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Cutting through the red tape in Hong Kong

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This is a summary only of recent legal and regulatory developments. It is not intended to be legal and regulatory advice in relation to particular circumstances.

Any reference to "Hong Kong" or "Hong Kong SAR" shall be construed as reference to "Hong Kong Special Administrative Region of the People's Republic of China".

- PERSONAL DATA COMPLAINTS
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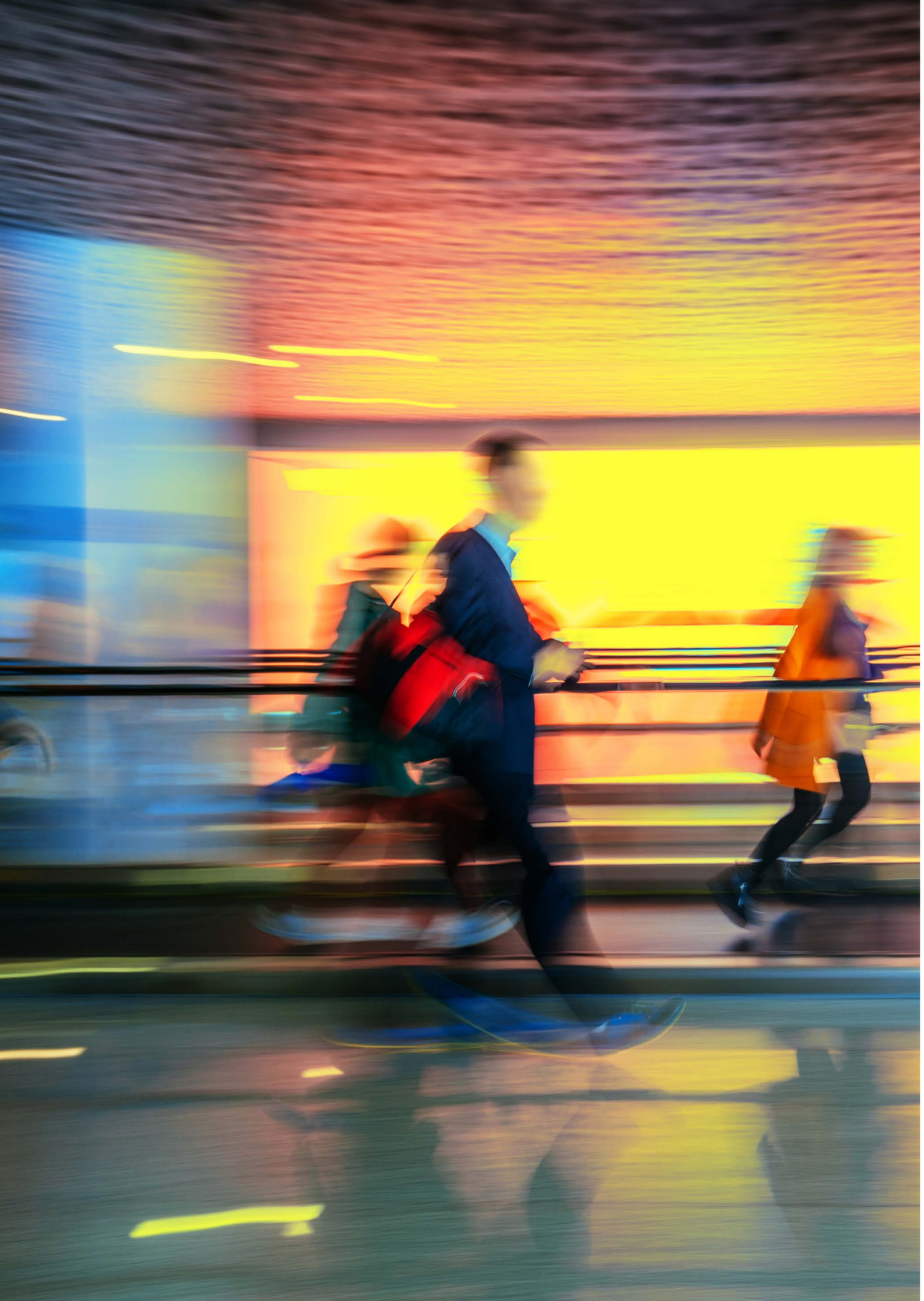
There has been an increase in regulation and the potential for intervention in business over the past decade. This has in part been reflective of worldwide trends (such as the development of data protection and cyber regulation as the use of information technology becomes potentially more insidious).

