

二零一五年六月十五日
討論文件

立法會衛生事務委員會

醫院管理局藥物名冊

目的

本文件載述自上次二零一四年三月向委員作出簡介後，醫院管理局(醫管局)藥物名冊的最新發展，以及醫管局為加強藥物名冊管理制度而採取的措施。

背景

2. 醫管局在二零零五年七月推出藥物名冊，目的是透過統一所有公立醫院和診所的藥物政策及用藥，確保病人可公平地獲處方具成本效益並經驗證為安全及有效的藥物。自此之後，醫管局一直透過既定的聯繫平台及委員會會議，就藥物名冊的發展與內部和外界的持份者保持緊密溝通。醫管局樂意接受公眾就藥物名冊提出的意見和建議。這些意見和建議主要涉及藥物名冊的涵蓋範圍(包括撒瑪利亞基金安全網的涵蓋範圍)和藥物名冊的管理(例如管治機制、運作透明度和持份者的參與)。透過政府增加撥款資助，加上醫管局採取了內部措施以加強藥物名冊的管理，該局已逐步在上述各方面取得進展，以期在最大程度上促進市民的健康利益，並達致一個更客觀、更具透明度和更具公信力的藥物名冊制度。

藥物名冊涵蓋範圍

3. 醫管局設有機制，定期評估新藥物和檢討藥物名冊內的藥物名單，以切合當前和不斷演化的服務需要。在二零零五年七月至二零一四年三月期間，醫管局共把 164 種新藥物加入藥物名冊，包括 15 種通用藥物、67 種專用藥物、45 種不獲安全網資助的自費藥物、26 種獲撒瑪利亞基金安全網資助的自費藥物，以及 11 種獲關愛基金醫療援助項目資助的自費藥物。現有藥物也會按實際情況重組類別(例如由自費藥物或獲安全網資助的自費藥物轉為專用藥物、由專用藥物轉為通用藥物等)，而一些過時或不再使用的藥物則會從藥物名冊中剔除。此外，政府在二零零九／一零年度至二零一三／一四年度共增撥

逾 7.8 億元經常撥款予醫管局，分階段把 19 種自費藥物(包括 6 種獲安全網資助和 13 種不獲安全網資助的自費藥物)轉為專用藥物，並擴闊藥物名冊內 35 類治療組別專用藥物的臨床應用，讓更多病人可在公立醫院及診所以標準費用使用安全和有效的藥物。醫管局的用藥總開支亦由二零零五至零六年度的 21.9 億元增至二零零九至一零年度的 26.8 億元，及二零一三至一四年度的 40.8 億元。

4. 此外，醫管局透過撒瑪利亞基金提供的安全網及關愛基金醫療援助項目近年已分階段擴大涵蓋範圍。政府也在二零一二至一三年度一筆過撥款 100 億元，支持撒瑪利亞基金的持續運作。為回應公眾有關放寬在安全網下發放資助所作的經濟審查的意見，醫管局於二零零八年放寬了經濟審查準則及重新釐定可動用收入、認可扣減項目及可動用資產的計算方法；並於二零一二年再度放寬經濟審查準則，於計算可動用資產時引入可扣減豁免額，簡化病人分擔藥費的級別，並調低病人須分擔藥費的最高比率，令更多醫管局病人符合資格獲這兩項基金資助購買所涵蓋的自費藥物。

5. 截至二零一三至一四年度末，撒瑪利亞基金及關愛基金醫療援助項目分別資助了 20 種及 9 種自費藥物。撒瑪利亞基金的藥物資助金額，由二零零五至零六年度的 3,410 萬元增至二零一二至一三年度的 2.416 億元及二零一三至一四年度的 2.802 億元。關愛基金醫療援助項目的藥物資助金額，也由二零一一至一二年度項目設立時的 1,030 萬元，增至二零一三至一四年度的 1.007 億元。

藥物名冊的管理

6. 作為受政府資助的醫療服務提供者，醫管局已制訂多項措施，加強藥物名冊的管治及運作透明度，以提升公眾對藥物名冊管理制度的認受程度和信心。醫管局於二零一三年七月重整藥物名冊的管治架構，成立了藥事管理委員會，負責醫管局藥物名冊的整體管理工作，並監察轄下兩個功能委員會，即藥物建議委員會和藥物名冊委員會。這兩個委員會分別負責在機構層面評估新藥物和定期檢討藥物名冊。

7. 多個不同專科的專家小組為藥物建議委員會和藥物名冊委員會提供支援。各聯網的藥事委員會則在聯網層面協調各方推行藥物政策，並促進醫管局藥事管理委員會與各醫院藥事委員會之間的溝通。透過重整管治架構，醫管局可確保政策制定和實施連貫一致，並可在機構、聯網及醫院層面清楚釐定藥物管理的責任，以及因應各聯網和醫院的不同服務需求作出合理和平衡的決定。

8. 醫管局一直透過既定的聯絡渠道，就藥物名冊及撒瑪利亞基金的涵蓋範圍等相關事宜與持份者和服務伙伴保持緊密聯繫。醫管局定期把藥物名冊內的藥物名單、可供病人在公立醫院藥劑部購買的自費藥物名單、藥物建議委員會的會議議程、所討論的藥物名單、評審結果，以及評審過程中曾參考的資料表單等，上載至醫管局的互聯網和內聯網站，以便公眾及相關的持份者查閱。

9. 醫管局已確立與病人團體的聯絡渠道，以確保妥善徵詢他們的意見，並適當地讓他們參與其中。醫管局每年召開兩次諮詢會，讓病人團體得知最新發展，並聽取他們對引入新藥物、檢討藥物名冊內的藥物名單，以及撒瑪利亞基金涵蓋的藥物的意見。此外，醫管局每年會就藥物名冊和撒瑪利亞基金的發展事宜，向由醫管局行政總裁主持的病人諮詢委員會提交進度報告，以及將所收集到的病人團體意見或建議，供相關的藥物委員會參考。醫管局也會發出通訊，定期通知病人團體有關藥物名冊的最新發展。醫管局亦會在有需要時與個別病人團體會面，討論他們所關注的事項。

10. 此外，醫管局一直與藥商就新藥物申請、特定藥物計劃和藥費資助計劃等事宜保持開放和持續的溝通，務求令更多有需要使用自費藥物的病人受惠。

11. 上述措施不但令市民對藥物名冊有更深入的認識，還提高了藥物名冊的運作透明度，確保當局在管理藥物名冊時妥善徵詢有關各方的意見，並適當地讓他們參與其中。

最新情況

擴大藥物名冊涵蓋範圍

12. 醫管局繼續在既定的藥物檢討機制下擴大藥物名冊，以涵蓋更多經驗證為安全及有效的藥物。在二零一四至一五年度，醫管局在藥物名冊內加入了 20 種新藥物，包括 1 種通用藥物、10 種專用藥物、1 種獲撒瑪利亞基金安全網資助的自費藥物，以及 8 種不獲安全網資助的自費藥物。透過政府增撥的 3,700 萬元經常撥款，醫管局也擴闊了藥物名冊內三類治療組別專用藥物的臨床應用。

13. 截至二零一五年三月三十一日，藥物名冊內共有 897 種通用藥物、338 種專用藥物、76 種不獲安全網資助的自費藥物、21 種獲撒瑪利亞基金安全網資助的自費藥物，以及 9 種獲關愛基金醫療援助項

目資助的自費藥物。醫管局的用藥總開支增加了 6%，由二零一三至一四年度的 40.8 億元增至二零一四至一五年度的 43.3 億元。此外，在二零一四至一五年度，撒瑪利亞基金共批出 2 230 宗藥物資助申請，資助總額為 3.108 億元，每宗成功申請獲得的資助平均為 14 萬元。在同一年度，關愛基金醫療援助項目共批出 1 680 宗藥物資助申請，資助總額為 1.494 億元，每宗成功申請獲得的資助平均為 9 萬元。

14. 在二零一五至一六年度，醫管局會在藥物名冊內新增 5 類治療癌症、慢性丙型肝炎及克隆氏症的藥物，並擴闊一種治療多發性硬化症的專用藥物的臨床應用。這些措施已於二零一五年第二季推行，涉及 4,450 萬元的額外經常財政開支。此外，醫管局會把一種新的自費藥物和一種現有安全網自費藥物的新臨床適應症納入安全網的資助範圍，並放寬 9 種現時獲安全網資助藥物的臨床適應症，以及在關愛基金醫療援助項目下增加一種獲資助的自費藥物。這些措施將於二零一五年第三季推行，以期讓更多有需要使用特定自費藥物的合資格的病人受惠。

在藥物名冊管理方面加強溝通策略

15. 除上文第 6 至 10 段提及的措施外，醫管局自二零一四至一五年度起採取了下列主要措施，以加深公眾對藥物名冊管理的了解和促進持份者參與其中，從而進一步提高藥物名冊的公信力：

a) 醫管局《藥物名冊管理手冊》(《手冊》)

醫管局已編製《藥物名冊管理手冊》，清楚說明整個藥物名冊管理制度，內容包括下列各項：

- i) 醫管局在藥物管理方面的管治架構，包括各功能委員會的組成，以及他們在整個機構和聯網層面上，就藥物管理方面所擔當的角色；
- ii) 新藥物納入藥物名冊的機制、原則、決策和運作程序；
- iii) 藥物名冊檢討的程序和不同藥物委員會之間的相互合作；
- iv) 內部持份者、藥物委員會成員和藥物評審員培訓；以及

- v) 藥物名冊管理和諮詢機制、持份者參與方式和獲取相關資訊的渠道。

《手冊》促進持份者和服務伙伴對藥物名冊的了解，使他們得以在不同的合作平台上順利地各司其職。此外，《手冊》就日後加強藥物名冊管理的相關討論提供共同基礎。《手冊》將於二零一五年第三季發布，屆時會分發予醫管局內部員工、病人團體、學界人士、藥業界和相關人士。《手冊》的預覽本載於附件（現時只備英文版本，中文版本會於正式發布時一同推出），以供委員參閱。

b) 藥物名冊管理網站

為方便市民取得資訊，並有效地向相關持份者和服務伙伴傳遞訊息，醫管局現正重整藥物名冊網站，以整合所有與藥物名冊管理相關的資訊。各持份者(包括醫管局內部員工、藥物委員會成員、病人團體、藥業界和市民大眾)將能更快地取得相關和適用的資訊。網站將於二零一五年第三季啟用，以配合《手冊》的發布工作。

c) 推廣計劃

醫管局已積極推廣重整後的藥物名冊管治架構、藥物評估與檢討的原則及機制、《手冊》的編製、網站重整，以及加強持份者參與藥物名冊管理的工作。醫管局的內部推廣已包括所有高級行政人員、相關的藥物委員會、專家小組、聯網藥事委員會及臨床統籌委員會。醫管局會繼續在聯網舉辦更多推廣活動，向局內的醫護專業闡明相關的機制和資訊。與此同時，醫管局已開展與藥業界及病人團體的溝通，並會在有需要時再作討論。此外，醫管局會透過適當途徑(包括傳媒)向公眾推廣藥物名冊管理制度，以加深市民的了解，並增強他們對該制度的信心。

未來路向

16. 管理藥物名冊是一項持續進行而且過程互動的工作，涉及多方的持份者和多元的考慮因素。為確保藥物名冊管理制度客觀、具透明度和具公信力，醫管局會繼續根據最新的科學實證、國際間的發展、社會不斷演化的需要、持份者的意見和財政資源，評估新藥物和檢討藥

物名冊。醫管局也會舉辦內部培訓，以加深員工對藥物名冊的認識，並為藥物評審員開拓更多元的專業培訓。醫管局會繼續進行公眾教育，與各持份者和服務伙伴保持聯繫，以確保他們對藥物名冊管理有正確的認識，並適當地徵詢他們的意見。

徵詢意見

17. 請委員察悉本文件的內容。

食物及衛生局
醫院管理局
二零一五年六月



醫院管理局

HOSPITAL
AUTHORITY

Hospital Authority Drug Formulary Management Manual

(Preview Version)

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PREAMBLE

Provision of sustainable and quality public healthcare services for residents of Hong Kong is the overarching mandate of the Hospital Authority (HA). To this end, HA embarked on developing its Drug Formulary in 2003 along the core values of evidence-based practice, rational use of public resources, target subsidies, opportunity cost considerations and facilitation of patients' choice. In July 2005, the HA Drug Formulary was formally launched and uniform principles of managing the Drug Formulary were adopted by all HA institutions.

Since the implementation of the HA Drug Formulary, new drugs of proven safety and efficacy have been introduced while the prevailing list of drugs is regularly reviewed under established mechanisms. Patients thus have equitable access to cost-effective drug treatments under the highly subsidised public healthcare system.

In the face of rising and competing demands for providing new drug treatments that vary widely in cost, therapeutic effectiveness, side effects and health outcome, it is imperative for HA, as a publicly funded organisation, to ensure rational use of limited resources in order to provide adequate medical care and optimise the health benefits for the society.

