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HKAPI's Recommendations on the Chief Executive's Policy Address 2020

Executive Summary:

Founded in 1968, the Hong Kong Association of the Pharmaceutical Industry (HKAPI) is one of the world's oldest pharmaceutical associations with 33 Research and Development (R&D) pharmaceutical company members that represent 70% of the supply of prescription medicine in Hong Kong.

The HKAPI embraces its mission to ensure expedient access to innovative healthcare solutions for people in Hong Kong and Macao with high ethical standards. To achieve such a mission, the HKAPI strives to advance the collaboration, constructive dialogue and understanding within the industry as well as among other stakeholders in the healthcare community.

The practical value of medicines is noticeable or even significant in daily life that benefits not only individuals but the entire community. The importance of this Industry is demonstrated particularly in the recent development of the Covid-19 pandemic. During the pandemic, the industry has been doing its utmost to maintain the uninterrupted supply of medicine despite the global lockdown. The industry has delivered phenomenal stability for the benefit of Hong Kong people.

Also, in its race against time to combat the global spread of Covid-19, the industry has been fully dedicated to its research on diagnostic tests, vaccinations and treatments. Up to date, 27 vaccine candidates are in the clinical phase of development, nearly 150 therapeutics are currently under clinical investigation for the management of Covid-19. Diagnostics options continue to expand, with at least 168 different technologies already approved or under review via the emergency authorization pathway of the US FDA. [1]

In Hong Kong, the industry sees it a prime time to turn the blatant challenges into opportunities in order to further enhance the healthcare system for better services, we therefore make the following recommendations:

1. Enhancement of THE OVERLOADED Public Healthcare system Including primary healthcare

1.1 Public Private Partnership

1.2 Digitalization of the healthcare system and services

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1.3 Strengthening the role of District Healthcare Centre (DHC)

2. EXPEDIATE PATIENTS' ACCESS TO INNOVATIVE MEDICINE

2.1. Speed up drug registration

2.2 Streamline drug enlistment process in Hospital Authority Drug Formulary (HADF)

2.3 Early access to innovative products with Managed Entry Agreement (MEA)

3. TO ENSURE A LONG TERM SUSTAINABLE DRUG PLANNING

3.1 Adopting Horizon Scanning System (HSS) for for future planning

3.2 Sustainability of Samaritan Fund

4. BIOMEDICAL TECHNOLOGIES AS AN ECONOMIC DRIVER

4.1 Effective use of big data

4.2 Partnership with Multinational Companies

4.3 Build a local foundation for R & D eco-system

4.4 Create a dedicated role to champion the mission

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1. Enhancement of THE OVERLOADED PUBLIC HEALTHCARE SYSTEM INCLUDING primary healthcare

The overloaded public healthcare system has been a long-existing issue in Hong Kong that however is set to be exacerbated by the ageing population.

Therefore, an on-going review of the system is necessary to keep pace with patients' demands. Such reviews should be conducted to map out innovative, efficient and viable plans for better resource allocation for implementation in a timely fashion.

During the Covid-19 pandemic, many healthcare settings are forced to reduce or even shut down many of their clinical services, including closure of clinics and postponement of medical appointments or non-emergency surgeries. While the situation sounds an alarm to Hong Kong for the need to re-assess the capacity of its healthcare system, it also creates an opportunity for Hong Kong to further enhance the system in various aspects.

1.1 To further expand the scope of Public-Private Partnership (PPP)

The long waiting time for the Hospital Authority (HA) services has always been a public concern. Latest official data show the median waiting time for stable new case booking at Specialist Out-patient Clinics (SOPC)'s medicine specialty at Kowloon East cluster is 115 weeks between July 1 2019 and June 30 this year.[3] For eye specialist, the longest waiting time is 172 weeks, also at Kowloon East. PPP can effectively alleviate the workload of the public sector that can also shorten the waiting time for patients, by making use of the capacity in the private sector to support diagnosis and treatment carried out by its public counterpart.

It is foreseeable that the waiting list in the public sector during Covid-19 pandemic shall grow longer, which prompts the urgency for the enhancement of PPP.

