## For information on 16 December 2019

#### Legislative Council Panel on Health Services Subcommittee on Issues Relating to the Support for Cancer Patients

#### **Support for Cancer Drug Treatment**

#### **PURPOSE**

This paper briefs Members on the support for cancer drug treatment, including the mechanism for evaluating cancer drugs for inclusion into the Hospital Authority Drug Formulary (HADF), and the provision of drug subsidy to cancer patients through the Samaritan Fund (SF) and the Community Care Fund (CCF) Medical Assistance Programmes<sup>1</sup> (collectively referred to as the "Safety Net").

#### **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, there are approximately 1 300 drugs listed on the HADF, which are categorised into the following four groups –

At present, there are three CCF Medical Assistance Programmes as implemented by the Hospital Authority (HA) –

<sup>(</sup>a) The First Phase Programme of Medical Assistance Programme (the "CCF First Phase Programme");

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

<sup>(</sup>c) Subsidy for Eligible Patients of Hospital Authority to Purchase Specified Implantable Medical Devices for Interventional Procedures (the "CCF Medical Devices Programme").

- (a) **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.
- (b) **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 them.
- (c) **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 cancer drugs which have not been brought into SF safety net but have been rapidly accumulating medical scientific evidence and with relatively higher efficacy, financial assistance could be provided through the CCF Medical Assistance Programmes.
- (d) **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 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 self-financed drugs. 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 for the PPMIs and specified self-financed drugs.

## NEW DRUG LISTING ON THE HOSPITAL AUTHOITY DRUG FORMULARY

- 4. The HA has an established mechanism for regular appraisal of new drugs and review of its HADF and the coverage of the Safety Net. The process follows an evidence-based approach, having regard to the safety, efficacy and cost-effectiveness of drugs and taking into account other relevant considerations, which include international recommendations and practices as well as professional views, so as to ensure equitable and rational use of public resources in providing optimal care for patients.
- 5. The HA clinicians would submit new drug applications, which are based on clinical service needs, to the HA Drug Advisory Committee (DAC) via their respective Chief 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 would complete the appraisal of a new drug within three months. Appraisal of new drugs is an on-going process driven by evolving medical evidence, latest clinical development and market dynamics. The DAC holds meetings to review and evaluate all new drug applications every three months. A flow chart on the process of listing of new drugs on the HADF is at **Annex A**.
- 6. As announced in the Budget for 2019-20, the Government

provides an additional recurrent subvention of \$400 million to the HA for widening the scope of the HADF. With the additional resources, the HA has expanded coverage of drugs for management of cancers in the HADF since April 2019. The expansion of coverage has incorporated specific new cancer drugs into the special drug category and extended the therapeutic applications of some cancer drugs in the HADF, which involved a recurrent amount of over \$50 million.

7. As of November 2019, the HADF covers 119 cancer drugs for treating various types of cancers. The number of new cancer drugs listed on the HADF over the past years is set out below –

	2015-16	2016-17	2017-18	2018-19	<b>2019-20</b> (as of Nov 2019)
No. of new cancer drugs listed on the	3	4	5	9	5
HADF					

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

## INCLUSION OF SELF-FINANCED DRUGS INTO THE SAFETY NET

9. The HA's Drug Management Committee (DMC) would regularly call for submissions from clinicians on the proposed self-financed drugs for inclusion into the Safety Net. To enable 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 recommended drugs for inclusion into the Safety Net will undergo the requisite governance

approval process.

final approval.

- 10. The Medical Services Development Committee under the HA Board will consider and approve the recommended drugs for inclusion into the SF's coverage.
- 11. As for the CCF Medical Assistance Programmes, the Commission on Poverty (CoP) endorsed in October 2019 to streamline the approval process for introducing new drugs / medical devices to the three CCF Medical Assistance Programmes starting from 2020-21. Under the streamlined procedure, the CoP will, subject to its approval of an annual indicative budget for each programme, delegate the authority to the CCF Task Force Chairperson to grant final approval to the lists of recommended new drugs and medical devices<sup>2</sup>. We expect that this could shorten the total lead time for introducing new drugs / medical devices (including cancer drugs) to the CCF Medical Assistance Programmes, thereby providing more timely support to needy patients. A flow chart illustrating the process of inclusion of self-financed drugs into the Safety Net is at **Annex B**.
- 12. As of November 2019, the SF covered 37 self-financed drugs, among which 18 are for treating different types of cancers, while the CCF First Phase Programme<sup>3</sup> covered 22 cancer drugs for treating 14 types of cancers. Coverage details of cancer drugs under the SF and the CCF First Phase Programme are at **Annex C**. The number of cancer drugs introduced into the SF and the CCF First Phase Programme over the past years is as follows –

Currently, proposals of introducing new drugs/medical devices to the three CCF Medical Assistance
 Programmes have to be supported by the CCF Task Force and subsequently submitted to the CoP for

<sup>&</sup>lt;sup>3</sup> The CCF First Phase Programme has been providing financial assistance since August 2011 to HA patients to purchase specific self-financed cancer drugs which have not yet been brought into the SF safety net but have been rapidly accumulating medical scientific evidence and with relatively higher efficacy.