HA has taken various measures to enhance the governance of the Drug Formulary, improve operational transparency and increase the engagement of stakeholders. Establishment of the Patient Advisory Committee, improved accessibility to information about new drug inclusion via HA's internet, strengthened communication with patient groups at different stages of new drug introduction and revamp of the HA Drug Formulary websites have all made the drug inclusion process more open and transparent as to gain higher credibility and public confidence in the HA Drug Formulary.

As a proactive measure to further enhance the transparency and communication on the prevailing HA Drug Formulary, this Manual is written to give an account of the governance structure and elucidate the principles and operational procedures for managing the HA Drug Formulary. In addition, the consultation and engagement processes for both internal and external stakeholders in managing the HA Drug Formulary are included.

This Manual is targeted for all HA staff, academics, patient groups and the public, as well as personnel in the pharmaceutical industry who are stakeholders of the HA Drug Formulary. It is a dynamic document that goes with any system changes in managing the HA Drug Formulary, which in turn is responsive to the evolving needs for an open, fair and equitable Drug Formulary in HA.

HA assures to keep on open discussion with all stakeholders in managing the HA Drug Formulary. This is also a driving force for a better healthcare system.

1 INTRODUCTION

The World Health Organisation has been actively promoting the concept of “essential medicine”. It recommends that health authorities around the world establish their own mechanisms for systematic selection of drugs to promote availability, accessibility, affordability, quality and rational use of medicines. In Hong Kong, it is the Government’s public healthcare policy that no one should be denied adequate medical treatment through lack of means. The Hospital Authority (HA) Ordinance also requires the Authority to ensure provision of hospital services of the highest possible standard within the resources obtainable.

To help achieve this, HA has long been evaluating new drugs and reviewing its existing drug list through the Drug Advisory Committee (DAC) and the former Drug Utilisation Review Committee (DURC)¹ respectively. In line with international developments and to standardise drug utilisation and payment practices among all its public hospitals and clinics, HA embarked on the development of its own Drug Formulary in 2003. This development was based on the guiding principle that public resources should be used to maximise the effects of healthcare and provide equitable access for all patients. Other core values, including evidence-based medical practice, rational use of public resources, targeted subsidy, opportunity cost considerations and facilitation of patients’ choice, have also underpinned the development of the HA Drug Formulary.

1.1 The HA Drug Formulary

HA has implemented its Drug Formulary since July 2005 with a view to ensuring equitable access by patients to cost effective drugs of proven safety and efficacy through standardisation of the drug policy and drug utilisation in all HA public hospitals and clinics. The Drug Formulary is supported by on-going evaluation of available new drugs and regular review of the prevailing list of drugs by relevant experts. At present, there are approximately 1,300 drugs listed on the Drug Formulary, which are categorised into the following four groups:

- a) **General Drugs** – These are 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 HA public hospitals and clinics.

¹ DURC was replaced by the Drug Management Committee (DMC) in October 2013

- b) **Special Drugs** – These are drugs used under specific clinical conditions with specific specialist authorisation. Special drugs are provided at standard fees and charges in HA 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.
- c) **Self-financed Items (SFIs) with Safety Net** – These are drugs which are proven to be of significant clinical benefits but are extremely expensive for HA to provide as part of its standard services. These drugs are not covered by the standard fees and charges in HA public hospitals and clinics. Patients who require 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 subsidise these drug expenses of patients who have financial difficulties.
- 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 (e.g. anti-obesity drugs). These drugs are not provided as part of HA’s standard services nor covered by the standard fees and charges in HA public hospitals and clinics. Patients who choose to use these drugs must purchase them at their own expense.

Rapid technological advances have brought many new drugs which differ in evidential support on safety, efficacy and cost-effectiveness to the market. Drugs in current use may become obsolete over time or may require modifications in their clinical indications. In addition they may need to be repositioned across the above categories in the light of the latest scientific and clinical evidence. It would be unrealistic and impracticable for HA, as a publicly funded organisation, to provide all registered drugs in the market through public funding. There is a continual need to review the development of the Drug Formulary under established mechanisms.

In recent years, there has been further progress in the development of the Drug Formulary, not only in its expanded coverage for new drug therapies, but also enhanced governance and operational transparency to meet the changing needs of society and to strengthen public confidence in HA’s overall management of the Drug Formulary.

1.2 Purpose of This Manual

The purpose of this HA Drug Formulary Management Manual is:

- a) To define the governance structure, roles and composition of functional committees in drug management at both corporate and cluster levels in HA;

- b) To elucidate the principles of Drug Formulary management in HA;
- c) To elaborate the operational processes of new drug listing and regular review of the HA Drug Formulary ;
- d) To identify the types of training available for personnel involved in Drug Formulary management in HA; and
- e) To describe the consultation, engagement and participation of different stakeholder groups in the management of the HA Drug Formulary.

2 GOVERNANCE OF DRUG MANAGEMENT IN HA

The governance structure for managing the HA Drug Formulary was revamped in 2013. The Drug Management Committee (DMC) was established under the Directors' Meeting to be responsible for HA's overall drug management. DMC is supported by various functional committees in HA, namely, the Drug Advisory Committee (DAC), Drug Formulary Committee (DFC), Drug Selection Committee (DSC) and Medication Safety Committee (MSC) at the corporate level, as well as the Drug and Therapeutics Committee (DTC) of all hospital clusters (Figure 1). DMC reports to and seeks policy direction from the Directors' Meeting, which in turn is accountable to the Medical Services Development Committee (MSDC) which oversees the development of clinical services at HA Board level.

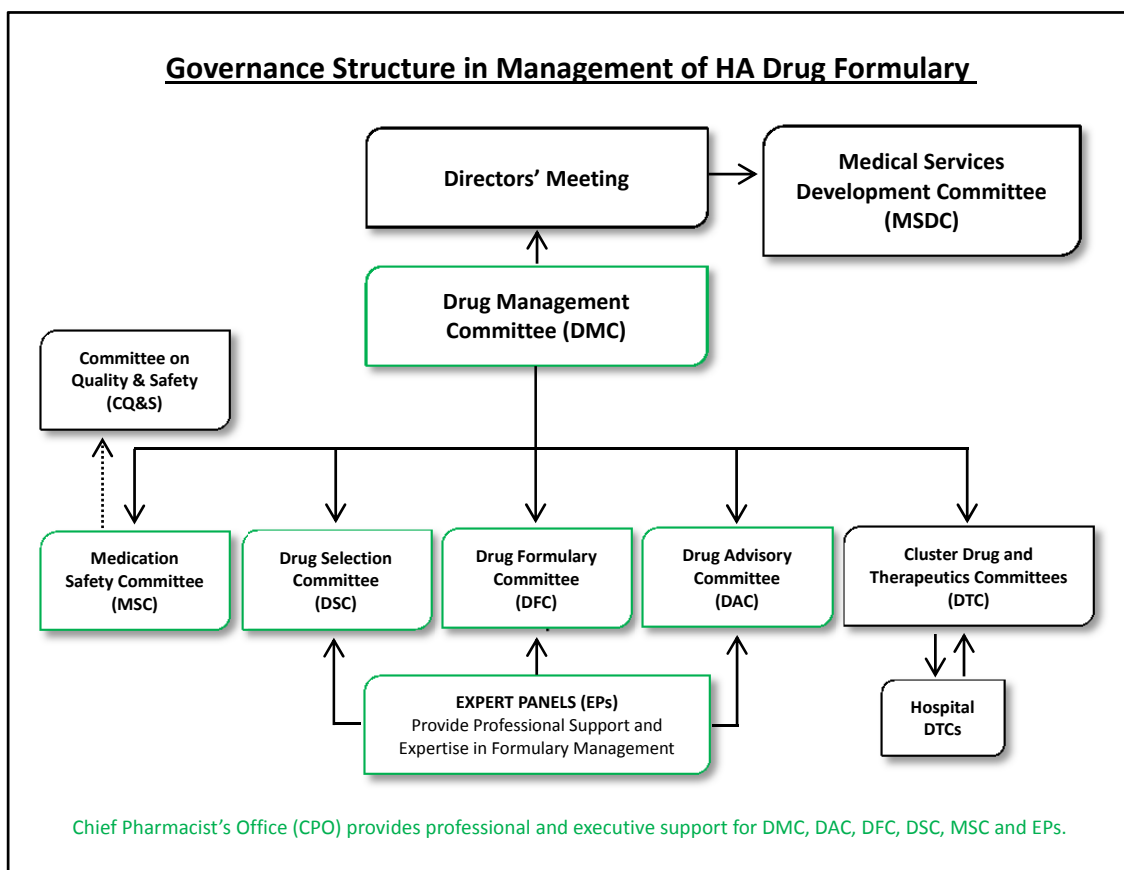


Figure 1

This chapter provides an overview of this revamped governance structure and defines the roles of each committee in drug management at both corporate and cluster / hospital levels. It should be noted that, while effective drug management encompasses the cooperation and interplay among various parties, the ensuing sections would focus on the terms of reference and composition of functional committees that are directly involved in the management of the HA Drug Formulary, namely, DMC, DAC, DFC and Cluster DTC. Those related to the Expert Panels, DSC and MSC are shown in Appendices I to III respectively for reference.

2.1 Drug Management Committee (DMC)

DMC reports to the Directors' Meeting and is responsible for the overall drug management in HA. The Committee is supported by various functional committees at both corporate and cluster levels so as to ensure consistency in policy formulation and implementation across HA as well as to provide clear accountability for drug management at all levels.

2.1.1 Terms of Reference

The Terms of Reference of DMC are:

- a) To recommend drug management policies and formulate guidelines in HA;
- b) To liaise and support implementation of drug policies and guidelines in HA;
- c) To monitor and evaluate impacts of drug policies on quality use of drugs in HA;
- d) To oversee development and management of Drug Formulary in HA;
- e) To prioritise drug programmes in the annual planning process and for safety net inclusion; and
- f) To conduct drug utilisation review in HA.

2.1.2 Composition

DMC is chaired by the corporate Director overseeing pharmaceutical service management [currently Director (Cluster Services)]. The DMC membership is as follows:

- a) Chairmen of DAC, DFC, DSC, MSC;
- b) Chairmen of all Cluster DTCs;
- c) Chief Pharmacist;
- d) Chief Manager (Nursing); and
- e) Two co-opted academics in healthcare-related disciplines (e.g. clinical pharmacologist) from local universities.

In-attendance: Cluster Clinical Stream Coordinators (Pharmacy) of all clusters.

DMC members are positional appointments whereas co-opted academics are personal appointments by invitation of the subject corporate Director and their membership would be reviewed biennially.

2.2 Drug Advisory Committee (DAC)

DAC plays a key role in evaluating new pharmaceuticals for listing on the HA Drug Formulary.

2.2.1 Terms of Reference

The Terms of Reference of DAC are:

- a) To evaluate new pharmaceuticals and decide on the indication for use for listing on the HA Drug Formulary;
- b) To decide on the category of new pharmaceuticals approved for listing on the HA Drug Formulary; and
- c) To advise all HA hospitals and clinics the review outcome of new pharmaceuticals put up for listing on the HA Drug Formulary.

2.2.2 Composition

DAC is chaired by a senior management executive appointed by the subject corporate Director. Its composition has balanced the representation of different clinical specialties with weighting on pharmaceutical technology development. The DAC membership is as follows:

- a) Corporate Director overseeing pharmaceutical service management;
- b) Chief Pharmacist;
- c) Eight rotational members from Expert Panels on HA Drug Formulary; and
- d) Two co-opted academics in healthcare-related disciplines (e.g. clinical pharmacologist) from local universities.

The subject corporate Director and Chief Pharmacist are again positional appointments. Rotational members nominated by Expert Panels on HA Drug Formulary assist in considering different aspects of drug use and providing balanced views on clinical outcomes in accordance with the best available scientific and clinical evidence. They contribute to the work of DAC as independent experts and are accountable to DAC on individual basis. There is no accountability relationship between rotational members and their respective Coordinating Committees (COCs), Central Committees (CCs) on disease groups or Expert Panels. The tenure of both DAC Chairman and rotational members is up to two years, with flexibility of extension for up to two or more terms. Co-opted academics are again personal appointments by invitation of the subject corporate Director and their membership would be reviewed biennially.

In view of the importance and complexity of new drug evaluations for the HA Drug Formulary, the successor of DAC Chairman would preferably be designated one year before expiration of the tenure of the current chairman, and attend DAC meetings as a co-opted member until he / she takes up the chairmanship. As for rotational members, renewal of membership would preferably be staggered in order to ensure smooth operation of the committee and to maintain consistency in the decision-making process.

2.3 Drug Formulary Committee (DFC)

DFC plays a key role in the management of the HA Drug Formulary and in the revision of the existing drug list.