HKAPI recommends

- Transparency in real-time waiting lists: The real-time waiting lists in different clusters/public clinics should be made public for patients to make informed choice as to where to receive treatments.
- The HA has already run the General Outpatient Clinic (GOPC) for some years that it is a right time to systematically extend the existing programmes to cover more patients e.g. diabetic patients , and to expand its services to more therapeutic areas with high social burden which need strong community

support, i.e. dementia . Similar expansion should take place in Specialist Outpatient Clinic (SOPC) services and in tertiary care such as cancer care.

- Further, HKAPI is of the view that patients in PPP programmes could access innovative medicine by means of healthcare vouchers and co-payment, so patients are able to have more treatment options.

1.2 Application of Digital Technology on healthcare system and services

For months, the Covid-19 pandemic has severely interrupted all walks of life that medical services make no exceptions. HKAPI is of the view that all interruptions nowadays have prompted an immediate need for digital/internet-based healthcare systems and services. We need to avoid the delays in "routine care" that the impact of the delay could be even more extensive than the direct clinical impact on patients infected with Covid-19.

One of the viable solutions is to set up 'virtual clinics' through the use of tele-medicine consultations. This could ensure patients standard clinical care while reducing physical crowding of patients in hospital.

Other options include the utilization of various Artificial Intelligence (AI)-based triage systems, such as medical 'chat bot' to help patients identify early symptoms, phone-based software to detect and record patients' medical conditions, and blockchain companies and pharmacies to deliver patients' medication

In summary, while the world continues to rely on conventional public-health measures to tackle the Covid-19 pandemic in 2020, the HKAPI highly recommends an immediate use and application of digital technology not only to resolve various issues caused by the Covid-19 lockdown but also support chronic disease management in future.

HKAPI recommends:

- Request the Primary Healthcare Steering Committee to develop strategic framework to support digital/internet based primary healthcare system, and to discuss how to adopt technology for further enhancing primary healthcare services in Hong Kong such as, "virtual clinics' healthcare, tele-pharmacy or e-drug consultation for patients' convenience.
- To review current regulations to conform to the operations of digital/internet-

based health services and to ensure the quality of the services.

- The committee to set targets which should be realistic and achievable with valid timeline for implementation.

1.3 Further enhancing primary healthcare

HKAPI believes in people-centered care. Patient Journey is one of the key concepts to develop people-centered care. It can be defined as the ongoing sequence of care events which a patient follows from the point of access into the health system, moving towards diagnosis and care, and ending in outpatient care. In reality, this journey is a cyclical, never-ending interaction of care events with the healthcare providers. In general, a patient journey follows the route as health/disease awareness, screening, diagnosis, treatment and palliative/ follow-up.

HKAPI is of the view that District Health Centre (DHC) has a pivotal part to cover the areas of health promotion, disease prevention, chronic disease management and community rehabilitation. Its role as primary health provider at district level is even more crucial during the lockdown due to Covid.

The first DHC in Hong Kong was opened last year. However, it is underutilized in terms of its functions. It is important for DHCs to closely collaborate with other primary healthcare providers including GOPC PPP of HA, Non-Governmental Organizations (NGOs), and community pharmacies to deliver a holistic healthcare model for patients while the collaboration is also able to achieve a more desirable result for resource allocation.

HKAPI recommends

DHCs should strengthen and expand their services in disease awareness, screening and health monitoring, and step up for prevention, early detection and screening of common chronic and geriatric diseases in particular diseases which always create heavy social burden, such as Alzheimer's , Diabetes.

DHCs are also suggested to help monitoring chronic patients via telemedicine and tele-pharmacy consultation and any other modes of non-face-to-face communication to serve chronic patients or patients who need follow up. DHCs should be allowed with more flexibility in operations, such as building a strong partnership with NGOs which are currently providing healthcare services at district level as well as with community pharmacies.

Meanwhile, the HKAPI suggests the professional role of pharmacists at DHCs to be better utilized to support the existing primary healthcare services, such as:

- Support the Drug Refill Services/ E-Fill: Eligible HA patients could visit the resident pharmacists at the DHCs regularly between consultation appointments to review their conditions and collect drug refills at the DHCs.