In other areas (such as the Financial Dispute Resolution Centre) it has been born from a desire to provide procedures to cope in the event of a repeat of mass consumer concerns over miss-selling of financial products.

Our teams at KWM are experienced in handling these regulations. In this compendium we give a nutshell guide to eight areas of regulation. For those running or advising businesses in Hong Kong, we hope and expect that you will find a number of items of interest.

This publication has been written by Peter Bullock, Francois Tung, Caroline Wong, Matthew Lee and Jenny Yu of King & Wood Mallesons Hong Kong office.



PERSONAL DATA COMPLAINTS

Attempt amicable resolution at the first opportunity

It is common knowledge that a data subject can lodge a complaint at the Office of the Privacy Commissioner for Personal Data ("**PCPD**") where a data user mishandles his/her personal data, but not many realise that PCPD recommends an aggrieved individual to get in touch with the organisation to seek redress directly **first**. In fact, PCPD's standard complaint form asks a data subject whether he/she has attempted to contact the party complained against and if not, whether he/she would make further attempt to do so.

A data user should therefore take this first opportunity to resolve the matter to minimise further complications down the road. Even where a response at this juncture may not be satisfactory to the complainant, a data user could at least demonstrate that genuine attempts have been made to resolve the complaint which may be a factor for PCPD's determination whether to take a conciliatory approach or launch a formal investigation as further elaborated below.

The data subject decides to take matters further, what next?

The PCPD would first conduct preliminary enquiries to see if the complainant has a substantial grievance under the Personal Data (Privacy) Ordinance ("**PDPO**"). Upon passing first screening, the PCPD will generally attempt to resolve the complaint through conciliation or mediation. This is more suited for cases of a less serious nature and in the case of breach may lead to PCPD issuing a verbal or written warning against the data user.

Matters of a more serious nature will generally lead to a formal investigation by the PCPD. A formal investigation is empowered by the PDPO which grants PCPD the power to enter a data user's premises to carry out an inspection and require any person with information relevant to the investigation furnish such information or produce documents to the PCPD. Upon completion of the investigation, the PCPD may, if it is in the public interest to do so, publish a report setting out the results of the investigation and make such comments as PCPD thinks fit. In addition to the investigation report, the PCPD also has the power to issue an Enforcement Notice against the data user requiring him/her to remedy the breach and, if appropriate, prevent any recurrence of the contravention. Failure to comply with an Enforcement Notice or PCPD's lawful requirements (for e.g. obstruct, hinder or resist PCPD's lawful investigation) is a criminal offence and is liable on conviction to a fine and/or imprisonment.

Be wary of data access requests (DARs)

Data Protection Principle 6 under the PDPO entitles a data subject to require a data user to provide access to his/her personal data within a reasonable time of the request. This has led to increasing tactical use of DARs to obtain information, particularly in a dispute context. It may be possible to limit or refuse such requests where they are being made for collateral purposes. You should obtain legal advice specific to the circumstances before doing so.

While not all information connected with an individual will be personal data, so not everything needs to be disclosed, there is considerable burden on a data user (particularly the data protection officer) to review all information which could be caught by the DARs and then work out exactly what needs to be provided and the reasons for not providing other restricted information, all within the short timeframe. One can easily imagine if a coordinated set of requests by a large number of individuals made at the same time could be time consuming, expensive and cause huge disruption to the business.

Data users should note that personal data complaints concerning direct marketing or non-compliance with data access/correction requests are generally directly referred by the PCPD to the Police for criminal investigation, which in turn leads to potential prosecution.

Remedies

Apart from criminal sanctions that can be imposed on a data user that has contravened the Ordinance, if a data subject suffered damage which includes injury to feelings, the individual has the right to seek compensation from the data user concerned through civil proceedings. The PCPD may grant legal assistance to a data subject, in particular if (a) the case raises a question of principle or (b) it is unreasonable, having regard to the complexity of the case or the data subject's position in relation to the data user or any other matter, to expect the data subject to deal with the case unaided.