2.3.1 Terms of Reference

The Terms of Reference of DFC are:

- a) To manage and review the HA Drug Formulary which serves as a standard and reference for all HA institutions;
- b) To conduct biennial comprehensive review of the HA Drug Formulary or upon request of DMC;
- c) To make recommendations for management and operation of the HA Drug Formulary to DMC; and
- d) To advise DMC on the number of expert panels required for operation of the HA Drug Formulary.

2.3.2 Composition

The DFC Chairman would be elected from among the DTC Chairmen of all seven clusters for a term of 2 years, usually prior to the biennial comprehensive review of the HA Drug Formulary. Their tenure can be renewed upon consensus among the Cluster DTC Chairmen. The DFC composition facilitates making of rational and balanced decisions to cater for the service needs of different clusters. DFC may co-opt additional members from the Expert Panels when necessary. The DFC membership is as follows:

- a) Corporate Director overseeing pharmaceutical service management;
- b) The remaining six chairmen of Cluster DTC; and
- c) Chief Pharmacist.

All DFC members are positional appointments.

2.4 Cluster and Hospital Drug and Therapeutics Committee (DTC)

The Cluster and Hospital DTCs play an essential supportive role in the management of HA Drug Formulary alongside their respective functions at the cluster / hospital level.

2.4.1 Terms of Reference

The Terms of Reference of Cluster and Hospital DTCs in respect of Drug Formulary management are:

- a) To implement DMC policies / guidelines and monitor / follow up DMC initiatives;
- b) To channel frontline feedback on management and operation of the HA Drug Formulary to DMC (via respective Cluster DTC);
- c) To disseminate DMC, DAC and DFC's information among cluster hospitals and collate feedback;
- d) To endorse cluster / hospital applications for new drug listing before submission to DAC;
- e) To approve programmes on compassionate use of unregistered drugs and drug samples as proposed by pharmaceutical companies; and
- f) To manage cluster and hospital drug formulary and review the need for non-formulary drugs regularly.

2.4.2 Composition

Cluster and Hospital DTCs are chaired by the responsible Cluster and Hospital Chief Executive or his / her delegate respectively. Members include Chief of Service of related specialties, Cluster Clinical Stream Coordinators, General Manager (Nursing) and pharmacists with a defined tenure. Cluster and Hospital DTCs may enlist additional members to meet operational needs, as and when required.

2.5 Expert Panels

Expert Panels provide specialist advice on selection of drugs and furnish professional views for review of existing drugs in related specialty areas. Multiple Expert Panels have been formed in support of DAC and DFC functions. The Terms of Reference and composition of Expert Panels are shown in Appendix I.

2.6 Secretariat of Corporate Drug Committees

The Chief Pharmacist's Office (CPO) of the HA Head Office is the key executive arm providing professional and secretariat support for all corporate drug committees and expert panels in processing new drug applications, conducting literature reviews, coordinating annual plan bids for drug new programmes, following through decisions made by drug committees, monitoring and reviewing use of drugs, keeping abreast of new drug developments and published information for regular review of the HA Drug Formulary, fostering medication safety, as well as communication with different stakeholders on matters related to the development, implementation and operation of the Drug Formulary through established channels.

2.7 Logistics for Corporate Drug Committee Meetings

2.7.1 Appointment of Members of Corporate Drug Committees

While different functional drug committees and expert panels are formed by virtue of members' position or through invitation / nomination, the corporate Director overseeing pharmaceutical service management would appoint all co-opted academics and issue appointment letters for Chairmen and members of the corporate drug committees and expert panels in HA.

2.7.2 Meeting Quorum

As a general rule, presence of half of the standing members of a committee is necessary to constitute a quorum to form a valid meeting while decisions would be made upon consensus of standing members present. In case voting is required to make a decision, only standing members have the right to vote.

2.7.3 Declaration of Interest

As a publicly funded organisation, it is the responsibility of HA to ensure that all drug management decisions are based on considerations of best public interest and scientific evidence. Additionally, it is the objective of the HA to protect and uphold its reputation, professionalism and integrity as well as that of its staff by avoiding actual or perceived conflict of interest situations.

Accordingly, members of corporate and cluster / hospital drug committees are required to complete a declaration form on conflict of interest prior to each scheduled meeting. In doing so, members should acquaint themselves with relevant HA human resource policies and guidance on declarations of conflict of interest.

In particular, members who have accepted sponsorships relevant to any concerned medications must, subject to the decision of the concerned committee chairman, abstain from engaging in situations that may lead to actual or perceived bias in the decision-making process for a reasonable period of time, which is normally six months. Such sponsorship could include attendance at local or overseas conferences, clinical trials or research, sponsorship for conventions, seminars and other health promotion activities.

3 LISTING OF NEW DRUGS ON HA DRUG FORMULARY

The HA Drug Formulary is continually updated with regular evaluation of new drugs and review of the prevailing list of drugs under established mechanisms. As mentioned in the preceding chapter, the Drug Advisory Committee (DAC) is responsible for regular evaluation of new drugs and new indications for listing on the HA Drug Formulary under an established mechanism. This chapter defines the scope of DAC in new drug evaluation, sets out the procedure for submitting / processing new drug applications, elaborates on the principal considerations and other factors for new drug evaluation, and stipulates the process of handling drugs not evaluated by DAC.

3.1 Scope of DAC in New Drug Evaluation

DAC accepts applications for new drug evaluation only if the concerned new drug entity or new indication has been registered in Hong Kong before the specified deadline for submitting such applications to the committee. An application can be submitted, via Cluster / Hospital DTC, for consideration of listing on the HA Drug Formulary if the concerned drug entity or indication fulfills the following criteria:

- a) It is indicated for prevention or treatment of conditions which are not covered by drugs in the existing HA Drug Formulary;
- b) It has an advantage in terms of efficacy and adverse effects over agents in the existing HA Drug Formulary for the same indication; or
- c) It is equivalent in terms of safety and efficacy as compared to existing agents in the HA Drug Formulary for the same indication and of lower treatment costs.

Certain new drugs and miscellaneous pharmaceutical items fall outside the scope of DAC's evaluation and are handled under other established mechanisms to meet operational needs. Details are shown in Appendix IX.

3.2 Submission of New Drug Applications from Hospital

As HA is a publicly funded healthcare service provider, the coverage of the HA Drug Formulary should be driven by service needs. Therefore, all applications for new drug listing should be initiated by HA clinicians and submitted to the DAC for consideration via the Cluster / Hospital DTC. DAC does not accept new drug applications submitted by pharmaceutical companies.

All new drug applications are required to go through peer review before submission. Clinicians intending to submit a new drug application should thus obtain prior endorsement of their respective Chief of Service before submitting to the Cluster / Hospital DTC.

Cluster / Hospital DTC, upon receipt of the clinician's application, should confirm that the concerned product and indication have been registered in Hong Kong before the submission deadline. The following should also be affirmed in respect of the new drug application:

- a) Relevant clinical needs for treatment of the proposed clinical population in the cluster;
- b) Positive intention to use the new drugs if approved by DAC; and
- c) Adequate published evidence on safety and efficacy of the concerned new drug to reasonably substantiate the application without requiring further extensive literature search.

Cluster / Hospital DTC should return the completed DAC New Drug Submission Form (Appendix IV), together with all supporting documents, to reach the DAC Secretariat (i.e. CPO) at least twelve weeks before the scheduled DAC meeting. All incomplete and late applications will automatically be deferred to the following DAC meeting for consideration.

3.2.1 Requisite Information for DAC's Evaluation

The following information in respect of the new drugs and the main comparators is required to facilitate DAC's evaluation for listing on the HA Drug Formulary:

A. Drug Particulars

These include:

- i) Generic name;
- ii) Brand name;
- iii) Pharmaceutical form(s) (e.g. ampoule, vial, sustained-release tablet);
- iv) Strength(s);
- v) Pack size(s); and
- vi) Price of each strength.

B. Target Population

Details of the target population for drug use must be clearly provided, including patient sub-groups, disease type, severity level and co-morbidity, etc. Since a drug may be cost-effective for treatment of certain groups of patients only, it is important to clearly identify the groups under study and undertake suitable analyses for different groups of patients. Moreover, as aforementioned, DAC only considers clinical indication(s) approved in Hong Kong. "Off-label" use of drug will not be considered.

C. Choice of Main Comparator

Provision of the principal pharmacological action and therapeutic class facilitates evaluation of a new drug against its main comparator, which is defined as an existing alternative pharmaceutical analogue in the HA Drug Formulary that prescribers would replace with the new drug in disease management. The following hierarchy can help identify the main comparator for new drug evaluation:

- i) *Existing pharmacological analogues* – If the new drug falls in a therapeutic class of the HA Drug Formulary where pharmacological analogues are already listed, the main comparator is the analogue that is currently used on the largest number of patients.
- ii) *New therapeutic class* – If the new drug falls in a new therapeutic class but is intended for use on an indication for which there are other widely used drugs in the HA Drug Formulary, the main comparator is the drug that is used to treat that indication for the largest number of patients.
- iii) *No currently listed drug* – In this circumstance, the main comparator is the standard medical management, which may include a drug not listed on the HA Drug Formulary, a surgical procedure or conservative management.

The selected main comparator should be in a form (if available) similar to that of the new drug (e.g. sustained release tablets or metered dose inhalers). In cases where the new drug has more than one indication for use, comparison with multiple main comparators is required. Main comparators may differ among patient sub-groups and relevant comparators include other drugs that are widely used for a specific condition, alternative medical clinical care like surgery as well as best supportive care. Pharmacoeconomic studies may also assist to identify one or a small number of relevant main comparators.

In essence, the new drug would first be compared with the standard treatment in efficacy and cost-effectiveness. The most frequently used or most effective therapy can be used in the absence of a standard therapy. The choice of alternatives must be justifiable and acceptable to the clinical community.

D. Level of Clinical Evidence

As the major concern for using new drugs for clinical intervention is efficacy, evidence provided by randomised controlled trials or meta-analysis of randomised controlled trials is the most desirable data for assessing the effectiveness of clinical intervention. Only published and peer reviewed clinical trials should be provided. Abstracts, posters and proceedings would not be accepted for evaluation of new drug applications. For other

types of intervention enlisting DAC's evaluation, the evidence hierarchy adopted by the Australian National Health and Medical Research Committee (NHMRC) set out in Table 1 below provides a useful reference.

Table 1 - Australian NHMRC Evidence Hierarchy: Designation of 'Level of Evidence' According to Type of Research Question

Level	Intervention	Diagnostic Accuracy	Prognosis	Aetiology	Screening Intervention
I	Systematic review of level II studies	Systematic review of level II studies	Systematic review of level II studies	Systematic review of level II studies	Systematic review of level II studies
II	Randomised controlled trial	Study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive persons with a defined clinical presentation	Prospective cohort study	Prospective cohort study	Randomised controlled trial
III-1	Pseudo-randomised controlled trial (i.e. alternate allocation or some other method)	Study of test accuracy with: an independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation	All or none	All or none	Pseudo-randomised controlled trial (i.e. alternate allocation or some other methods)

Level	Intervention	Diagnostic Accuracy	Prognosis	Aetiology	Screening Intervention
III-2	<p>Comparative study with concurrent controls:</p> <ul style="list-style-type: none"> ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-controlled study ▪ Interrupted time series with a control group 	<p>Comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence</p>	<p>Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial</p>	<p>Retrospective cohort study</p>	<p>Comparative study with concurrent controls:</p> <ul style="list-style-type: none"> ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-controlled study
III-3	<p>Comparative study without concurrent controls:</p> <ul style="list-style-type: none"> ▪ Historical control study ▪ Two or more single arm study ▪ Interrupted time series without a parallel control group 				
IV	<p>Case series with either post-test or pre-test / post-test outcomes</p>	<p>Study of diagnostic yield (no reference standard)</p>	<p>Case series, or cohort study of persons at different stages of disease</p>	<p>Cross-sectional study or case series</p>	<p>Case series</p>

3.3 Processing of New Drug Applications by Chief Pharmacist’s Office

3.3.1 Key Timeline

DAC meetings are held quarterly in January, April, July and October each year to evaluate new drug applications for listing on the HA Drug Formulary. The DAC Secretariat [i.e. Chief Pharmacist’s Office (CPO)] would disseminate the meeting schedule to all hospitals before the meetings. The key timeline for submitting and processing new drug applications for listing on the HA Drug Formulary is set out in Table 2 below with details elaborated in the ensuing paragraphs.