- Pharmacists or nurses in DHCs could contact patients via telephone calls or SMS messages to remind them to collect drug refills. With reminders and regular reviews, it would be easier to ensure patients' compliance and to monitor their health conditions.

- For patients who have episodes of medical consultations or hospital admissions with changes in medications or having drug-related issues, the pharmacists at DHCs could review patients' drug profiles, perform medication review and reconciliation, and could then arrange telephone calls or even face-to-face appointment to follow up, if necessary. This could subsequently shorten the waiting time for patients in public hospitals.

2. EXPEDITE PATIENT'S ACCESS TO INNOVATIVE MEDICINE

It normally takes 22 to 24 months from the time an innovative medicine is introduced in Hong Kong to the moment it can be widely available to patients in public hospitals, including, an average of 5 to 7 months for an innovative medicine to be registered in Hong Kong, and a median of another 17 months for the drug to be enlisted in HA Drug Formulary.

We believe that improvement can be made at two levels, namely , by allowing early submission and early evaluation to move forward the time for registration, and secondly by reducing the time of enlistment in HA to no more than 12 months with details as follows:-

2.1 Speed up drug registration at regulatory level

2.1.1 Ensure the predictability of registration timeline: Removal of LegCo negative vetting.

In most countries, the registration and classification of drugs fall entirely within the responsibility of the health authority. Given that the decision on drug registration

should be purely based on scientific evaluation, it becomes unnecessary to involve legislative procedures in the registration process. None of the legislative arm in benchmark countries and regions such as Australia, Korea, Singapore, Taiwan, the UE, and the United States, play any role in the drug registration process.

HKAPI Recommends

HKAPI is of the view that the entire LegCo vetting (for negative vetting) for New Chemical Entity (NCE) registration in Hong Kong can be completely removed, which would effectively avoid unnecessary delay caused by any unforeseeable disruptions. The removal is also in line with the basic principle that drug registration is purely based upon scientific evaluation. To run in parallel with such a proposal, the Drug Office should be empowered to amend the Poisons List without LegCo vetting to avoid delays in NCE registration.

2.1.2 Early submission for registration

Regulatory systems can be very resource-intensive. The increasing complexity of supply chains prompts the need for international cooperation to ensure the safety, quality, and efficacy of the products. Good Reliance Practice (GReiP) is found to be a means to regulate medical products in a modern way.

In the draft working document for Good Reliance Practices, the World Health Organization (WHO) emphasizes that Reliance is not a lesser form of regulatory oversight but rather a strategy seeking to make the best use of the available resources in any given setting. This would allow the allocation of resources to other areas of regulatory functions. If implemented effectively, GReiP can lead to consistent regulatory processes, sound regulatory decision-making, increased efficiency of regulatory systems and better public health outcomes.[5]

HKAPI recommends

For early submission, the Drug Office is encouraged to implement Good Reliance Practice (GReIP) as recommended by WHO, which is also to recognize conditional approval/registration of other authorities for life-threatening/infectious diseases that replace the current standard requirements of waiting for 2 Certificate of Pharmaceutical Products (CPP).

2.1.3 Further enhance the administrative efficiency of the authority

The ongoing Covid-19 pandemic poses challenges to the local regulatory authority in

addition to the daily operations; the industry has the following suggestions for further enhancing the administrative efficiency of the authority.

2.1.3.1 Digitalization of process

- For the support of digital development of healthcare education via electronic Product Information (prescribing information and patient information) to end-users (healthcare professional and patients)

- For the preparation of Good Reliance Pathway (as regulatory affair systems should be linked among authorities), and

- Setting up Portal for online clinical trial application and amendment submission to facilitate drug research in Hong Kong.

2.1.3.2 Increase manpower in the regulatory authority

The industry has to wait 9 months for a "change of particular" approval in order to add a new indication of a drug which is in the market, to change the package insert in order to update warnings in the package, or to seek an approval for generic drugs to be marketed and sold in Hong Kong. The time for all these approvals is likely to be further delayed after a considerable portion of Drug Office staff are seconded to the airport to support Covid-19 testing.

The manpower shortage in the Drug Office jeopardizes patients' opportunity for early treatment of new drugs, it also delays the timeline for clinical trial certificate application which would further weaken the competitiveness of Hong Kong as the regional biomedical hub. Hence, the industry suggests the Drug Office to have its manpower increase to benchmark with similar authorities in the region with clearly defined service pledges.