	2015-16	2016-17	2017-18	2018-19	<b>2019-20</b> (as of Nov 2019)
No. of cancer drugs introduced to the SF and the CCF First Phase Programme <sup>4</sup>	1	6	4	11	4

#### PROVISION OF DRUG SUBSIDY THROUGH THE SAFETY NET

#### **Eligibility**

- 13. To be eligible for drug subsidy under the Safety Net, the patient must be an HA patient and fulfil all of the following requirements –
- (a) **Clinical requirement** the patient's treatment plan must be signed or issued by a designated HA doctor in accordance with the prevailing clinical guidelines;
- (b) **Identity requirement** the patient must be an "Eligible Person" within the meaning of the latest relevant government gazette published under the Hospital Authority Ordinance (Cap. 113)<sup>5</sup>; and
- (c) **Financial requirement** the patient must undergo a household-based financial assessment conducted by Medical Social Worker to determine the level of co-payment.

#### Financial assessment

14. Patients applying for financial assistance from the Safety Net have to undergo means test to assess their ability to pay and determine their share of contribution. Similar to other publicly-funded safety nets, the financial assessment for subsidies under the Safety Net is household-based. For drug subsidy application, the means test mechanism assesses the financial ability of patients' household by their annual disposable financial resources

<sup>&</sup>lt;sup>4</sup> Including new drugs repositioned from the CCF Medical Assistance Programmes to the SF and 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 therapeutic application.

<sup>&</sup>lt;sup>5</sup> For the CCF Ultra-expensive Drugs Programme, the patient must be a permanent resident of the Hong Kong Special Administrative Region according to the Immigration Ordinance (Cap. 115).

(ADFR) and determines their contribution with a sliding scale formula, which is capped at 20% of the ADFR<sup>6</sup>.

- 15. In early 2019, the Government and the HA introduced the following measures to enhance the means test mechanism under the Safety Net –
- (a) modifying the calculation of the ADFR for drug subsidy application by counting only 50% of the patients' household net assets<sup>7</sup>; and
- (b) refining the definition of "household" adopted in financial assessment to cover only core family members living under the same roof and having direct financial connection with the patient concerned<sup>8</sup>.
- 16. We expect that the enhancement measures will alleviate the financial burden of patients' families arising from drug expenditure and lessen the friction caused by requiring family members who are not

 $ADFR = [(Monthly\ Household\ Gross\ Income - Monthly\ Allowable\ Deductions)\ x\ 12\ + \\ (Disposable\ Capital - Deductible\ Allowance)\ x\ 50\%]$ 

If a patient's household ADFR are \$60,000 or below but exceed \$20,000, the patient's contribution will be a fixed amount.

<sup>8</sup> Under the refined definition of "household", the first step is to determine whether the patient is a dependent member of the household. Under the Safety Net's means test mechanism, a dependent is defined as 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. The following table lists out major scenarios under the revised household definition –

Patient Type	Refined Household Definition
A dependent patient	The patient, his/her parents/legal guardians, and dependent siblings living under the same roof
A non-dependent	If married – the patient, his/her spouse, and dependent children (but not parents/legal guardians or siblings) living under the same roof
patient	If unmarried – the patient would be treated as a single person household (irrespective of whether parents/legal guardians or siblings are living under the same roof)

<sup>&</sup>lt;sup>6</sup> For the CCF Ultra-expensive Drugs Programme, the patient contribution is capped at 20% of the ADFR or \$1 million (whichever is the lower).

Patients' household ADFR is calculated by summing up its annual household disposable income (less allowable deductions) and household net assets (i.e. disposable capital less deductible allowance). The enhanced formula for calculation of the ADFR is as follows –

financially connected with the patient to contribute and disclose their income and assets. We will closely monitor the impact of the enhancement measures on patients' applications and collect relevant data with a view to reviewing the effectiveness of the enhancement measures and continuing to study other issues on the means test mechanism.

#### Subsidy statistics

17. In 2018-19, the drug subsidies granted under the SF amounted to \$421.8 million, of which 78% was related to cancer drugs. The table below sets out the statistics of cancer drug subsidy application under the SF in the past years –

Year	No. of approved cancer drug subsidy applications	Total Subsidy amount for cancer drugs (\$ million)	Average subsidy amount (\$)
2015-16	1 521	250.2	164,489
2016-17	1 727	256.7	148,658
2017-18	1 523	250.4	164,431
2018-19	1 846	327.7	177,538
2019-20 (first six months)	1 651	263.5	159,608

- 18. In view of the implementation of the means test enhancement measures, introduction of more new drugs to the SF's coverage and increase in overall demand, we estimate that the projected total drug subsidy granted under the SF will reach around \$800 million in 2019-20, representing a 90% increase as compared with 2018-19.
- 19. As for the CCF First Phase Programme, the CoP has approved a budget limit of \$512.86 million for approval of drug applications for 2019 20. Since its introduction in August 2011, the total subsidy granted under the CCF First Phase Programme amounted to \$974.24 million as of September 2019. The table below sets out the application statistics of the CCF First Phase Programme in the past years –

Year	No. of approved drug subsidy applications	Total Subsidy amount (\$ million)	Average subsidy amount (\$)
2015-16	1 678	156.8	93,436
2016-17	1 831	160.4	87,601
2017-18	2 012	168.8	83,885
2018-19	2 263	231.8	102,434
2019-20 (first six months)	890	155.6	174,837

20. The total amount of subsidy for cancer drugs provided under the Safety Net in the past years is illustrated by the graph at **Annex D**.