Table 2 – Key Timeline for Submitting and Processing New Drug Applications

Action	Timeline
a) Cluster / Hospital DTC to submit completed DAC New Drug Submission Form to DAC Secretariat	12 weeks before DAC meeting
b) DAC Secretariat to send completed DAC Evaluation Reports to DAC members	2 weeks before DAC meeting
c) DAC Secretariat to send DAC’s Recommendation and the DAC Evaluation Report to concerned Cluster / Hospital DTC	7 working days after DAC meeting
d) DAC Secretariat to send written request to Cluster / Hospital DTC for further information (if required)	7 working days after DAC meeting
e) DAC Secretariat to send written request for expert advice (if required)	7 working days after DAC meeting
f) Concerned Expert Panel(s) to send consolidated expert advice to DAC Secretariat	2 weeks before next DAC meeting

3.3.2 Proceedings before DAC Meeting

The required activities for handling new drug applications for listing on the HA Drug Formulary before the DAC meeting are:

- a) Upon receipt of the completed DAC New Drug Submission Forms, the DAC Secretariat would issue a formal letter (Appendix V) to the concerned drug companies, inviting provision of any relevant clinical data and information to facilitate evaluation of the new drug applications. The drug companies would be asked to provide a price quotation which, net of any offered bonus terms, would stand valid for at least two years from the date of approved listing on the HA Drug Formulary.

- b) The DAC Secretariat would review the currently available published scientific evidence and cost-benefit analysis in respect of the new drugs' licensed indication(s) specific for the submissions in Hong Kong, and send the completed DAC Evaluation Reports to all DAC members for consideration two weeks before the scheduled DAC meeting.
- c) The DAC Secretariat would post the agenda of DAC meeting in HA's intranet and internet websites on the HA Drug Formulary. The HA Head Office department responsible for patient engagement would then notify patient groups, through email (Appendix VI), of the DAC agenda and invite them to submit relevant suggestions and feedback related to the HA Drug Formulary.
- d) All DAC members are required to send the completed declaration form on conflict of interest in evaluating new drug applications to the DAC Secretariat before the scheduled meeting. Subject to the decision of the concerned committee chairman, members making a declaration of conflict of interest may have to abstain from engaging in situations that may lead to actual or perceived bias in the decision-making process for a reasonable period of time, which is normally six months.
- e) DAC has the discretion to enlist relevant clinical experts or individuals of academic / research institutes to provide expert opinions or additional information for evaluation of the new drug applications.
- f) Member(s) who is / are unable to attend scheduled DAC meeting may complete and return the DAC Members' Comment Form (Appendix VII) in respect of each new drug application to the DAC Secretariat before the scheduled meeting for onward consideration at the DAC meeting. Members, unable to attend and submitting the DAC Members' Comment Form, must also send the completed declaration form on conflict of interest.

3.3.3 Proceedings at DAC Meeting

The proceedings of handling new drug applications for listing on the HA Drug Formulary at the DAC meeting are:

- a) Before the start of the DAC meeting, the Chairman would firstly note members' written declaration of conflict of interest and then verbally confirm with members again to see if there are any conflicts of interest in evaluating the new drug applications on that meeting agenda. Subject to the decision of the concerned committee chairman, members making a declaration of conflict of interest may be required to temporarily withdraw from the meeting during, or not participate in, the discussion concerning the relevant new drug. The declaration and subsequent action should be recorded in the minutes of meeting.

- b) Upon start of the meeting, as a standing agenda item, CPO would report all suggestions and feedback received from patients / patient groups related to the HA Drug Formulary.
- c) At the meeting, the drug reviewer (i.e. CPO pharmacist) would verbally present evaluation reports on the new drugs and raise any issues that require special attention. DAC members would express views and advise if the concerned drugs would satisfy the inclusion criteria for listing on the HA Drug Formulary.
- d) DAC members would evaluate new drug applications with reference to the principal considerations and other relevant factors for making a decision (Section 3.4). If DAC considers that Expert Panel advice or further information is required before a decision can be made, the DAC Secretariat would coordinate to gather such advice or information. Evaluation of the concerned new drug application(s) would be deferred to the earliest scheduled meeting after receipt of the required Expert Panel advice or further information.
- e) With consensus of the majority of members, DAC may make the following decisions in respect of each new drug application:
 - i) Approval for use as General Drug;
 - ii) Approval for use as Special Drug with restrictions on specialty, prescriber or disease conditions;
 - iii) Approval for use as Self-financed Item with or without restrictions;
 - iv) Pending (e.g. Expert Panel advice or further information); or
 - v) Rejection.

3.3.4 Proceedings after DAC Meeting

The proceedings for handling new drug applications for listing on the HA Drug Formulary after the DAC meeting are:

A. Dissemination of Evaluation Outcome

- i) The DAC Secretariat would send the **DAC Recommendation** (Appendix VIII) and the **DAC Evaluation Report** to the applying hospital within seven working days after the DAC meeting. The DAC Recommendation would also be sent to DMC for information. The new drugs would be listed on the HA Drug Formulary in around three months after the DAC meeting.

- ii) The DAC Secretariat would disseminate, through memorandum, the evaluation outcome and rationale of DAC's decisions to all Cluster / Hospital DTC Chairmen. A brief summary of the meeting outcomes, including the primary reason for rejection, would be uploaded to HA's intranet and internet websites on the Drug Formulary with hyperlinks to references reviewed for the new drug applications.
- iii) Upon receipt of DAC Secretariat's notification, Cluster / Hospital DTCs should discuss at their upcoming meeting whether the new drugs approved by DAC would be included in their respective hospital formulary. Once the new drugs are included, DTCs should monitor the utilisation of new drugs in cluster hospitals and ensure compliance with any restrictions as recommended by DAC. *DTCs are strongly advised to continue reviewing the clinical benefits and safety of new drugs included in the HA Drug Formulary.*

B. For Drug Applications Pending DAC's Decision

- i) In cases where Expert Panel advice is required before a decision can be made, the DAC Secretariat would send, within seven days after the DAC meeting, a written request, together with the DAC Evaluation Report and all relevant materials, to the concerned Expert Panel(s) for collection of expert advice. In general, expert advice is sought on clinical protocol and place of new drugs, use or potential misuse of drugs, categorisation of new drugs, practicality and reasonableness of proposed indications and authorisation, relative cost-impact of new drugs under the proposed conditions of use, etc. The concerned Expert Panel(s) would send the consolidated advice to the DAC Secretariat two weeks before the next scheduled DAC meeting for onward conveyance to all DAC members for consideration.
- ii) In cases where further information of the new drug applications is required for DAC's evaluation, the DAC Secretariat would send, within seven days after the DAC meeting, a written request to the concerned Cluster / Hospital DTCs for the required information. Additional information received would be sent to all DAC members two weeks before the next scheduled DAC meeting for consideration.

C. Resubmission

- i) For drugs not approved for listing on the HA Drug Formulary, DAC would evaluate a resubmission only if new information is available to support the listing.

- ii) To resubmit an application for listing a rejected drug on the HA Drug Formulary, Cluster / Hospital DTC should complete the DAC New Drug Submission Form and send it, together with all relevant supplementary documents and additional information that may address DAC’s concerns raised for the rejected application(s), to the DAC Secretariat according to laid-down timeframe as aforementioned. There is no limit on the number of resubmissions that can be made by Cluster / Hospital DTCs in respect of rejected new drug applications.
- iii) In view of the prevailing mechanism for handling resubmitted applications, and the lead time required for gathering new information to substantiate a new drug application, there is no need to set up an appeal mechanism for rejected new drug applications for listing on the HA Drug Formulary.

3.3.5 Summary

The above DAC proceedings for handling new drug applications for listing on the HA Drug Formulary are summarised in Figure 2 below.

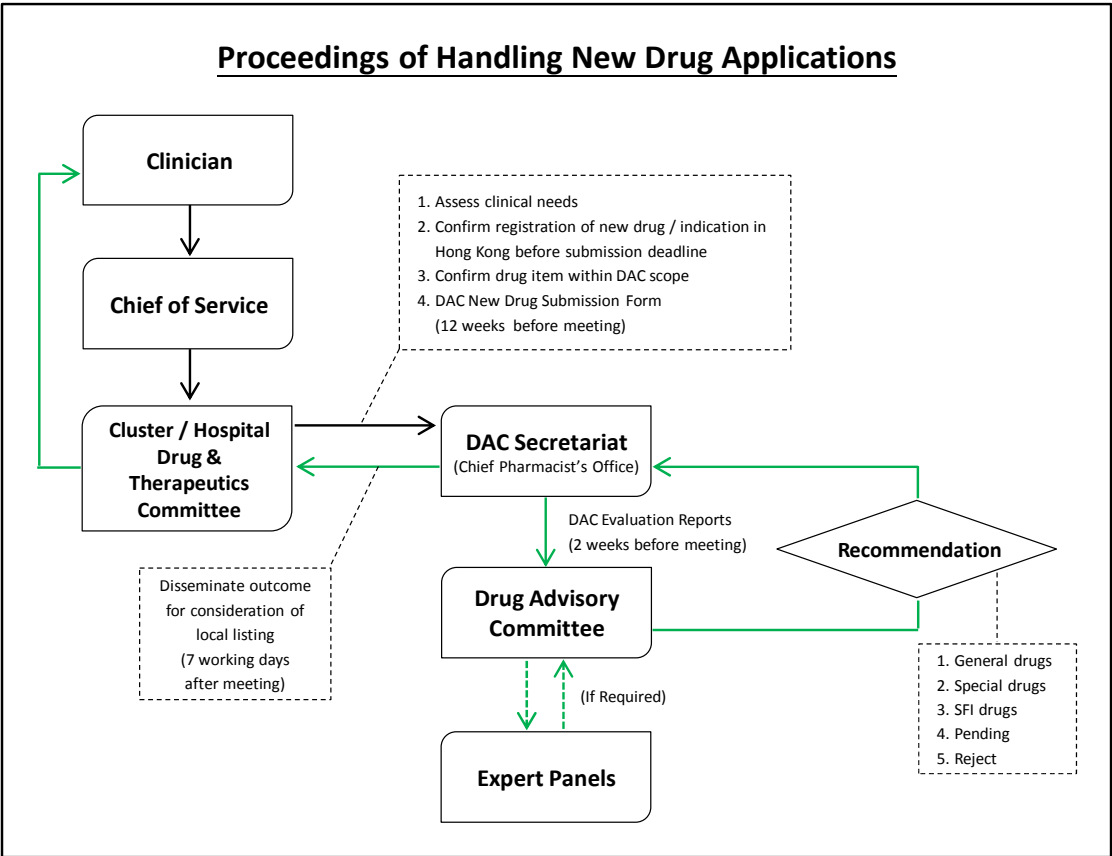


Figure 2

3.4 Considerations for New Drug Evaluation

As with health authorities in most other countries, HA takes the “Consensus Adopter” approach² in adopting new medical technologies. It ensures timely adoption and diffusion of appropriate clinical technology for enhanced medical care for patients.

DAC follows an evidence-based approach in evaluating new drug applications for listing on the HA Drug Formulary, having regard to three principal considerations of safety, efficacy and cost-effectiveness while taking into account other relevant factors, including international recommendations and practices, advance 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 as well as views of professionals and patient groups.

3.4.1 Principal Considerations

A. Safety

DAC evaluates the safety profile of a new drug by weighting its clinical benefits against its risks, and compares the adverse effect profiles between the new drug and its alternatives. Short and long-term safety profiles and potential for serious adverse effects are also considered with reference to any black box warning, post-marketing surveillance reports and safety alerts issued by overseas health authorities. Special attention would be given to drugs that have potential risks of causing serious harm to patients when used in therapeutic doses or after inadvertent use.

B. Efficacy

DAC compares the efficacy a new drug with that of other existing treatment alternatives in the HA Drug Formulary for the same disease condition where appropriate. Head-to-head, direct comparative randomised trials which offer the highest level of evidence are preferred over indirect comparisons. However, if a treatment alternative is not available, then properly designed and conducted indirect comparison using a common comparator in practice or placebo-controlled trial would be adopted in order to quantify the clinical benefits of the new drug. The weighting would follow the normal hierarchy of clinical evidence as advocated by evidence-based medicine (Table 1 in Section 3.2.2).

² Under the “Consensus Adopter” approach, technologies that are generally accepted and broadly available in the market would be implemented while new approaches would be taken after several years of report at national meetings.

Regarding the choice of endpoints, clinical trials which measure hard clinically important primary outcome endpoints are preferred over those using surrogate endpoints that only demonstrate strong correlation with the true clinical endpoint. Long-term outcome endpoints are always preferred. If these are not available, the limitation would be taken into account. Other elements of clinical study design that may affect data reliability, significance and relevance of trial results are also considered, such as precautions to minimise bias, randomisation, statistical methodology, trial size, duration of study, generalisability of trial population and relevance to the local target patient population, etc.