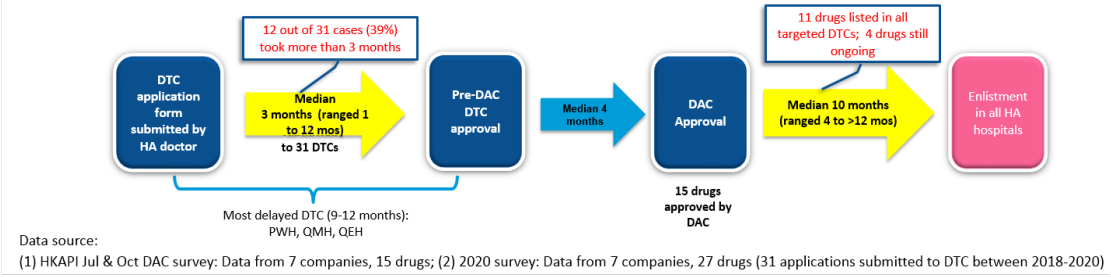
2.2 Streamlining HA drug enlistment process

HKAPI calls for structural enhancement for the HA drug enlistment system (please see the following diagram) by clearly defining the procedures and its criteria, eliminating unnecessary and duplicated procedures, and enhancing the efficiency of administrative procedures in order to reduce the entire drug enlistment timeline to no more than 12 months.

Based on the HKAPI survey, it currently takes 17 months to enlist a new drug into the

Hospital Authority Drug Formulary (HADF), from its first submission to the time the medicine can become widely available to patients in individual hospitals. The process is shown in below the graphic:

Graphic 1: HADF enlistment process with timeline



HKAPI recommends

2.2.1 Clearly define procedures and criteria, eliminate the duplications:

- To remove duplications in the scientific evaluation process of drugs at the pre-Drug Advisory Committee (DAC) and post-DAC stages.
- To clearly delineate the decision-making criteria of DAC and Drug and Therapeutics Committee (DTC) to reduce time for repeated clinical and pricing discussions.
- To clearly define the process and criteria of reposition of self-financed items into special drug, and to general drug, in order to address affordability issues and provide patients effective access to medicine.

2.2.3 Further enhance the efficiency of administrative process

- Consider further enhancing the efficiency of meetings by adopting flexible meeting mode i.e. the Drug and Therapeutics Committee (DTC) should adopt the mode of negative vetting for drug enlistment meetings to replace conventional discussions, e-meetings replace physical attendance of members, decisions made by email circulation…etc
    - To review the administrative process to further improve its efficiency , such as shortening the time for drug code creation to no more than one week from currently 3 months.
    - To digitalize administrative procedures to improve efficiency, e.g., adoption of digital signatures.

2.3 Introduction of Managed Entry Agreement (MEA) for patients' early access to innovative medicine

Many innovative therapies that are able to demonstrate significant benefit to

patients' health at the early stage of clinical development can receive fast track/conditional regulatory approval, but not able to get in the existing public hospital settings or reimbursement system because the acquisition cost of this kind of treatment is normally higher than that of the existing alternatives.

MEA provides a viable solution to the dilemma. It has been adopted in Australia, two-thirds of OECD and EU countries, [6] according to an OECD working paper.

HKAPI recommends:

- By introducing performance-based MEA to help healthcare payers to manage or even mitigate the uncertainty of the financial impact and the performance of new drugs.
- To update the outcome of MEA after implementation of 1-2 years as a reference for future listing decisions.

3. TO ENSURE LONG TERM AND FORWARD LOOKING BUDGET PLANNING FOR TREATENTS

3.1 Adopt Horizon Scanning System for future planning

Horizon scanning is a method to investigate evidences systematically about future trends. This forward-looking approach in healthcare helps to keep track of the trend of new medical treatments and medicines, which could assist decision-makers in mapping out effective plans for resource allocation.

The Horizon Scanning System (HSS) has been widely applied in many places overseas including US, UK, Australia, Canada, Europe and Japan.