Assistance by the PCPD may include giving advice (or arranging a solicitor or counsel to do so), arranging legal representation for the data subject or any other forms of assistance as PCPD considers appropriate in the circumstances.

CYBER NOTIFICATIONS

A data breach may arise when personal data is exposed to the risk of unauthorised or accidental access, processing, erasure, loss or use. The adoption of the General Data Protection Regulation in the European Union in 2018 sparked reform in many parts of the world on cyber notifications. The issues frequently touched upon include:

1. whether cyber notifications are mandated, advised or not required;
2. whether a regulator is set up to handle cyber notifications or data breach issues; and
3. who should cyber notifications be made to – law enforcement agencies, regulators and/or affected data subjects?

In Hong Kong, a data breach may amount to a contravention of Data Protection Principle 4 in Schedule 1 of the Personal Data (Privacy) Ordinance ("**PDPO**"). While data users are not mandated to notify the Privacy Commissioner for Personal Data ("**PCPD**") on a data breach, cyber notification is recommended by the PCPD and data users are advised to follow the procedures and requirements in the guidance note.

4 steps to handle potential data breaches

Gather information immediately – promptly collect information on (i) when, where and how the breach occurred, (ii) the cause of the breach, (iii) the kind and extent of personal data involved and (iv) the number of data subjects being affected. This requires close coordination and effective communication between technical teams (both internal and external) and management, and across subsidiaries and branches.

Adopt measures to contain the breach – take containment measures by (i) taking down the system which caused the breach, (ii) changing users' passwords and system configuration to control access and use and (iii) ceasing or changing the access rights of individuals suspected to have committed the data breach.

Assess the risk of harm – assess the real risk of harm arising from the data breach and deal with the particular risk (e.g. threat to personal safety, identity theft, financial loss, humiliation or loss of dignity, damage to reputation or relationship as well as loss of business opportunities).

Make the notifications – despite the lack of legal compulsion, it may nevertheless be appropriate to notify the PCPD and affected data subjects. In the event criminal activities are likely to have been committed by the unauthorised use of the personal data, you should also quickly report to law enforcement agencies (normally the police).

When: The PCPD recommends data users to notify the PCPD and affected data subjects as soon as practicable after assessing the impact of the data breach and circumstances of the case. We recommend you notify the PCPD and affected data subjects once you have completed a preliminary assessment. You need to have gathered sufficient information to make a meaningful notification to allow PCPD's assistance or remediation actions by affected data subjects.

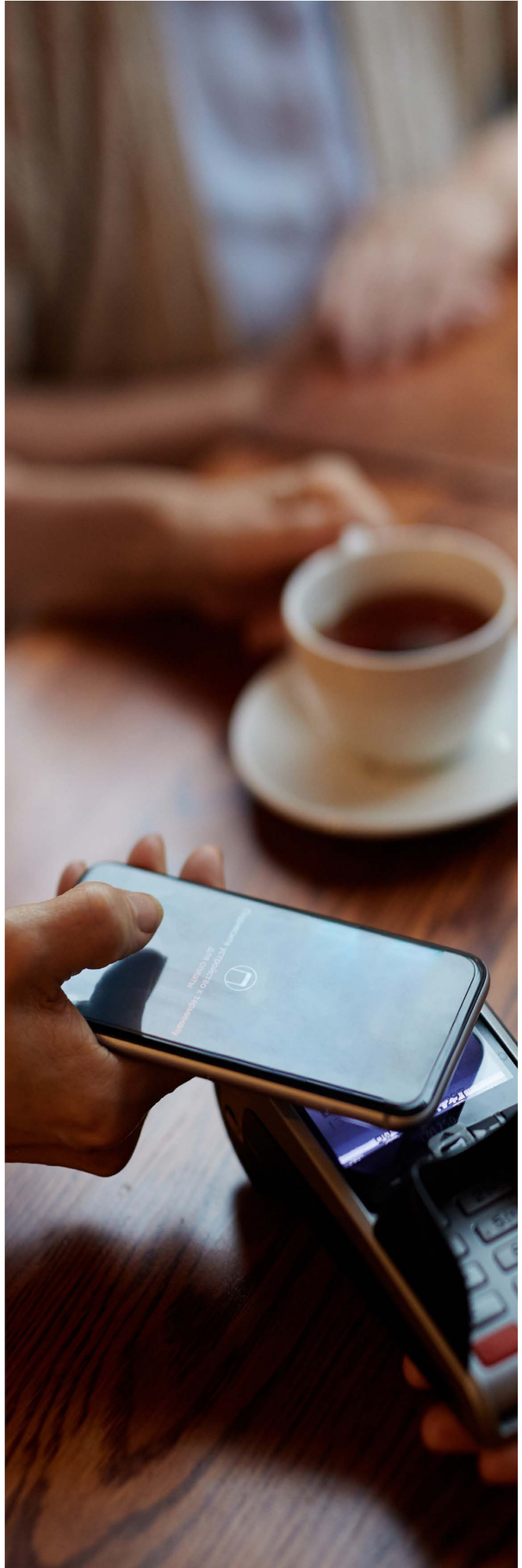
How: The quickest way to m ake a notification to the PCPD is through the online form. Notification to the affected data subjects can be by phone, in writing, via email or in person, or otherwise through media or website if the data subjects are not identifiable immediately.