C. Cost Effectiveness

DAC evaluates the cost-effectiveness of a new drug by assessing its total cost impacts and making reference to related overseas pharmacoeconomic evaluation studies.

i) Total Cost Impacts

DAC evaluates the total impacts of a new drug on direct healthcare costs, including costs of drug acquisition and administration, treatment-associated in-/out-patient service utilisation and monitoring of adverse reactions, in order to determine whether listing the new drug on the HA Drug Formulary would be cost-saving, cost neutral or would pose a significantly higher cost to HA. The budget impact is assessed in the light of total service needs under the new drug's prescribing criteria and according to estimated disease incidence / prevalence, cost of drug treatment and associated healthcare costs as opposed to those of existing treatments. The potential cumulative impacts on HA's budget arising from drug initiation for new cases and continuation of treatment for existing patients, together with opportunity cost of using the new drug, would also be assessed. New drugs having significant budget impacts on HA would be addressed through the annual planning process with a view to soliciting additional funding allocation to list the new drugs on the HA Drug Formulary.

ii) Pharmacoeconomic Evaluation Studies

DAC makes reference to pharmacoeconomic evaluation studies in technology assessments conducted by overseas health authorities, in particular those with national reimbursement schemes comparable to the fees and charges for medical services provided by HA in Hong Kong, e.g. the United Kingdom, Australia and some Asian countries. It is well recognized that each healthcare jurisdiction has its unique system and no international studies and recommendations of overseas health authorities can be fully applicable. HA may make reference to local pharmacoeconomic evaluation studies, if available, and may consider commissioning such studies, if required, for evaluation of a new drug.

3.4.2 Other Factors

A. International Recommendations and Practices

In line with HA's position as a "Consensus Adopter" in technology adoption, DAC makes reference to international authoritative recommendations for disease management and reimbursement status of the concerned drugs in overseas countries with similar health systems where applicable.

B. Advance in Technology

Different drugs vary in their clinical effects on different groups of patients. DAC considers whether a new drug would differ fundamentally from the existing treatments in relation to the pharmacological class for treating a disease condition (i.e. pharmacodynamic profile), pharmacokinetic profile or new pharmaceutical technology advancement, such that the new drug is anticipated to bring meaningful benefits to different target groups of patients. However, if there are already a large number of "me-too" drugs in the HA Drug Formulary and the new drug does not offer any significant advantage, it may be necessary to limit the range of similar products.

C. Disease State

If there is no specific drug treatment licensed for a certain disease condition, a new drug with such niche may fill the gap in the current treatment modality. DAC also considers the significance of different disease burdens, including associated disability and complications, on healthcare costs and population health in both the short and long terms.

D. Patient Compliance

In comparing a new drug with treatment alternatives listed on the HA Drug Formulary, DAC considers different factors that may affect patient compliance, e.g. ease of formulation for self-medication by patients, complexity / frequency of administration regimen and adverse effect profile which may pose negative impacts on patient compliance. DAC also considers characteristics and disease conditions of the target population in assessing patient compliance.

E. Quality of Life

DAC considers the impact of a new drug on patients' quality of life through integrated and holistic assessment of patients' physical (i.e. functional and symptomatic), emotional (or psychological) and social functions as well as general health. Such assessment is particularly important for diseases where patients have significantly impaired quality of life or suffer from end-of-life diseases.

F. Actual Experience in Use of Drugs

DAC considers the clinical effectiveness of a new drug, i.e. how the drug is used in actual clinical practice, by making reference to well-conducted cohort studies or experiences in the use of drug on local population. DAC also considers the clinical operation in practice, local culture and behaviour, where appropriate.

G. Views of Professionals and Patient Groups

DAC is supported by multiple Expert Panels in different specialty areas. DAC solicits expert advice to facilitate new drug evaluation where appropriate, and considers patient groups' suggestions and feedback collected through established communication channels in considering new drug applications.

3.4.3 Summary

The evaluation of new drugs for listing on the HA Drug Formulary is a complex and dynamic process. As a publicly funded organisation, HA places high emphasis on maximising health benefits for the community while balancing the interests between different patient groups and individuals. Applicability of the listed considerations and the interplay between these factors differ among drugs. It is prudent not to rely on any single model of drug evaluation, for experience has shown that none alone can fully address all concerns and integrate the multifactorial considerations into the evaluation process. HA will keep on evaluating new drugs under the established mechanism, having regard to the principles of effective use of public resources and maximising health benefits for more patients.

3.5 Handling of Drugs outside scope of DAC evaluation

Provision of healthcare is a complex process which encompasses situations that sometimes require special handling under different mechanisms to ensure smooth operation and service delivery.

3.5.1 Formulary Drugs

Drug applications that fall outside the scope of DAC evaluation (Section 3.1) are handled under established mechanisms tabulated in Appendix IX. While the principles of new drug evaluation would be adopted as far as possible, certain drugs may not have the necessary evidence readily available or there may be an obvious operational need for these drugs. These drugs would be listed on the HA Drug Formulary once endorsement of DFC is obtained.

3.5.2 Non-formulary Drugs

A hospital may, at its discretion, acquire a new drug that is required in emergency / life-threatening situations or specific circumstances through urgent request. If it is intended to include the new drug in the HA Drug Formulary, the concerned cluster / hospital should follow the normal procedure and return the completed DAC New Drug Submission Form to the DAC Secretariat for approval processing. Examples of these situations are provided below:

- a) Drugs that await DAC evaluation but are required for urgent use;
- b) Drugs that are required for urgent use but for which an application is yet to be submitted for DAC evaluation – Hospitals should indicate when the DAC New Drug Submission Form would be submitted at the time of requesting for the new drugs;
- c) Drugs that are required for one-off use in urgent situations – Cluster / Hospital DTC may acquire the new drugs through urgent request; and
- d) Drugs that are required by non-HA services through HA pharmacies.

3.5.3 Unregistered Drugs for Named Patients

If a drug not registered in Hong Kong is required for use on certain named patients, the concerned clinician must obtain prior endorsement from the respective Cluster / Hospital DTC via the Chief of Service. The clinician should inform the concerned patients on the use of unregistered products and that adverse effects of drug use would be monitored and reported. The concerned supplier of the unregistered drugs should provide, together with the application for importation, a certificate of analysis, in the absence of which the requesting clinician is required to sign an additional declaration to take up responsibility for use of the unregistered drugs. HA would regularly monitor the use of unregistered drugs for named patients and hospitals should inform CPO when use of the unregistered drugs is no longer required.

4 REVIEW OF HA DRUG FORMULARY

Development of the HA Drug Formulary is a complex and dynamic process. To keep clinical practice and drug use in sync with medical technology advancements and the latest scientific evidence, HA has mechanisms in place to conduct ad hoc and regular reviews of the HA Drug Formulary. The review process follows an evidence-based approach, having regard to the safety, efficacy and cost-effectiveness of drugs while taking into account the latest international practice as well as views of professionals and patient groups.

The Drug Formulary Committee (DFC), with the support of multiple Expert Panels, is tasked to review the current drug list on the HA Drug Formulary. Other corporate drug committees would come into play when the change involves significant budget impact or prioritisation for safety net coverage. This chapter highlights the ad hoc and regular review processes and the interplay among different corporate drug committees in reviewing the HA Drug Formulary.

4.1 Review Process

4.1.1 Ad Hoc Review

DFC initiates ad hoc reviews of the HA Drug Formulary, through relevant Expert Panels, in situations where an alert issued by a health authority indicates a potential impact on change in clinical practice. If a change in the prescribing indications is recommended, DFC would be convened for a decision. Urgent changes can be effected once support of DFC is obtained, and be put up for DMC's retrospective endorsement at its next meeting.

4.1.2 Regular Review

DFC conducts a biennial comprehensive review of the existing drug list and prescribing indications in the HA Drug Formulary with support of multiple Expert Panels under a preset timeline. On initiation of the review, relevant stakeholders, including the pharmaceutical industry, would be notified through established communication channels. Members of Expert Panels would collect feedback and requests in their respective specialties and clusters with regard to the category of drugs, prescribing indications and authorisation rights for drug therapies within the HA Drug Formulary. All these, together with feedback received from patient groups and information provided by the industry, would be conveyed to DFC and relevant EPs for attention.

Expert Panels support the review of existing drugs and prescribing indications in the HA Drug Formulary in their respective specialty areas while issues of common concern would be brought up for discussion at relevant Expert Panel meetings. With the consensus of members and where the proposed changes in the Drug Formulary do not carry a budget impact on HA, Expert Panels may make the following recommendations where appropriate for DFC's consideration and DMC's final endorsement:

- a) Reposition of drugs across categories without budget impact;
- b) Restriction or relaxation of prescribing indications for Special drugs³;
- c) Addition or deletion of authorisation specialty for Special drugs; or
- d) Deletion of obsolete drugs⁴.

Changes in authorisation specialty approved by DMC are applicable to the initiation of drug prescriptions in all HA institutions, but not to continuation of prescriptions, while modifications of authorisation rights for Special drugs can be made by Cluster / Hospital DTC in the light of operational needs. Hospitals have a mechanism in place to monitor the need for such modifications. On the other hand, if deletion of an obsolete drug from the HA Drug Formulary involves more than one specialty or cluster, consensus of all concerned specialties or clusters is required before a recommendation for drug deletion is put up for endorsement.

4.2 Repositioning of Self-financed Drugs or Safety Net Drugs as General or Special Drugs and Relaxation of Prescribing Indications for Special Drugs with Budget Impact

In situations where the review of the HA Drug Formulary involves the repositioning of Self-financed drugs or Safety Net drugs as General or Special drugs or relaxation of prescribing indications for existing Special drugs in the Drug Formulary, and where such repositioning / relaxation proposals carry budget impact on HA, the annual planning process would come into play.

Annual planning refers to the service and budget planning process where new initiatives and service improvement proposals are prioritised for resource bidding and allocation under an established mechanism. The process starts in the first quarter of each year and all concerned COCs and CCs on disease groups, hospital clusters and HA Head Office divisions would submit annual plan proposals within a preset timeframe. The proposals are then presented in HA's Annual Planning Forums and deliberated by HA's Service and Budget Planning Committee (SBPC) in the coming financial year. Supported proposals would be prioritised for resource bidding while programmes approved for funding allocation would be implemented in the concerned clusters / hospitals in the ensuing financial year.

³ For listing of new indications, the evaluation is conducted by DAC.

⁴ Obsolete drugs include those discontinued by manufacturers or no longer used in HA due to change in practice. Discontinued drugs can be deleted once the hospital stock is depleted.

With regard to repositioning of Self-financed drugs or Safety Net drugs as General or Special drugs and relaxation of prescribing indications for Special drugs with budget impact, the relevant COCs or CCs on disease groups are required to submit drug proposals in response to the corporate call for submission of annual plan proposals. The Strategy and Planning Division of HA Head Office, as the central coordinator in the exercise, collates and sends all drug proposals to DMC for consideration. The concerned COCs and CCs on disease groups would be invited to present the clinical evidence and budget impact of their drug proposals to DMC; and DMC would compile a composite annual plan proposal with a list of prioritised drugs for submission. The composite proposal would then undergo the SBPC prioritisation process for resource bidding and funding consideration. All approved drug programmes would be implemented in the concerned clusters / hospitals in the new financial year and the concerned COCs and CCs on disease groups would be notified of the funding decisions in due course.

4.3 Repositioning of Self-financed Drugs as Safety Net Drugs and Relaxation of Safety Net Indications

Requests for expanding HA's safety net to cover additional self-financed drugs (SFI drugs), relax the prescribing indications for Safety Net drugs (SN indications) and reposition of drugs covered by the Community Care Fund (CCF) as Safety Net drugs in the HA Drug Formulary undergo a similar prioritisation process. The concerned COCs and CCs on disease groups should keep in view the prevailing list of SFI drugs and SN indications, and submit proposals in response to DMC's call for inclusion of SFI drugs in the safety net or relaxation of SN indications. DMC usually calls for proposal submissions in the fourth quarter of each year.

Following COCs / CCs' submissions, DMC would convene a special meeting to prioritise all drug-related safety net proposals. The concerned COCs and CCs would be invited to present the clinical evidence and budget impact of their submitted proposals. DMC would then recommend a list of SFI drugs and SN indications, in order of priority, that are proposed for safety net coverage and relaxation in the new financial year. The recommended list would be sent to HA's Samaritan Fund Office (SFO) for processing and onward prioritisation by the Samaritan Fund Management Committee (SFMC). SFO would then submit SFMC's recommendation with the prioritised list of SFI drugs and SN indications to the Medical Services Development Committee under the HA Board for consideration and final endorsement before implementation. The concerned COCs and CCs on disease groups would be notified of the funding decisions in due course.

Proposals for reposition of SFI drugs as safety net drugs and relaxation of prescribing indications under the coverage of CCF would undergo the same review and prioritisation processes, except that proposals prioritised by DMC would be sent for support by the HA Community Care Fund Administration Committee. The supported list of SFI drugs and

CCF indications would be sent to the Community Care Fund Task Force and then the Commission on Poverty for consideration and final approval. The concerned COCs and CCs on disease groups would be notified of the funding decisions in due course.