HKAPI Recommends

- Hong Kong to adopt HSS for evidence-based decision making with timely information on new health technologies and possible consequences for the healthcare system.
- HSS can provide a blueprint for future funding decision i.e. Samaritan Fund budget planning.

3.2. *Sustainability of Samaritan Fund*

The Samaritan Fund (SF) was established to provide financial assistance to the needy patients who meet the specified clinical criteria and pass the means test to cover their expenses for designated medical treatment which are not covered by the standard fees and charges in public hospitals and clinics. Last year the means test

mechanism was reviewed and relaxed. However, it was back in 2012, the HK$10 billion grant was injected to support its operation for the next ten years. It is now a proper time for an overall review of the grant for its sustainability beyond 2022 in light of an expected rise in demands due to both the economic downturn and the additional costs brought by medical inflation and advancements.

HKAPI recommends:

- To ensure the new injection of funds will be able to catch up with medical inflation in relation to innovation and technology advancement, HKAPI suggests the amount of new injection should seriously consider this factor. In addition, HSS should be adopted in guiding SF budget planning to address the financial budget brought by medical technology advancement.
- Pharmaceutical companies call for a process that companies can actively apply for their products to be enlisted in SF with transparent criteria, so that we could contribute to patients to address their affordability as to access innovative medicine in a proactive manner.

4. DEVELOP A BETTER ECO-SYSTEM FOR BIOMEDICAL INDUSTRY

The Hong Kong Government has announced recently the strategic development of genomic medicine in Hong Kong which is not only for research but also for clinical applications such as diagnosis and treatment to benefit patients.

The bureau is dedicated to coordinate the implementation with stakeholders including the Department of Health, HA, universities, medical and relevant professional bodies and private sectors and to set aside $1.2 billion for execution.

The industry is of the view that Hong Kong has great potential to develop as a regional center for Genomic Medicine, which however needs a further optimized infrastructure on databases, sophisticated Artificial Intelligence (AI), and innovative researchers as the backbone to play significant roles to support the initiative.

HA Clinical Data Analysis and Reporting System (CDARS), which is one of the important edges we have in developing genomic medicine, is a centralized system of patient records that covers 90% of the Hong Kong population. Since its birth, this database has been collecting patient data for more than 25 years and it contains essential real-world clinical information including patient demographics,

hospitalizations, visits to outpatient clinics and emergency departments, diagnoses, laboratory results, procedures, prescriptions, dispensing of medications and deaths. It is powerful and feasible for collective research and analysis in an anonymized approach – each patient is assigned with a unique patient identifier to safeguard confidentiality/privacy and ensure high compliance with relevant regulations on data protection.

The importance of utilizing CDARS for research and medical advancement for the common good and wellbeing of the Hong Kong population was recognized as early as in the 2018 Policy Address, which required all government departments (including HA) to formulate open data plans. HA was said to be active in preparation for a "Big Data Analytics Platform" to facilitate the access of academics and researchers to the clinical data which is in HA's custody. Nevertheless, after two years, a truly user-friendly, open and clear mechanism for its access is still awaited and long expected by researchers, academics and the industry to maximize data usage and unleash its full potential for drug development and healthcare services enhancement.

HKAPI recommends

***4.1 To expedite effective use of big data by following measures*:**

- To ensure the data is user-friendly and future-focused by seeking inputs from users' perspectives through which relevant stakeholders such as academics, scientists, medical researchers, pharmaceutical industry and etc. could be engaged in developing and optimizing HA Big Data Analytics Platform.

- To drive the formation of consortium by relevant stakeholders to develop and govern a transparent and structured system for open access to HA CDARS, so as to ensure an access to data under a structured system supplemented with clear approval procedures, criteria and timelines, similar to the databases operated in other developed countries such as US FDA and UK CPRD.

- To establish a dedicated body to handle the administrative work for the applications for accessing data to strengthen collaborations across government bureau, healthcare institutions and industries in analytics of data robustly collected through HA.

- To set the database as a publicly available resource with access strictly controlled by an independent department and granted by the consortium. The criteria and

timeline for granting access to specific clinical parameters should be clearly listed for applicants.