What: Compared to the notification form of other countries, the one in Hong Kong is relatively straight forward and uses open questions. You are expected to provide information such as date, time and duration of the breach, types of personal data, risk of harm and measures taken. It is understandable that it takes time to collect all information required and more details may be revealed as investigations progress. In light of this, failing to provide all the information should not prevent you from submitting a notification – you can always file an update later.

Practical tips

Act fast – The longer it takes to detect and contain the data breach, the greater harm the incident may cause. Once a breach is detected, your technical teams should take immediate actions to contain the breach and investigate the incident. Management should consider involving independent technical experts. Employees should also be well informed and guided. The PCPD will very likely ask for justifications if you fail to act promptly after detection of the breach.

Global coordination – Time zone variations, language barriers, differences in jurisdictional requirements on cyber notifications, legal costs sharing between offices and teams, centralised / decentralised decision-making processes … these could all pose difficulties when the data breach incident impacts a system shared between you, your subsidiaries and branches around the globe, especially if a subsidiary is not fully owned by your company. You should quickly decide (preferably in accordance with pre-existing protocols): (i) will headquarters lead and make all decisions, and if not, what decisions will be made by local management; (ii) how will local management receive most up to date information from headquarters (e.g. dedicated phone line, periodic updates, etc.); and (iii) should local management assist in conducting any investigation or reporting to the media?



Provide appropriate level of details – One very common question we have been asked by clients is how much information a data user should provide in its notification to the PCPD, the media and the affected data subjects. If you provide too few details, this will likely trigger follow-up questions from the PCPD and may not be helpful to affected data subjects. If you provide too much detail, you may easily expose yourself to liability and potentially compromise investigations concurrently undertaken. You should seek legal advice on this aspect.

Be specific – When you notify each affected data subject, it is best to be specific (e.g. what types of personal data could have been breached, the risks of the leakage of such personal data and what specific actions he/she should take). A general description of the incident would not be helpful.

Keep the evidence – By keeping all evidence collected during the investigations, it will help you answer questions or respond to challenges from the PCPD, defend your company in potential investigations and identify issues with the existing internal systems, security features or personal data handling processes.

Other regulators – While the PCPD is the main regulator for handling data breaches, there are other regulators you may need to notify if you are operating in certain industries:

- Regulated institutions of the Hong Kong Monetary Authority ("**HKMA**") have to report data breaches to the HKMA and affected customers.
- If the data breach involves the leakage of insider information as defined in s.245(1) of the Securities and Futures Ordinance (Cap.571) ("**SFO**"), Hong Kong public listed companies are subject to mandatory disclosure requirements under s. 307B of the SFO.

Legal reforms – The PCPD has recently proposed amendments to the PDPO, including the implementation of a mandatory data breach notification mechanism and the broadening of the definition of "personal data" from information relating to an "identified" person to information relating to an "identifiable" person. Please refer to our article on these proposed amendments.

FINANCIAL DISPUTE RESOLUTION CENTRE ("FDRC")

What is it and when might I use it?