4.4 Updates on HA Drug Formulary

CPO would update the HA Drug Formulary every three months to incorporate the following changes to the drug list endorsed by relevant committees under established mechanisms. All Hospital Chief Executives, chairmen and members of all corporate drug committees, chairmen of Cluster / Hospital DTCs as well as frontline pharmacy managers would be notified of the changes where appropriate for further dissemination to relevant staff.

- a) New drugs and indications approved at recent DAC meeting;
- b) Addition of drugs not evaluated by DAC (Section 3.5);
- c) Changes in drug category status arising from funded programmes for new drugs and expansion of safety net coverage;
- d) Changes resulting from biennial comprehensive review as endorsed by DMC; and
- e) Deletion of drugs due to dormant use or product discontinuation.

4.5 Summary

The interplay among different corporate drug committees in reviewing the existing drug list on the HA Drug Formulary is summarised in Figure 3 below.

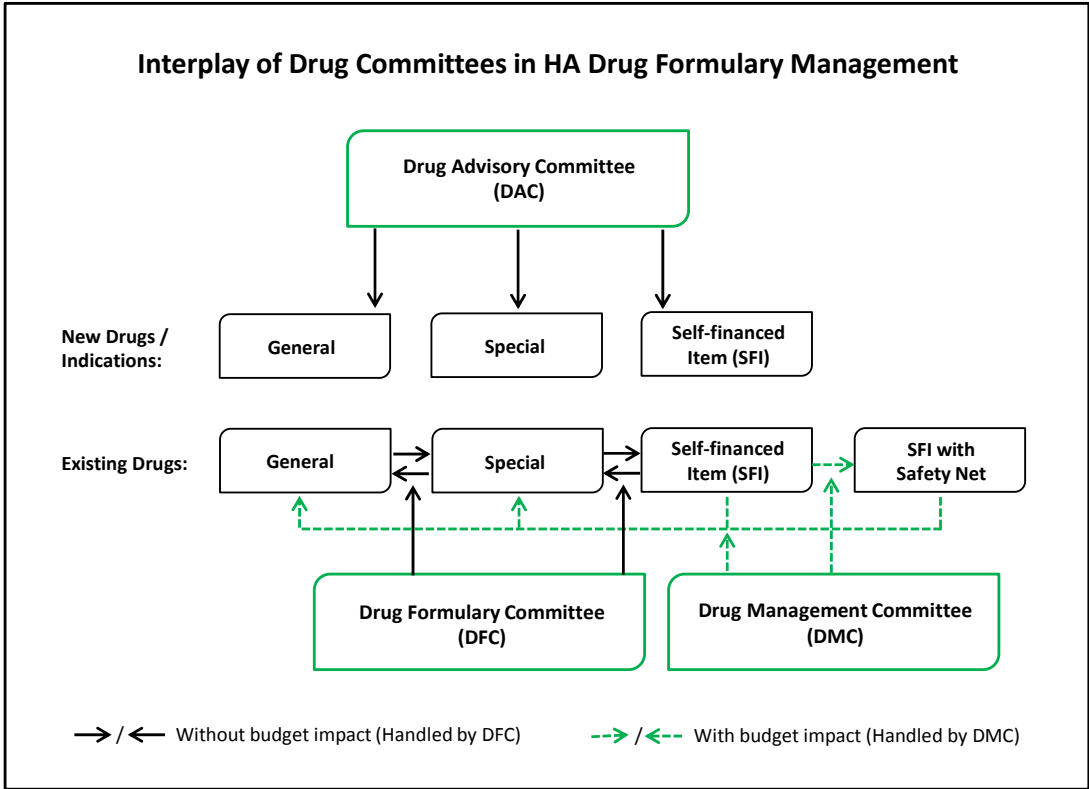


Figure 3

5 TRAINING

To ensure members of drug-related committees and drug reviewers are familiar with the guiding principles, prevailing mechanisms and the latest development in Drug Formulary management, HA conducts training at regular intervals and when necessary. This chapter highlights the general training for internal stakeholders, advanced training for members of drug-related committees and customised training for drug reviewers of the Chief Pharmacist's Office (CPO).

5.1 General Training for Internal Stakeholders

HA provides general training for internal stakeholders and healthcare professionals, through multiple platforms and channels, on mechanisms for managing the HA Drug Formulary as well as roles and responsibilities of various drug-related committees. In addition, an e-learning toolkit will be developed and updated as appropriate.

5.2 Advanced Training for Members of Drug-related Committees

HA conducts short courses for key players in the decision making process on fundamental concepts of health technology assessment related to formulary management, pharmacoeconomics, drug evaluation, health outcomes assessment, economic modeling, drug utilisation review and budget impact analysis as appropriate.

5.3 Customised Training for Drug Reviewers

HA organises didactic training through lectures and workshops for drug reviewers of CPO in support of various drug-related committees in order to keep them abreast of the latest development of formulary management and familiar with the technical know-how in drug evaluation for listing on the HA Drug Formulary. Customised and hands-on training through short-term attachment to overseas regulatory authorities will be organised in order to develop local expertise and internal capability to perform pharmacoeconomic evaluation of new drugs, if required.

6 CONSULTATION, ENGAGEMENT AND PARTICIPATION OF STAKEHOLDERS

Development of the HA Drug Formulary involves interplay of multifactorial considerations and participation of various groups of stakeholders. Since implementation of the HA Drug Formulary in July 2005, HA has taken various measures to enhance operational transparency and strengthen stakeholder communication in the management of HA Drug Formulary. This chapter gives an account of the prevailing mechanisms and means of engaging different stakeholders in managing the HA Drug Formulary.

6.1 Internal Stakeholders

6.1.1 Established Engagement Mechanism

HA has a mechanism in place to engage its internal staff in the Drug Formulary management and decision-making processes. Various drug-related committees have been established at both corporate and hospital levels with the representation of different COCs, CCs on disease groups, specialties and disciplines of healthcare professionals including clinicians, pharmacists and nurses. They all play a key part in managing the HA Drug Formulary and implementing drug policies to ensure equitable access by patients to safe and efficacious drugs in HA institutions. Their roles and responsibilities are shown in the Terms of Reference of different committees laid down in the preceding chapters and Appendix X.

6.1.2 Other Communication Means

Apart from the established engagement mechanism, frontline clinicians may also participate in and keep abreast of the latest development of Drug Formulary management in HA, as follows:

- a) Initiate new drug applications to Cluster / Hospital DTC via respective Chiefs of Service as driven by clinical needs and anticipated improvement in clinical outcome, and receive DTC's notification of the review outcome in respect of their new drug applications;
- b) Provide feedback on management of the HA Drug Formulary via established means, e.g. Cluster / Hospital DTC via respective Chiefs of Service, COCs and CCs on disease groups, as well as Expert Panels with representation of clinicians from different specialties – All feedback received would be conveyed to the corporate drug committees for attention; and

- c) Acquire current information regarding the mechanism for managing the HA Drug Formulary, terms of reference of various drug-related committees, as well as DAC agenda and review outcomes of new drug applications via HA's intranet website on HA Drug Formulary as appropriate.

Details of the engagement points, roles and responsibilities, types of receivable information and tools of communication on formulary management in respect of different groups of internal stakeholders are set out in Appendix X for reference.

6.2 External Stakeholders

A. Patient Groups

Since implementation of the HA Drug Formulary in July 2005, HA has maintained close communication with patient groups on various formulary-related matters through established liaison channels. In view of the potential conflict of interest of enlisting patient group representatives into HA's drug committees and the hindrance to the candid discussion of experts in the committees, established communication channels have been formalised to ensure proper consultation with patient groups and their appropriate participation in Drug Formulary matters.

HA convenes two consultation meetings with patient groups every year, one in the second quarter of each year to keep them abreast of the latest development of the HA Drug Formulary and the other in the fourth quarter to gather their major concerns, feedback and wish list on the HA Drug Formulary for annual planning consideration. Representatives of patient groups who are unable to attend the consultation meetings are welcome to submit written suggestions and feedback to HA within one month. Since early 2011, HA has set up the Patient Advisory Committee, through which HA's Chief Executive regularly meets with patient representatives to collect their views in various areas of patient services, including the HA Drug Formulary.

Ad hoc meetings are also convened with individual patient groups to discuss specific issues of concern where necessary. HA welcomes suggestions and feedback from both patient groups and individual patients from time to time. All received suggestions and feedback are conveyed to the relevant drug committees for attention and consideration.

The HA Head Office department responsible for patient engagement regularly notifies, through email, patient groups of the DAC meeting agenda and the list of new drugs put up for review before the scheduled meetings, and disseminates the review outcome (including the primary reason for rejection) for each of the new drug applications after the meetings. Patient groups may send in their views on the new drug candidates before the meeting. Annual updates of the HA Drug Formulary would also be published in HA's newsletter

“CarePlus” which is distributed to patient groups and available to the general public for information.

B. Academics

HA enlists support from academics of local universities in the evaluation of new drugs and collaborates with them in the development of training programmes related to the management of HA Drug Formulary as appropriate.

C. Pharmaceutical Industry

HA maintains an open and on-going dialogue with the pharmaceutical industry, which is one of its key service partners in managing the HA Drug Formulary. Apart from communication on the HA Drug Formulary, HA notifies the concerned drug companies upon receipt of new drug applications and invites them to provide clinical evidence and relevant information for consideration. In addition, HA welcomes the supply of market intelligence data from the industry at any time and maintains close collaboration to facilitate the implementation of special drug programmes and drug subsidy schemes which may benefit needy patients.

D. General Public

HA makes available the following information in its internet website for public access:

- i) HA Drug Formulary Management Manual;
- ii) Current drug list of HA Drug Formulary;
- iii) DAC composition;
- iv) Agenda of DAC meeting with a list of new drugs put up for review;
- v) DAC review outcome;
- vi) List of references that have been taken into account in the evaluation process; and
- vii) List of self-financed items purchased by patients at HA pharmacies.

Members of the general public are welcome to give suggestions and feedback on any matters related to the HA Drug Formulary. Their suggestions and feedback will be conveyed to relevant drug committees of HA for attention and consideration.

Expert Panels

Expert Panels are formed to provide professional support for DAC and DFC in the management of HA Drug Formulary. The number of Expert Panels may change as necessary.

Terms of Reference

In Support of DAC :

- a) To provide expert opinions on introduction of new drugs, clinical guidelines or protocols upon request; and
- b) To nominate representatives as DAC members upon invitation.

In Support of DFC :

- a) To conduct biennial comprehensive review of HA Drug Formulary and consultation on drug issues upon request;
- b) To make recommendation on proposed changes in HA Drug Formulary;
- c) To advise on use of alternatives for obsolete drugs; and
- d) To advise on appropriate use of unregistered and non-formulary drugs.

Composition

- a) Co-convenors
 - DFC Chairman and Chief Pharmacist
- b) Members
 - i) One representative of relevant COCs / CCs on disease groups;
 - ii) Seven cluster specialist representatives nominated by CCEs; and
 - iii) Two Cluster Clinical Stream Coordinators (Pharmacy) / Senior Pharmacists nominated by Chief Pharmacist.

Members' tenure goes with the cycle of biennial comprehensive review of the HA Drug Formulary and all members can be re-appointed upon nomination by their respective CCEs, COCs / CCs on disease groups or Chief Pharmacist as appropriate.

List of Expert Panel on HA Drug Formulary

1. Anaesthesiology and Pain Medicine
2. Dermatology
3. Ear, Nose and Throat
4. Family Medicine
5. Infectious Disease
6. Medicine (Cardiology)
7. Medicine (Endocrine and Diabetes Mellitus)
8. Medicine (Gastrointestinal and Liver)
9. Medicine (Haematology)
10. Medicine (Neurology)
11. Medicine (Renal)
12. Medicine (Respiratory)
13. Medicine (Rheumatology)
14. Oncology
15. Obstetrics and Gynaecology
16. Orthopaedics and Traumatology
17. Ophthalmology
18. Paediatrics
19. Psychiatry
20. Surgery

Drug Selection Committee (DSC)

Terms of Reference

- a) To review and make recommendations on procurement policy for generic pharmaceutical products;
- b) To consider and advise on acceptability of generic drug products for use in HA public hospitals and clinics; and
- c) To advise on monitoring of efficacy and quality of drugs selected for use in HA public hospitals and clinics.

Composition

- a) Chairman
 - University Clinical Pharmacologist*
- b) Members
 - i) Director (Cluster Services);
 - ii) University Clinical Pharmacologist*;
 - iii) Assistant Director (Drug), Department of Health;
 - iv) Chairman of DAC;
 - v) Chairman of DFC;
 - vi) One Cluster DTC Chairman*;
 - vii) Chief Pharmacist; and
 - viii) Two Pharmacy Department Managers / Senior Pharmacists*.
- c) Secretary
 - Senior Pharmacist of CPO

The tenure of members marked with “*” is two years. The other members are appointed by position and their tenure will lapse upon expiry of their designated positions.

