fund (SF) and the Community Care Fund (CCF) Medical Assistance Programmes[1] (collectively referred to as the "Safety Net") by the Hospital Authority (HA).

BACKGROUND

Hospital Authority Drug Formulary

2. The HA has implemented the HADF since July 2005 with a view to ensuring equitable access by patients to cost-effective drugs of proven safety and efficacy through standardisation of drug policy and drug utilisation in all public hospitals and clinics. At present, the drugs listed on the HADF are categorised into the following four groups –

(i) **General Drugs** – drugs 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.

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[1] At present, there are three CCF Medical Assistance Programmes as implemented by the HA –

(a) The First Phase Programme of Medical Assistance Programme;

(b) Subsidy for Eligible Patients to Purchase Ultra-expensive Drugs (Including Those for Treating Uncommon Disorders) (the "CCF Ultra-expensive Drugs Programme"); and

(c) Subsidy for Eligible Patients of Hospital Authority to Purchase Specified Implantable Medical Devices for Interventional Procedures.

(ii) **Special Drugs** – drugs used under specific clinical conditions with specific specialist authorisation. Special drugs are provided at standard fees and charges in public hospitals and clinics when prescribed under specific clinical conditions. Patients who do not meet the specified clinical conditions but choose to use special drugs are required to pay for the drugs.

(iii) **Self-financed Items (SFIs) with Safety Net** – drugs proven to be of significant clinical benefits but are very expensive and outside the scope of the highly subsidised services provided by the HA at standard fees and charges in public hospitals and clinics. Patients who require these drugs and can afford the costs have to purchase the drugs at their own expense. A safety net is provided through the SF to subsidise the drug expenses of patients who have financial difficulties. For those self-financed drugs which have not been brought into the SF safety net but have been rapidly accumulating medical scientific evidence and with relatively higher efficacy, financial assistance can be provided through the CCF Medical Assistance Programmes.

(iv) **SFIs without Safety Net** – these include drugs with preliminary medical evidence only, drugs with marginal benefits over available alternatives but at significant higher costs, and lifestyle drugs. These drugs are not provided as part of the HA's standard services nor covered by the standard fees and charges in public hospitals and clinics. Patients who choose to use these drugs have to purchase them at their own expense.

Safety Net

3. In line with the Government's public healthcare policy to ensure that no one is denied adequate medical treatment due to lack of means, the HA provides medical services and drugs or medical items to patients at highly subsidised rates based on their clinical needs and in accordance with the HA's treatment guidelines. Guided by the principles of evidence-based medical practice, targeted subsidy and opportunity cost consideration, the standard fees and charges in public hospitals and clinics do not apply to designated Privately Purchased Medical Items (PPMIs) and SFIs. While patients who need these items/drugs and have the ability to pay for their costs have to purchase at their own expense, financial assistance is provided through the Safety Net to subsidise the medical expenses of patients who have financial difficulties in purchasing PPMIs or specified SFIs listed on the HADF at their own costs.

INTRODUCTION OF NEW DRUGS

4. Regarding the registration of new drugs, the Government has been making strenuous efforts to enhance the existing mechanism and rolled out a number of measures in recent years to expedite the registration process. Under the Pharmacy and Poisons Ordinance (Cap. 138), "pharmaceutical products" shall meet the criteria of safety, efficacy and quality for registration with the Pharmacy and Poisons Board of Hong Kong (the Board) before they can be sold or distributed in Hong Kong. For pharmaceutical products containing new chemical or biological entity (NC/BE) (i.e. containing active ingredients which have not been registered in Hong Kong), applications for registration should be submitted to the Board for approval. In such case, legislative amendments are required in order to incorporate the NC/BE into the relevant schedules of the legislation and to impose necessary sales control.

5. In order to facilitate the timely registration of new drugs for treatment of patients in Hong Kong, the Government has introduced various measures in recent years to expedite the registration of drugs containing NC/BE. Since 2015, legislative amendments relating to NC/BE could be made via the negative vetting procedure. In 2018, the Board implemented the Enhanced Procedures for Registration of New Drugs (Enhanced Procedures). Upon receipt of an application for registration of a new drug by a pharmaceutical company, or when a new drug is covered under the "Expanded Access Programme" of the HA or other relevant drug programmes subsidised by the Government, the Board will initiate the legislative procedures with a view to shortening the time required for registration. The time required for processing application for registration of pharmaceutical products is generally shortened by two to three months. As at March 2021, the Department of Health has handled a total of 68 pharmaceutical products containing NC/BE since the implementation of the Enhanced Procedures.