The FDRC was established in the wake of the exponential growth of consumer claims arising from alleged mini-bond mis-selling at the time of the 2008 financial crisis. All financial institutions or financial services providers (together "**FIs**") authorised by the HKMA or licensed by the SFC have agreed to deal with the FDRC (except those only providing credit rating services).

Under the strapline "Mediation First, Arbitration Next", the FDRC operates panels of mediators and arbitrators and offers fixed price dispute resolution services for cases generally up to a total (claim plus counterclaim) of HK$1 million (but extendible in some circumstances if both sides agree to HK$10 million). FIs bear around 85% of the fixed charges, with the Claimant paying the balance.

The arbitration options (by which an independent arbitrator will adjudicate the claims) have historically not been taken up often, not least because mediation is required to be undertaken first. Although mediation is intended to be facilitative (whereby a neutral third party seeks to facilitate a negotiated settlement) rather than evaluative (whereby the mediator expresses her opinion on the merits of the parties' positions), it is hoped that the process will give a real opportunity for customers of FIs to air grievances as to the selling of financial products in an even-handed way.

Dealing with FDRC as Claimant

SMEs (having annual turnover not exceeding HK$50 million, gross assets not exceeding HK$50 million and not more than 50 employees in Hong Kong), as well as sole proprietors and individuals, each of whom had a customer relationship with an FI or who has been provided with a Financial Service are eligible to make claims of a monetary nature arising out of a contract arising in Hong Kong.

Case Officers are on hand to check claims against eligibility criteria and (where necessary) to chivvy FIs to enter into the process. FDRC maintains a List of Mediators, and there are specific FDRC Mediation Rules. Mediations are conducted on a confidential and 'without prejudice' basis, so as not to be referable in any subsequent legal proceedings. If settlement can be reached, a binding settlement agreement is drawn up by the mediator with the help of the parties.

If settlement is not reached through mediation, the mediator will report to the FDRC in a Mediation Certificate. The Claimant may request arbitration within 60 days from the date of the Mediation Certificate. Arbitration will generally proceed on a documents-only basis. Again, there are rules and proformas applicable. The arbitrator should generally render her Award within one month of the receipt of the last document in case of documents-only proceedings.

Dealing with FDRC as an FI

Although the FDRC was primarily intended as a platform to handle customer led claims (including potentially numerous claims arising from the same or similar products or circumstances), it is possible for FIs to make their own claims and/or counterclaims. FIs need to have regard to the options of running claims or circumstances through the FDRC processes. However, there may be various circumstances where this is appropriate.

Where a Customer Claim exceeds HK$1 million, or an FI Claim or FI Counterclaim is brought, Case Officers will consider whether to accept the case through an "Extended Eligibility" process. There are various potential avenues for rejection of the claim, including if the claim has been the subject of court proceedings, or is being considered by the Insurance Complaints Bureau.

Maximising your effectiveness through FDRC processes

1. Gentle but firm persuasion, rather than scorched earth lawyering, should reap dividends when handling FDRC processes.
2. It is important to understand whether your case is one of a class of similar cases, or an individual case. Either way, no precedent will be set for others to follow.
3. Case Officers, some of whom have been in post for many years, can be helpful and thoughtful.

PRODUCT RECALL

In Hong Kong, the product recall regime is governed by several pieces of legislation depending on the products being recalled. The general legislation governing consumer products is the Consumer Goods Safety Ordinance (Cap. 456) (the "**CGSO**") with the Customs and Excise Department ("**C&ED**") being the responsible authority. CGSO is applicable to all consumer products with the exception of products which are specifically carved-out, including food and water, pleasure craft and vessels, motor vehicles, gas, electrical products, pesticides, pharmaceutical products, traditional Chinese medicines, toys and children's products and any other goods the safety of which is controlled by specific legislation.

Recall of Consumer Products

A mandatory recall will take place when the Commissioner of C&ED has a reasonable belief that the goods do not comply with an approved standard or a safety standard or safety specifications established by regulation; or in a case for which safety standards have not been approved, are, or may be, unsafe; and there is a significant risk that the consumer goods will cause a serious injury. In those circumstances, the Commissioner may serve a notice requiring the immediate withdrawal of those consumer goods from being supplied and the retrieval of those items already supplied.

A voluntary recall can be conducted by traders to remove non-complying or defective products which may be unsafe to consumers from the distribution chain and, if necessary, to retrieve the items from the consumers, and to disseminate relevant information to the public about the product of concern.