Evaluations undertaken by DSC are conducted by circulation. Each member is required to sign a written declaration of conflict of interest for each tender evaluation to affirm that no conflict arises between his / her private interest and that of DSC.

Medication Safety Committee (MSC)

Terms of Reference

- a) To advocate culture of medication safety in HA;
- b) To propose corporate strategies, formulate guidelines and provide training and advice on medication safety to DMC;
- c) To ensure sustained and effective implementation of medication safety related policies / guidelines in HA;
- d) To promote culture of reporting, analysing and sharing of medication incidents / near misses in HA; and
- e) To report to DMC on issues related to medication safety in HA.

Composition

- a) Chairman
 - Senior Management Executive appointed by DMC
- b) Members
 - i) Chief Pharmacist;
 - ii) Seven cluster physician representatives nominated by respective CCEs;
 - iii) Seven cluster pharmacist representatives nominated by respective CCEs;
 - iv) Seven cluster nurse representatives nominated by respective CCEs;
 - v) Chief Manager (Patient Safety & Risk Management) of Quality and Safety Division, HA Head Office; and
 - vi) One Manager of Nursing Services Department, HA Head Office.
- c) Secretary
 - Pharmacist of CPO

Individual cluster representatives, nominated by Cluster Chief Executives, are mostly involved in Quality & Safety or Medication Safety improvement exercises in their own clusters.

With representatives from both hospitals and HA Head Office, MSC aims to facilitate exchange of ideas to improve medication safety, discussion of medication safety-related issues and implementation of guidelines across HA institutions.

HA Drug Advisory Committee

New Drug Submission Form

An application can be submitted, via Cluster / Hospital DTC, for consideration of listing on the HA Drug Formulary if the concerned drug entity or indication fulfills the following criteria:

- a) It is indicated for prevention or treatment of conditions which are not covered by drugs in the existing HA Drug Formulary;
- b) It has an advantage in terms of efficacy and adverse effects over agents in the existing HA Drug Formulary for the same indication; or
- c) It is equivalent in terms of safety and efficacy as compared to existing agents in the HA Drug Formulary for the same indication and of lower treatment costs.

Please complete ALL sections and attach relevant supporting documents in order to facilitate the evaluation. Incomplete information may lead to delay in the submission process.

FOR INTERNAL USE ONLY

DAC Ref. No.:

Date received:

1. GENERAL INFORMATION

1.1 Submitting hospital:

1.2 Name of drug: Generic (Trade)

1.3 Name of manufacturer / supplier:

1.4 Strength & form:

1.5 Cost (per unit):

1.6 Current formulary status of this drug:

- Non-Formulary use - SFI
- Non-Formulary use - Hospital-funded
- Sample use

1.7 Proposed financing method: Hospital-funded SFI**1.8 Status of application:**1.7.1 Approved by hospital YesDTC: pending

1.7.2 Date of DTC meeting: _____

1.9 Applying doctor (name, rank, specialty)

Name:

Rank:

Specialty:

2. PROPOSED PLACE IN THERAPY IF INTRODUCED INTO HADF**2.1 Licensed indication(s) of this new drug in HK (specific for this submission)**

e.g. Erosive Esophagitis

2.2 Worldwide registration status for this indication (if known)*(e.g. registration status and month/year in Australia, Canada, EU, US)*

e.g.

Country	Dosage	Indication	Approval Date
Hong Kong	30mg capsules 60mg capsules	Erosive Esophagitis	Nov 2010
USA	30mg capsules 60mg capsules	Erosive Esophagitis Maintenance of healed EE Symptomatic non-erosive GERD (no need to list these indications which are unlicensed in HK/not for this application)	Jan 2009 May 2005 May 2005
Australia	30mg capsules 60mg capsules	Erosive Esophagitis Maintenance of healed EE Symptomatic non-erosive GERD	Jul 2010 Apr 2006 Apr 2006

2.3 Natural History of the disease

(e.g. survival time, time to progression of the disease)

e.g. The median survival for patients with the disease ranges from approximately 2–11 years depending on risk stratification; the median survival time for patients with intermediate–2–risk is 4 years and 2 years for patients with high-risk disease.

2.4 Existing treatment protocol for this disease in HA

(Please list out all existing treatment alternatives, dose regimens and sequence of use)

2.4.1 Existing treatment alternatives with dose regimens *(Note:- alternatives must be available in HA):*

e.g.
Insulin Lispro - individualised dose
Insulin Aspart - individualised dose

e.g.
sitagliptin 5mg once daily
vildagliptin 50mg-100mg once daily

2.4.2 Sequence of use:

e.g.
In patients with T2DM
Step 1: Initiate with metformin
Step 2: After failed the optimal doses of metformin, add a sulphylurea
Step 3: After failed the optimal doses of metformin and a sulphonylurea, add DPP-4
Step 4: After failed all oral anti-diabetic agents, give insulin

2.5 Proposed place in therapy of this new drug in relation to 2.4.2

(Proposed treatment protocol or algorithm for this disease after introduction of this new drug)

e.g.(1) IF NEW DRUG IS IN ADDITION TO EXISTING TREATMENT

Use the new drug as an alternative to insulin:-

In patients with T2DM
Step 1: Initiate with metformin
Step 2: After failed the optimal doses of metformin, add a sulphylurea
Step 3: After failed the optimal doses of metformin and a sulphonylurea, add DPP-4
Step 4: After failed all the above treatments, give Drug A (new drug)
Step 5: After failed all the above treatments, give insulin

e.g.(2) IF NEW DRUG IS AN ALTERNATIVE TO EXISTING TREATMENT

e.g. The new drug Insulin A is another options for existing short-acting insulin available in HA

e.g. (3) IF THERE IS NO EXISTING ALTERNATIVE

e.g. Bosentan for pulmonary aterial hypertension NYHA/WHO Functional Class IV symptoms

2.6 Treatment initiation and exit criteria for the new drug

2.6.1 Initiation criteria:

e.g. (1) in patients refractory to the alternatives stated in Section 2.4.1

e.g. (2) patients who had received at least 1 prior course of chemotherapy and had disease progression or relapse since chemotherapy

2.6.2 Exit criteria:

e.g. (1) patient not responding after 3 months of treatment

e.g. (2) Treatment will be terminated if the patient develops progressive disease or unmanageable toxicities

e.g. (3) discontinue if fail to achieve HbA_{1c}<8% within 6-8 months

2.7 Proposed HA Drug Formulary Indication(s) for this new drug

(Please list out proposed indication wordings as would appear in MOE, each indication should be within 200 characters including punctuation marks and spacing)

e.g. Short-term treatment of moderate to severe atopic dermatitis in non-immunocompromised patients unresponsive to other topical treatments or when those treatment are not advisable (total 177 characters)

2.8 Authorisation for prescribing this new drug for this indication (which specialty)

e.g. Specialists: Derm / Paed

2.9 Proposed HA Drug Formulary status

(General / Special / SFI)

e.g. Special

3. SUMMARY OF BENEFITS OF THIS NEW DRUG OVER EXISTING OPTIONS LISTED IN SECTION 2.4

(DETAILS TO BE PROVIDED IN SECTION 4)

3.1 Benefit in Efficacy
<ul style="list-style-type: none">e.g. (1) Median time to progression was significantly longer in patients receiving the new drug compared to drug A [drug A must be currently available in HA] (14.3 months vs. 6 months, HR=0.34, p=0.001)e.g. (2) The percentage of 24-h heartburn-free days and night was significantly greater in patients receiving the new drug than placebo (69% vs. 15%, p=0.001)e.g. (3) Improvement in symptom severity and overall quality of life were maintained over 6 month
3.2 Benefit/Concerns in Safety Issues
<ul style="list-style-type: none">e.g. (1) The new drug has lower incidence of EPS than both haloperidol (13% vs. 25%, p<0.001) and risperidone (17% vs. 22%, p=0.1), but a significantly higher increase in QT interval (7% vs. 0.5%, p<0.001) and a weight gain of 4.6kg over 1 yeare.g. (2) The new drug is well tolerated with an adverse event profile similar to that of placebo; however, the incidence of hypoglycemia was higher than existing alternatives listed in Section 2.4.1 (8% vs. 3%, p<0.001)
3.3 Other Benefit(s)
<ul style="list-style-type: none">e.g. (1) Less drug-drug interaction than existing alternatives listed in Section 2.4.1e.g. (2) First drug in the class available in oral form, more convenient than the existing alternatives; more acceptable by patientse.g. (3) The controlled released formulation improves compliance than the multiple dosing of the immediate-release formulation.

4. DETAILS ON CLAIMED BENEFIT(S) OF THIS NEW DRUG AS SUMMARISED IN SECTION 3

- All supporting documents MUST be clearly referred to
- Do not include any data on unlicensed indication(s)
- Only provide the highest level of evidence for each individual claimed benefit listed in Section 3
(e.g. if efficacy has already been proven in phase III randomised-controlled trials, there is no need to provide evidence from placebo-controlled trials etc.)
- Only accept fully published clinical trials (no abstracts or posters)

4.1 Benefit in Efficacy

4.2 Benefit in Safety Issues

4.3 Other Benefit(s)

5. AVAILABLE INTERNATIONAL GUIDELINES AND OVERSEAS REIMBURSEMENT ASSESSMENT DOCUMENTS

(All supporting documents MUST be clearly referred to)

5.1 Please list out relevant international guidelines and their summaries

e.g. The new drug has been recommended in the US guidelines (American College of Cardiology Foundation/American heart Association Take Force on Practice Guidelines) as an alternative to warfarin for the prevention of stroke and systemic thromboembolism in patients with paroxysmal to permanent AF and risk factors for stroke or systemic embolisation who do not have a prosthetic heart valve or haemodynamically significant valve disease, severe renal failures (CrCL<15 ml/min), or advanced liver disease (impaired baseline clotting function).

5.2 Please indicate if this new drug has been evaluated by Australia Pharmaceutical Benefits Scheme (PBS), UK National Institute of Clinical Excellence (NICE), Scottish Medicines Consortium (SMC), and their recommendation(s)

5.2.1 PBS: e.g. not listed in PBS

5.2.2 NICE: e.g. under review

5.2.3 SMC: e.g. accepted for use as first-line treatment in patients with locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor activating mutations.

6. COST COMPARISON AND BUDGET IMPACT

6.1 Cost comparison of this new drug with existing alternatives in HADF as listed in 2.4.1

HADF status	Drug	Strength	Unit cost \$	Dose regimen (also provide maximum maintenance dose)	Daily cost/ cost per cycle	Annual/Treatment cost \$
	New Drug	e.g. (1) 150mg	\$520	50mg once daily continuous till remission/progression/lifetime Max 50mg once daily	\$520/day	Annual cost \$189,800
		e.g. (2) 50mg	\$8400/vial	e.g. 50mg/m ² i.v. on day1 every 3 week, rest 1 week , then repeat; max 75mg/m ² for 8 cycles	\$16,800/cycle Max \$25,200 (@1.6m ²)	Total treatment cost for 8 cycles \$134,400 Max \$201,600
		e.g. (3) 50mg	\$8400/vial	e.g. 70mg/m ² s.c. every 2 weeks; max 100mg, for 6 months	\$25,200/2 weeks Max \$33,600/2 weeks (@1.6m ²)	Total treatment cost for 6 months \$302,400 Max \$403,200
G/S/SFI/SN	Alternative					
G/S/SFI/SN	Alternative					
G/S/SFI/SN	Alternative					
G/S/SFI/SN	Alternative					

6.2 Budget impact	
(1) Prevalence data	<p>(1) Total no. of patients with this disease in HK = e.g. 200,000</p> <p>(2) Total no. of patients with this disease in HA = e.g. 100,000</p> <p>(3) Total no. of patients in HA who fulfil the proposed HADF indication as stated in Section 2.7 = e.g. 6,000</p> <p>(4) Total no. of NEW patients in HA who fulfil the proposed HADF indication as stated in Section 2.7 = e.g. 800</p> <p>(5) Data source (<i>Please state how this is estimated e.g. patient registry, CDARS, recommendation from HADF Expert Panel</i>) : e.g. Cancer registry 2012</p>
(2) Total budget impact per annum in HA	<p><i>(Please indicate if there is any increase in patient no. in the next few years)</i></p> <p>e.g. Year 1 = 6,000 (backlog) + 800 (NEW) = 6,800 Year 2 = 6,800 + 800 – 200 (withdrawal/progression) = 7,400</p>
(3) Possible cost saving	<p>(1) Replacement of existing option(s) as stated in Section 2.4 (<i>please list out</i>) =</p> <p>(2) Other resource(s) = (<i>e.g. lab, shorten hospitalisation, delay of surgery etc.</i>)</p>

7. SUPPORTING DOCUMENTS FOR THIS SUBMISSION

Please submit the following documents for evaluation (in hard and soft copies)

- (1) Prescribing information sheet (package insert)
- (2) Supporting references for sections 1 – 6 where applicable
 - List out the references under this section
 - Please ensure that all supporting documents are clearly numbered and referred to
 - Provide soft copy of the references in PDF format and the full reference list in Microsoft word

References:

8. CHAIRPERSON OF THE DRUG AND THERAPEUTICS COMMITTEE

Name:

Designation:

Signature:

Date:

Our Ref:
Drug Company contact
Fax:

Date

Dear

I would like to inform you that a New Drug Submission Form for Generic Name (Brand Name[®]) has been submitted by HA Hospital name to our office. This drug will be discussed at the HA Drug Advisory Committee meeting on DAC meeting date.