#### **WAY FORWARD**

21. The Government is committed to providing suitable and affordable drug treatment to cancer patients. This is manifested by the enhancement 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. patients' early access to drug treatment, the HA will continue to follow the latest medical development in cancer drug treatment with a view to including suitable drugs to the HADF and coverage of the Safety Net, and stay open to the proposals from pharmaceutical companies to facilitate early access by individual patients to new drugs. On the subsidy aspect, the Government and the HA will closely monitor the operation of the Safety Net, particularly the subsidy level and the means test mechanism, and continue to explore scope of further enhancement for strengthening the sustainability and accessibility of our support.

## ADVICE SOUGHT

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

Food and Health Bureau Hospital Authority December 2019

#### Listing of New Drugs on the Hospital Authority Drug Formulary

HA clinicians submit new drug application via respective Chief of Service and Cluster / Hospital Drug and Therapeutics Committee to Drug Advisory Committee (DAC) based on clinical service needs



DAC holds meeting to evaluate new drug applications every three months (January, April, July and October)



Evaluation outcome to be disseminated within seven working days after the DAC meeting







New drugs (General drugs, Special drugs and Self-financed Items) will be listed on HA Drug Formulary in around three months after the DAC meeting

Advice from Expert Panel is sought for consideration at the next DAC meeting Clinicians may resubmit application upon availability of new information

#### **Introduction of Self-Financed Drugs into the Safety Net**

HA Drug Management Committee (DMC) calls for proposal submissions from Coordinating Committees and Central Committees on disease groups



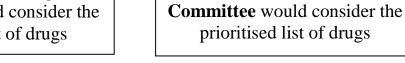
**DMC conducts prioritisation exercise** for including self-financed drugs into the safety net in the second and fourth quarters of each year

Recommended for inclusion in Samaritan Fund



Recommended for inclusion in <u>CCF Medical Assistance</u> <u>Programmes</u>

Samaritan Fund Management Committee would consider the prioritised list of drugs







**HA CCF Administration** 

The supported list of drugs would be submitted to **Medical Services Development Committee** under the HA Board for final approval

The supported list of drugs would be submitted to **CCF Task Force Chairperson** for final approval\*





HADF will be updated to include list of self-financed drugs covered by the Safety Net

## Cancer Drugs Supported by the Samaritan Fund and Community Care Fund Medical Assistance Programmes

### (I) Samaritan Fund (as of November 2019)

	Drug	Type of Cancer
1	Afatinib	Lung cancer
2	Azacitidine	Myelodysplastic syndromes
		Leukaemia
3	Bortezomib	Multiple myeloma
4	Ceritinib	Lung cancer
5	Cetuximab	Colorectal cancer
6	Crizotinib	Lung cancer
7	Dasatinib	Leukaemia
8	Erlotinib	Lung cancer
9	Gefitinib	Lung cancer
10	Ibrutinib	Lymphoma
11	Imatinib	Gastrointestinal stromal tumour
12	Lenalidomide	Multiple myeloma
13	Nilotinib	Leukaemia
14	Obinutuzumab	Lymphoma
15	Panitumumab	Colorectal cancer
16	Rituximab	Lymphoma & Leukaemia
17	Temozolomide	Glioma
18	Trastuzumab	Breast cancer

# (II) Community Care Fund Medical Assistance Programme (First Phase Programme) (as of November 2019)

	Drug	Type of Cancer
1	Abiraterone	Prostate cancer
2	Alectinib	Lung cancer
3	Axitinib	Renal cell carcinoma
4	Bendamustine	Leukaemia
5	Bevacizumab	Colorectal cancer
		Epithelial ovarian cancer,
		Fallopian tube cancer,
		Primary peritoneal cancer
6	Ceritinib	Lung cancer
7	Enzalutamide	Prostate cancer
8	Everolimus	Breast cancer
9	Lapatinib	Breast cancer
10	Nivolumab	Skin cancer
11	Obinutuzumab	Leukaemia
12	Osimertinib	Lung cancer
13	Palbociclib	Breast cancer
14	Pazopanib	Renal cell carcinoma
15	Pegylated Liposomal	Ovarian cancer
	Doxorubicin	
16	Pertuzumab	Breast cancer
17	Ribociclib	Breast cancer
18	Sorafenib	Liver cancer
19	Sunitinib	Renal cell carcinoma
		Gastrointestinal tumour
20	Trastuzumab	Gastric carcinoma
21	Trastuzumab emtansine	Breast cancer
	(T-DM1)	
22	Vemurafenib	Skin cancer

#### Annex D

### Amount of Subsidy for Cancer Drugs Granted under the Safety Net