LISTING OF NEW DRUGS ON THE HADF

6. As for listing of new drugs on the HADF for use in public hospitals and clinics, the HA has an established mechanism for regular appraisal of registered new drugs or their clinical indications and review of the HADF and the coverage of the Safety Net with the support of multiple expert panels of different specialities, in order to cater for prevailing and evolving service needs. The review process follows an evidence-based approach, having regard to the safety, efficacy and cost-effectiveness of drugs and other relevant considerations, which include international

recommendations and practices as well as professional views, so as to ensure equitable and effective use of public resources in providing optimal treatment for patients.

7. The HA clinicians will submit new drug applications, which are based on clinical service needs, to the HA Drug Advisory Committee (DAC) via their respective Chiefs of Service and the Cluster / Hospital Drug and Therapeutics Committee for consideration of listing on the HADF. Subject to completion of new drug submission formalities and availability of all relevant clinical data and information, relevant experts of the DAC will complete the appraisal of a new drug within three months. Appraisal of new drugs is an ongoing process driven by evolving medical evidence, the latest clinical developments and market dynamics. The DAC holds meetings to evaluate new drug applications every three months. A flow chart on the process of listing of new drugs on the HADF is at **Annex I**.

8. As at March 2021, a total of around 1 400 drugs were covered by the HADF. The number of new drugs incorporated into the HADF in the past three years is set out below –

	2018-19	**2019-20**	**2020-21**
No. of new drugs listed on the HADF	38	57	48

9. Under the current HADF mechanism, existing drugs will be repositioned among categories (for example, from SFIs or SFIs with Safety Net to Special drugs, or from Special drugs to General drugs, etc.) where appropriate, whereas drugs that are obsolete or no longer in use will be removed from the HADF. Besides, clinicians may use non-HADF drugs under exceptional situations in order to manage urgent cases or meet the clinical needs of individual patients. To ensure that patients are provided with timely and optimal treatment, clinicians will prescribe appropriate drug treatment based on their professional judgment, taking into consideration the clinical conditions of individual patients.

10. To facilitate patients' early access to drugs, the HA welcomes every opportunity to collaborate with the pharmaceutical industry to formulate programmes in providing affordable, sustainable and appropriate support for patients' drug treatment, and will continue to ensure equitable access to cost-effective drugs of proven efficacy and safety in the HA hospitals and clinics. The HA will stay open to the proposals from pharmaceutical companies to facilitate early access to new drugs by individual patients.

INCLUSION OF SELF-FINANCED DRUGS INTO THE SAFETY NET

11. The HA's Drug Management Committee (DMC) will regularly call for submissions from clinicians on self-financed drugs proposed for inclusion into the Safety Net. To enable patients' earlier access to suitable new drugs, the DMC has, since 2018, increased its review exercise of new drug proposals for inclusion into the Safety Net from once to twice a year. Upon professional deliberation by the DMC, the list of drugs recommended for inclusion into the Safety Net will undergo the requisite governance approval process.

12. The Medical Services Development Committee under the HA Board will assess and approve the recommended drugs for inclusion into the SF's coverage. As for recommended drugs for inclusion into the CCF Medical Assistance Programmes, the Commission on Poverty (CoP) has streamlined the approval process[2] for introducing new drugs/medical devices into the three programmes starting from 2020-21 in order to provide more timely support to needy patients. Under the streamlined process, the CoP will, subject to its approval of an annual indicative subsidy budget for each programme, delegate the authority to the Chairperson of the CCF Task Force to grant final approval[3] to the lists of recommended new drugs and medical devices. A flow chart illustrating the process of inclusion of new drugs/medical devices into the Safety Net is at **Annex II**.

13. As at March 2021, the numbers of drugs covered by the SF and the CCF Medical Assistance Programmes were 51 and 37 respectively. The number of drugs included in the Safety Net[4] in the past three years is set out below –

No. of drugs included	2018-19	2019-20	2020-21
SF	6	10	9
CCF Medical Assistance Programmes	10	4	11

[2] Before 2020-21, proposals for introducing new drugs/medical devices into the three CCF Medical Assistance Programmes have to be supported by the CCF Task Force and subsequently submitted to the CoP for final approval.

[3] The list of approved new drugs/medical devices will be circulated to members of the CoP and CCF Task Force for information.