In order to facilitate our evaluation, I would be grateful if you could kindly provide the following information:

1. **Package insert and Summary of Product Characteristics (with month/year of approval) in HK** (If there is a change/addition in the licensed indication, please supply the updated one already approved by HK DoH or already in use in HK for the changed indication)
2. **Name of the drug in Chinese** – both generic and brand names
3. **Licensed indication(s) in Chinese**
4. **Certificate of drug/product registration in HK**
5. **Worldwide registration status** – include month/year of registration for the indication(s) specific for this DAC submission. Do not include worldwide registration status of other indications that are not relevant for this submission.
6. **Overseas reimbursement status for the indication(s) specific for this DAC submission (i.e. for this licensed indication(s))** – PBS (Australia), Pharmac (New Zealand), SMC (Scottish Medicine Consortium), UK NICE evaluation, Korea, Taiwan, WHO Essential Drug list
7. **Price quotation in HK dollar** – please specify any bonus terms (if applicable) and the effective period (at least 2 years from the date of approved listing in the HADF), and provide a separate copy to Mr. Anthony Wong, SP(CPM) for reference
8. **Clinical data relevant to the evaluation for the indication(s) specific for this DAC submission**, including:
 - Please provide only the highest level of evidence (e.g. If head-to-head clinical trial compared with an HA alternative is available, there is no need to provide placebo-controlled trials. If phase III randomized-controlled trials are available, there is no need to provide lower evidence level trials.)
 - Please provide only fully published clinical trials, no abstracts or posters
 - Please provide other safety data e.g. US black box warning, post-marketing surveillance, current risk alerts
 - Relevant international guidelines from relevant authoritative organisations or associations (e.g. ESMO, ASCO, EULAR, AHA)

Thank you for your help. Please kindly contact CPO Pharmacist at Tel No. if you have any queries.

Yours sincerely,

Eileen Ma
Secretary, Drug Advisory Committee
Hospital Authority

Email Correspondence with Patient Groups (Chinese Only)

主旨：藥物建議委員會 2014 年第三季會議議程

致：各病人組織主席

醫管局藥物建議委員會於 2014 年第三季的會議議程已定出。將討論的新藥物/適應症，待決藥物及重新提交申請的藥物已列出，並夾附此電郵。

有關訊息亦已上載於醫管局的網站: <http://www.ha.org.hk/hadf/welcome.html>,
<http://www.ha.org.hk/hadf/download.html>

歡迎各病友組織表達對醫管局藥物名冊的建議。

(備註: 因大多數藥物未有註冊中文譯名，所以大部分相關文件只備英文版。)

順祝安康!

醫院管理局健康資訊天地啟
(病人賦能及社區協作組)

主旨：藥物建議委員會 2014 年第三季會議結果

致：各病人組織主席

醫管局藥物建議委員會於 2014 年第三季的會議結果經已推出。藥物建議委員會就個別專科的藥物篩選及專家提供的意見已列出，並夾附此電郵，以茲參考。

有關訊息亦已上載於醫管局的網站: <http://www.ha.org.hk/hadf/welcome.html>,
<http://www.ha.org.hk/hadf/download.html>。

(備註: 因大多數藥物未有註冊中文譯名，所以大部分相關文件只備英文版。)

順祝安康!

醫院管理局健康資訊天地啟
(病人賦能及社區協作組)

DAC Ref. No. :
 Hospital Ref. No. :

DRUG ADVISORY COMMITTEE OF THE HOSPITAL AUTHORITY

Please complete this form and return to the Secretary in case of absence from DAC meeting.

Recommendation from Member to DAC

To: Secretary, Drug Advisory Committee, HA

Drug item

*With reference to the above drug recommendation,

1. I support the recommendation that the above item is to be used in the HA
2. I support the recommendation that the above item is to be used in the HA only for:
 (Please state) specialty - _____
 prescribers - _____
 disease - _____
 The following information may be required upon request _____
3. I do not support the recommendation that the above item is to be used in the HA because of:
 insufficient evidence on safety/efficacy
 insufficient evidence on cost-effectiveness
 suitable alternative available in HA
 others _____
4. I propose to postpone the discussion pending on the availability of the following information:
5. I propose to seek expert advice -
 Proposed expert name(s) _____

Additional comments:

Name of member:

Designation/ Hospital:

Signature:

Date:

New Drug Recommendation of HA Drug Advisory Committee

DAC Meeting no.

Date:

DAC ref. no.:

Drug

Licensed indication(s)

1. (applied indication)

DAC recommendations

- HA Drug Formulary
- General Drug
- Special Drug
 - Authorization
 - Indications

Self-financed item

Pending recommendation

Not approved

•

The above recommendation is based on a review and analysis of the currently available scientific evidence and cost benefit considerations for the drug's current licensed indication(s).

Chairperson:

Signature:

Date:

**Mechanisms for Listing New Drug Items
Not Reviewed by Drug Advisory Committee**

		ITEM CATEGORY		
Recommended by	DFC		<ul style="list-style-type: none"> - Fluids and electrolytes - Vitamins and Minerals supplements - Blood Products (excluding recombinant preparations) - New presentation or strength of an existing drug in the HA Drug Formulary for the same indication and without price premium 	For DFC Endorsement
	Expert Panels	Renal	- Peritoneal and Haemodialysis fluids	
		Anaesthesia / Respiratory	- Medical gases	
		Gastrointestinal / Paediatric / Surgical	- Intravenous and oral nutrition	
	COC / CC	Intensive Care Unit	- Intravenous and oral nutrition	
		Radiology	- Diagnostics agents including radiopharmaceuticals	
		Toxicology Services	- Antidotes	
	DSAC		- Antiseptics and Disinfectants	
CHP Scientific Sub-committee * HA may follow the sub-committee's recommendations		- Vaccines		
Hospital's IRB / DH's Committee		- Clinical trial medications		
For critical screening and endorsement by DTC and HAHO		<ul style="list-style-type: none"> - Non-Formulary pharmaceuticals - Un-registered pharmaceuticals 		

Engagement of Internal Stakeholders in Management of HA Drug Formulary

Group	Engagement Point in Formulary Management	Roles & Responsibilities in Formulary Management	Types of Information Received	Dissemination Tool
Frontline Clinicians	New Drug Listing	Apply for new drug listing to DAC via Cluster / Hospital DTC	DAC recommendations via Cluster / Hospital DTC / pharmacy	Internal communication between DTC and applicants
	HA Drug Formulary Implementation / Review	<ul style="list-style-type: none"> - Comply with HADF - Feedback on HADF via cluster representatives in COCs / CCs, Cluster DTCs or Expert Panel or hospital pharmacy 	Quarterly updates on HA Drug Formulary Operation Guideline	HA intranet
Frontline Pharmacists	New Drug Listing	Prepare evaluation of new drugs	<ul style="list-style-type: none"> - DAC application process and forms - DAC meeting schedules and timelines - DAC recommendations 	<ul style="list-style-type: none"> - HA intranet - Email circulation
	HA Drug Formulary Implementation / Review	<ul style="list-style-type: none"> - Participate in Cluster / Hospital DTC - Report compliance with HADF - Participate in review of HADF 	<ul style="list-style-type: none"> - Quarterly updates on HA Drug Formulary Operation Guideline - Cluster's monitoring report on funded programmes in drug pressure areas 	
Cluster / Hospital DTC	New Drug Listing	Screen, endorse and submit application for new drug listing to DAC	<ul style="list-style-type: none"> - DAC composition - DAC meeting schedules and timelines - DAC application process and forms - Acknowledgement receipt of new drug applications - DAC agenda - DAC recommendations 	<ul style="list-style-type: none"> - HA intranet - Email circulation - Written memo
	HA Drug Formulary Implementation / Review	<ul style="list-style-type: none"> - Review and manage cluster / hospital drug formularies - Collect frontline feedback on HA Drug Formulary - Monitor compliance with HADF 	<ul style="list-style-type: none"> - Quarterly updates on HA Drug Formulary Operation Guideline - Drug policies and guidelines - Cluster's monitoring report on funded programmes in drug pressure areas 	

Group	Engagement Point in Formulary Management	Roles & Responsibilities in Formulary Management	Types of Information Received	Dissemination Tool
COCs / CCs on Disease Groups	New Drug Listing	<ul style="list-style-type: none"> - Support DFC upon specific enquiries 		Email circulation
	HA Drug Formulary Implementation / Review	<ul style="list-style-type: none"> - Nominate representatives for Expert Panels - Submit proposals for <ul style="list-style-type: none"> i) Drugs with pressure areas ii) Repositioning of drugs with budget impact 	<ul style="list-style-type: none"> - Notification for submission of annual plan proposals - Notification for nomination of a representative to Expert Panels 	
DMC members	HA Drug Formulary Implementation / Review	<ul style="list-style-type: none"> - Set drug management policies and guidelines - Prioritise annual plan programmes for listing new drugs in pressure areas and safety net inclusion - Oversee development and management of HA Drug Formulary - Review drug utilisation trends in HA 	<ul style="list-style-type: none"> - Quarterly updates on HA Drug Formulary Operation Guideline - Drug policies and guidelines - Patient suggestions and feedback on HA Drug Formulary - Monitoring report on new drug funding programmes 	<ul style="list-style-type: none"> - HA intranet - Email circulation - DMC minutes
DAC	HA Drug Formulary Implementation / Review	<ul style="list-style-type: none"> - Evaluate new drug applications - Recommend drug listing on HA Drug Formulary 	<ul style="list-style-type: none"> - Drug Evaluation Report - DAC recommendation - Patient suggestions and feedback on HA Drug Formulary 	<ul style="list-style-type: none"> - HA intranet - Internal mail - DAC minutes
DFC	New Drug Listing	Endorse new drugs not reviewed by DAC	<ul style="list-style-type: none"> - New Drug Information - Recommendations from other Expert Committees 	<ul style="list-style-type: none"> - HA intranet - Email circulation - DFC minutes
	HA Drug Formulary Implementation / Review	<ul style="list-style-type: none"> - Recommend to DMC on drug formulary management - Conduct biennial review of HA Drug Formulary with support of Expert Panels 	<ul style="list-style-type: none"> - Quarterly updates on HA Drug Formulary Operation Guideline - Drug policies and guidelines - Patient suggestions and feedback on HA Drug Formulary 	

Group	Engagement Point in Formulary Management	Roles & Responsibilities in Formulary Management	Types of Information Received	Dissemination Tool
Expert Panels	New Drug Listing	<ul style="list-style-type: none"> - Nominate a member to DAC upon invitation - Support DAC and DFC on specific enquiries 	<ul style="list-style-type: none"> - DAC drug evaluation report upon enquiries lodged 	<ul style="list-style-type: none"> - HA intranet; - Email circulation - Expert Panel minutes
	HA Drug Formulary Implementation / Review	<ul style="list-style-type: none"> - Provide expert opinions on drug matters - Identify drug pressure areas - Collect feedback on HADF from frontline staff - Support regular review of HA Drug Formulary 	<ul style="list-style-type: none"> - Quarterly updates on HA Drug Formulary Operation Guideline - List of identified drug programmes in pressure areas - Patient suggestions and feedback on HA Drug Formulary 	

Acronyms

CC	Central Committee
CCE	Cluster Chief Executive
CCF	Community Care Fund
CHP	Centre for Health Protection
COC	Coordinating Committee
CPO	Chief Pharmacist's Office
DAC	Drug Advisory Committee
DFC	Drug Formulary Committee
DH	Department of Health
DMC	Drug Management Committee
DoH	Director of Health
DSAC	Disinfectant and Sterilant Assessment Committee
DSC	Drug Selection Committee
DTC	Drug and Therapeutics Committee
DURC	Drug Utilisation Review Committee
EP	Expert Panel
HA	Hospital Authority
HAHO	Hospital Authority Head Office
IRB	Institutional Review Board
MSC	Medication Safety Committee
MSDC	Medical Services Development Committee
SBPC	Service and Budget Planning Committee
SFI	Self-financed Item
SFMC	Samaritan Fund Management Committee
SFO	Samaritan Fund Office
SN	Safety Net