Guidelines on Voluntary Recall of Unsafe Products provide useful information for traders who wish to conduct a voluntary recall of consumer products, particularly on:

1. the recall arrangements;
2. content requirements for recall notifications. All notifications to be disseminated to the public should contain accurate information in plain and understandable language and should use both Chinese and English;
3. requirements to monitor the recall progress; and
4. requirements to notify C&ED before commencing a voluntary recall.

Liabilities

A person who supplies, manufactures or imports into Hong Kong consumer goods that do not meet general safety requirements or the approved standard, will be liable (a) to a fine of HK$100,000 and to imprisonment for 1 year on first conviction, and (b) to a fine of HK$500,000 and to imprisonment for 2 years for subsequent conviction. There will be an additional daily fine of HK$1,000 for continuing offences.

Information on voluntary recall of specific products

The table below sets out the key information relating to recalls of specific products:

Products to be recalled	Who is responsible	Which authority	When to report	Useful references
Toys & children's products	Traders in toy & children's products	C&ED	A notification should be submitted to C&ED before commencement of the recall.	Guidelines on Voluntary Recall of Unsafe Products
Food Products	Food traders	Food and Environmental Hygiene Department	Food traders to immediately notify the authority as soon as an incidence of a potential food recall arises.	Food Recall Guidelines
Pharmaceutical Products	Manufacturers, importers, distributors or certificate holders of pharmaceutical products ("Licensees")	Drug Office of the Department of Health	When the Licensee decides to initiate a recall on a pharmaceutical product. Serious problems that may lead to recall of products must be reported within 24 hours of receipt of the complaint or report for investigation.	Pharmaceutical Products Recall Guidelines
Chinese Medicines	Chinese medicines traders, including: 1. licensed wholesalers of Chinese herbal medicines; and 2. licensed manufacturers and wholesalers of proprietary Chinese medicines.	Chinese Medicines Board of the Chinese Medicine Council of Hong Kong	Once the Chinese medicines trader has decided to initiate the recall action.	Recall Guidelines for Chinese Medicine Products
Medical devices	The local responsible person ("LRP") of a listed medical device	Medical Device Control Office	Upon the issuance of recall by manufacturer or overseas authorities, and not later than 10 calendar days after such issuance.	Code of Practice for Local Responsible Persons
Electrical Products	Manufacturers, importers or suppliers of electrical products	Electrical Mechanical Services Department ("EMSD")	Before conducting the recall, the responsible party should consult with EMSD to reach prior agreement on the recall strategy.	Guidelines on Voluntary Recall of Electrical Products Not Complying with the Safety Requirements

Tips for smooth handling of product recalls

1. C&ED and other authorities do closely monitor overseas product recall announcements. They will usually be able to determine whether a product is being made available in Hong Kong. If they have not previously been contacted by the local traders in respect of plans for a Hong Kong recall, they may publicise the overseas recall announcement on their website and initiate contact with the relevant traders. To avoid this, it is important to (1) coordinate recalls between different jurisdictions and (2) keep C&ED or the relevant regulators informed of recalls on a "countdown" basis.
2. There can be uncertainty as to which class of products a particular item falls within. For example, certain items of apparel and infant paraphernalia may be classed as toys and children products or consumer products, with consequent impact on required safety standards and recall protocols. It is important for traders to understand these nuances in advance.

FOOD AND BEVERAGE LICENSING

The Public Health and Municipal Services Ordinance (Cap 132) and the Food Business Regulation (Cap 132X) empower the Director of Food and Environmental Hygiene to licence and supervise food businesses in Hong Kong. The purpose of the licensing regime is to ensure food safety and hygiene. Further, the Dutiable Commodities Ordinance (Cap. 109) and the Dutiable Commodities (Liquor) Regulations (Cap. 109B) empower the Liquor Licensing Board under the Food and Environmental Hygiene Department ("**FEHD**") to regulate the sales of liquor.