[4] Including new drugs repositioned from the CCF Medical Assistance Programmes to the SF as well as new drugs which are originally covered by either the SF or the CCF Medical Assistance Programmes and subsequently introduced to the other source of funding for different clinical indications.

PROVISION OF DRUG SUBSIDY THROUGH THE SAFETY NET

Financial assessment

14. Patients eligible[5] for applying for financial assistance from the Safety Net have to undergo means tests to assess their ability to pay and determine their share of contribution. For drug subsidy application, the means test mechanism assesses the financial ability of patients' household by their annual disposable financial resources (ADFR) and determines their contribution with a sliding scale formula, which is capped at 20% of the ADFR[6].

15. In early 2019, the Government and the HA enhanced the means test mechanism under the Safety Net. Specific measures include –

(1) modifying the calculation of the ADFR for drug subsidy application by counting only 50% of the patients' household net assets; and

(2) refining the definition of "household"[7] adopted in financial assessment to cover only core family members living under the same roof and having direct financial connection with the patient concerned.

16. Analysis revealed that the enhancement measures have broadened the coverage of drug subsidy under the Safety Net by lowering the level of co-payment by individual patients and extending the group of beneficiary to those who did not fall under the coverage previously.

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[5] To be eligible for drug subsidy under the Safety Net, the patient must be an HA patient and fulfil the clinical, identity and financial requirements.

[6] For specified ultra-expensive drugs under the SF and the CCF Ultra-expensive Drugs Programme, the patient's contribution is capped at 20% of the ADFR or $1 million (whichever is the lower).

[7] Before the enhancements, the definition of "household" was the patient and his/her core family members living under the same roof, including the patient's spouse, children, parents and dependent siblings. Under the refined definition of "household", the first step is to determine whether the patient is a dependent member of the household. A dependent is a person who is unmarried and either (i) under 18 years old; or (ii) 18-25 years old receiving full-time education. A patient who does not fulfil the above requirements is classified as a non-dependent patient. If the patient is a dependent patient, his/her family members will only include his/her parents or legal guardians and dependent siblings living under the same roof. If the patient is a non-dependent patient and is married, his/her family members will only include his/her spouse and dependent children (but not parents living under the same roof), while a non-dependent patient who is unmarried will be treated as a single person household (irrespective of whether the patient's parents or siblings are living under the same roof).

17. To ease the financial burden of patients requiring long-term medication, the Government and the HA have implemented measures to further refine the means test mechanism starting from late April 2021. Specific measures include –

(1) modifying the calculation of ADFR for recurrent applications[8];

(2) including more allowable deduction items[9] in the calculation of ADFR and adjusting the calculation[10] of income for all applications; and

(3) extending the validity period[11] of the financial assessment of recurrent applicants.

Subsidy statistics

18. With the implementation of the aforesaid improvement measures on top of the enhancements introduced in early 2019 and the new subsidised items, the subsidies granted under the SF and CCF Medical Assistance Programmes could reach $3.1 billion in 2021-22, representing an increase of 47.6% over 2020-21. The table below sets out the statistics of drug subsidy application under the Safety Net in the past three years –

		2018-19	**2019-20**	**2020-21**
SF	No. of approved drug subsidy applications	2 866	4 375	4 416
	Total drug subsidy amount ($ million)	421.8	576.1	718.8
	Average subsidy amount ($)	147,162	131,674	162,777

[8] The drug expenses paid by a patient for the last treatment course (i.e. the expenses on the drugs under application at public hospitals/clinics in the last 12 months) will be deducted and only 80% of the patient's household disposable income will be calculated.

[9] School fees on tertiary education for full-time students aged 25 or below and maintenance payments will be included.

[10] 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.

[11] 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's contribution is not more than $2,000. In addition, the HA will waive the requirement to submit financial documents if the patient has been referred to a second application within one to two months after the first application.

		2018-19	2019-20	2020-21
CCF Medical Assistance Programmes	No. of approved drug subsidy applications	2 277	1 984	2 900
	Total drug subsidy amount ($ million)	278.2	427.6	719.8
	Average subsidy amount ($)	122,199	215,499	248,205

WAY FORWARD

19. The Government is committed to providing suitable and affordable drug treatment to patients. This is manifested by the enhancement and improvement measures introduced on both the drug coverage and means test mechanism under the Safety Net, as well as the rising trend of drug subsidy provided under the Safety Net in the past years. To facilitate patients' early access to drug treatment, the HA will keep abreast of the latest medical developments with a view to including suitable drugs on the HADF and the coverage of the Safety Net, and stay open to the proposals from pharmaceutical companies to facilitate early access to new drugs by individual patients. As for subsidy, the Government and the HA will closely monitor the operation of the Safety Net, and explore from time to time the scope of further enhancement so as to provide sustainable and appropriate support to patients.