4.2 To partner with Multinational Companies (MNC)

In light of its dedication to the development of genomic medicine, the Hong Kong government is urged to set up an "attractive incentive scheme" for MNC Biomedical / Biotech firms to form partnerships with local firms / institutions on commercial projects of interest, such as covid-19. It is expected to have more collaboration with the MNC to expand the capacity of research and development in the areas of disease diagnosis and treatments.

4.3 To build a local foundation for Research and Development ecosystem

The pandemic of Covid-19 alerts us that it is currently a prime time to make use of the existing data to build an eco-system for local development of the biomedical and bio-technology industry, in order to leverage the competitive advantages we have across Greater Bay Area (GBA) by measures such as:

- To build a consortium for data base based on existing local data
- To encourage exchange advisory and communication with WHO, similar to the current Cancer Registry.
- To attract investments from Asia Pacific region and China in the areas of AI and R&D for related commercial activities in Hong Kong

4.4 Create a dedicated role to Champion the mission

The Hong Kong Government has announced its dedication to develop Hong Kong as a regional biomedical hub and has invested about 70 billion dollars in this area[i]. The industry would like to see if there are a visible outcomes that we could learn from public access information about the return on investment.

While we appreciate the vision of the government, as an industry in research & development on pharmaceutical and treatment options, we found the government's policies and plans being too fragmented that implementation is always an issue. Therefore, we see the need to bridge the gap through better coordination in the implementation of different government policies to achieve the designated targets in an effective manner.

With all the above recommendations, it is critically important to appoint a Chief Scientific Officer (CSO), reporting to Chief Executive and Secretary for Food and

Health[9], commissioned for goals and with duties as:, (i) leading the implementation and cooperation of the Hong Kong SAR to develop a R&D bio-medical hub and undertaking related core projects, (ii) developing a prioritized clinical trial centre, (iii) overseeing and advancing the

Healthcare Data Analytics platform, (iv) advising relevant government departments and stakeholders such as Hong Kong Science and Technology Park (HKSTP) and academic institutions on matters relating to funding, manpower developments, and more importantly a coordinated strategic action plan with clear timeline, roadmap of milestones, measurable outcomes and etc.

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[1] https://s3-ap-southeast-2.amazonaws.com/policy-cures-website-assets/app/uploads/2020/08/06130247/Covid-19-RD-tracker-update3_6-August_final.pdf

[2] The definition of people-centered care of this paper refer to: https://www.who.int/servicedeliverysafety/areas/people-centred-care/ipchs-what/en/

[3] https://www.info.gov.hk/gia/general/201904/17/P2019041700580p.htm

[4] https://www.ejinsight.com/eji/article/id/2078827/20190312-govt-proposes-cap-on-health-vouchers-for-optometry-services

[5]https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS20_851_good_reliance_practices.pdf?ua=1

[6] https://www.oecd-ilibrary.org/social-issues-migration-health/performance-based-managed-entry-agreements-for-new-medicines-in-oecd-countries-and-eu-member-states_6e5e4c0f-en

[7] https://www.bbntimes.com/technology/big-data-in-the-pharmaceutical-industry

[8] https://www.scmp.com/news/hong-kong/health-environment/article/3046258/government-should-embrace-innovation-health-care
Speaking on a panel at the latest edition of the “Redefining Hong Kong Debate Series”, a forum held in Central and organized by the *South China Morning Post*,[8] representatives from the medical and pharmaceutical sectors have called on the government to be more open minded to innovation in the healthcare sector in light of the urgency of its needs and applications in the area.

[9] Countries such as the UK, the US, Canada and India, etc., all have such a role with similar functions in the government. The UK Government Chief Scientific Adviser (GCSA) is the personal adviser on science and technology-related activities

and policies to the Prime Minister and the Cabinet; and head of the Government Office for Science. In Canada, the Chief Scientific Adviser has a significant public role as the government's most visible scientific expert. They are also head of the Science and Engineering Profession in government.

- provide advice on the development and implementation of guidelines to ensure that government science is fully available to the public and that federal scientists are able to speak freely about their work;
- provide advice on creating and implementing processes to ensure that scientific analyses are considered when the Government makes decisions;
- assess and recommend ways to improve the existing science advisory function within the federal government; and
- Assess and recommend ways for the Government to better support quality scientific research within the federal system.