ADVICE SOUGHT

20. Members are invited to note the content of the paper.

Food and Health Bureau
Department of Health
Hospital Authority
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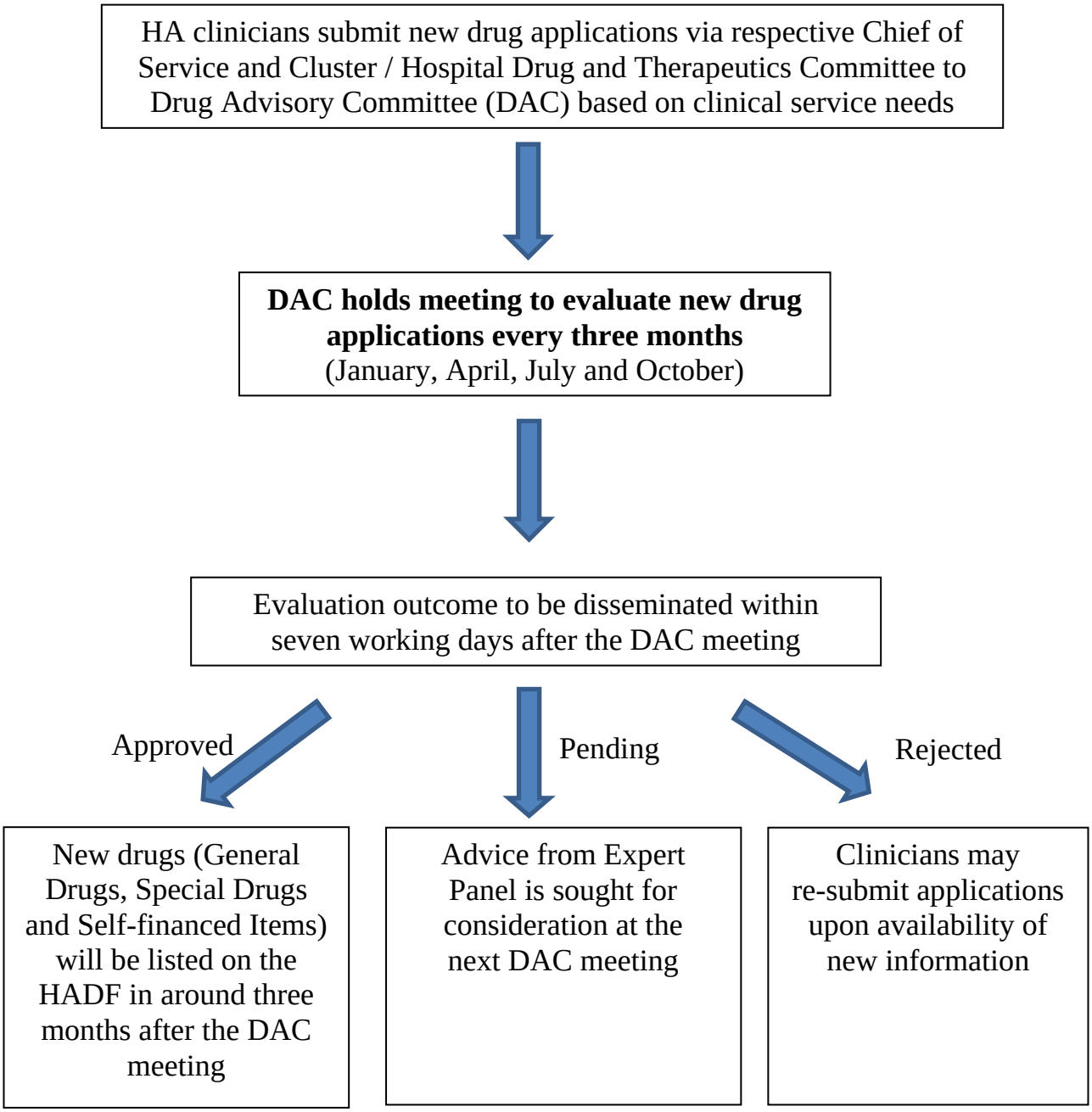
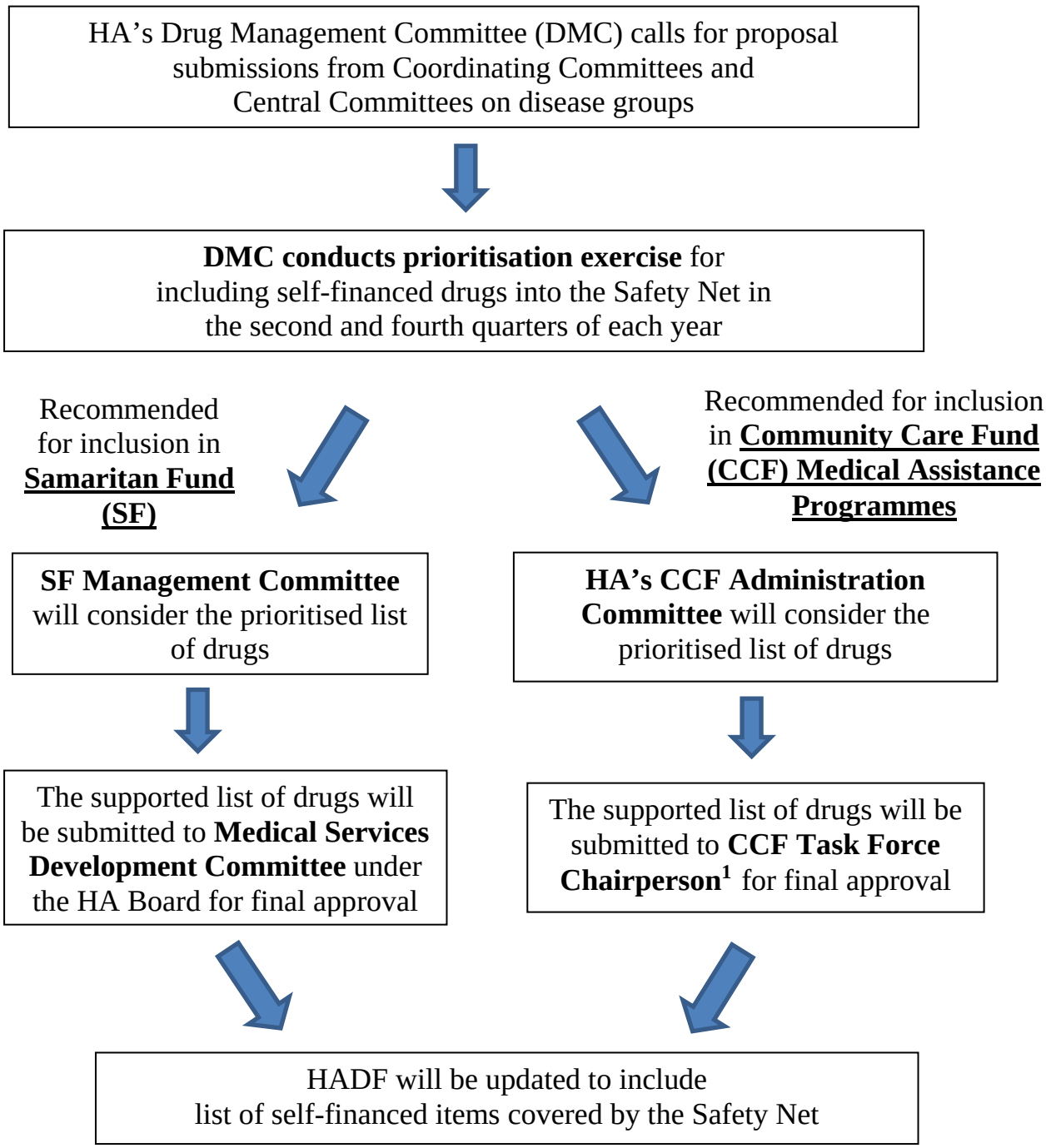
Annex I

Listing of New Drugs on the Hospital Authority Drug Formulary (HADF)



Annex II

Introduction of Self-Financed Drugs into the Safety Net



[1] Starting from 2020-21, the Commission on Poverty (CoP) will, subject to its approval of an annual indicative subsidy budget for each programme, delegate the authority to the Chairperson of the CCF Task Force to grant final approval to the lists of recommended new drugs/medical devices. The lists of approved drugs/medical devices will be circulated to members of the CoP and CCF Task Force for information.