If you are contemplating the following types of business, you should be aware that a licence, permit, registration or other form of application will very likely be required before commencement of business operation:

- **Type of business** – You need a "licence" if you intend to operate a restaurant, bakery, cold store, factory canteen, food or milk factory and composite food shops.
- **Kind of food and beverage** – You need a "permit" if you intend to sell restricted foods such as non-bottled drinks, milk and milk beverages, raw meat and food sold by vending machines. Separately, if you intend to sell liquor at any premises for consumption on the premises, or if the supply of liquor is intended at any premises used by a club for the purpose of the club, you will need a "liquor licence" and "club liquor licence" respectively.
- **Origin of the food and raw ingredients** – You need a "registration" if you intend to import goods into Hong Kong and need a further application if you import perishable and high-risk food items, including game, meat, poultry and eggs, milk and milk beverages, frozen confections and marine products.

It is advisable to apply for the licences and permits well ahead of business launch

Many types of "narrowly-scoped" licences – The licensing regime for food and beverage in Hong Kong is very complex as there are many categories and sub-categories of licences and permits with different licensing requirements and application procedures, and your business operation may well require more than one class of licences or permits. If you intend to operate your business in multiple locations, separate licences or permits may be required for each such location. Government fees are charged on a per licence or permit basis and these costs can mount up.

Preparing the application documents – In general, application documents comprise of an application form (some of them can be submitted online), business records (e.g. business registration certificate and articles of association), floor plans, certificates etc, which take time to prepare, especially when there are multiple business locations.

Licensing conditions may affect business planning – Conditions to obtain and maintain licences and permits vary and the Director of Food and Environmental Hygiene has the autonomy to stipulate conditions additional to the standard conditions. These conditions may affect your business model or structure (e.g. location of warehouse, food transportation arrangements, supply chain and workforce planning). You may also wish to allocate responsibility for satisfying some of these conditions to other parties (e.g. landlord to provide storage facilities and employees to provide vaccination records) during the contract negotiation process.

Lengthy application process – The FEHD operates a "provisional licensing system" to facilitate the setting up of food businesses. A provisional food business licence is issued to premises that have satisfied all essential health, building and fire safety requirements within one working day. A provisional licence is valid for six months, during which the licensee needs to complete all outstanding requirements for the issuance of a full licence. Having said that, if you intend to apply for a "permit" but not a "licence", there is no faster route. It could be difficult for the FEHD to give an indication (let alone a promise) on the time needed to approve your licence or permit application as they need to review application documents, work with other government departments and arrange site visits. You should expect multiple rounds of requisitions from the FEHD (or possibly phone calls and meetings with the FEHD) and be prepared to supply additional information or documents requested.

Tips to facilitate the application process

Review the guides to application – The FEHD publishes detailed guides on how to apply for each class of licence and permit. The guides contain important information such as licensing requirements, application process and standard conditions.

Check the exemptions – You should be aware that there are exemptions for some licences or permits if you are holding another kind of licence or permit. These exemptions are usually stated in the guides, or otherwise, the application forms.

Make a general enquiry with the FEHD – Rapid technological advances create opportunities for food and beverage industries but at the same time could result in uncertainties in the regulatory regime. We have seen occasions where the FEHD has not kept pace with technological changes, such that (i) it could be difficult to understand whether your business requires a licence or permit merely based on the guides to application and (ii) the expectation of the FEHD might not have been adequately and clearly reflected in the guide. We have also observed inconsistencies in the naming of the licences and permits which may create confusion. For instance, "Permit to sell food by means of vending machines" and "Coin-operated Automatic Vending Machine Permit" mean the same thing. We suggest making a call to the FEHD in case of any confusion.

Check the licences and permits obtained by comparable businesses – The website of FEHD contains a search engine for searching existing licensees and licensed premises for free. This is a very useful tool if you are uncertain on the type of licences or permits required but you are aware that another company is pursuing comparable business.

BROADCASTING AND TELECOMMUNICATIONS LICENSING

In Hong Kong, the Broadcasting Ordinance (Cap 562) and the Telecommunications Ordinance (Cap 106) ("**TO**") empower the Communications Authority ("**CA**") to oversee the licensing regime for the provision of broadcasting services and telecommunications services respectively.

Broadcasting services

The scope of "Broadcasting service" is limited to television programme service and the licences are not numerous:

Provision of television programme service – If you intend to provide a television programme service, you will need a **Television Programme Service Licence**. The class of licence you need will depend on whether the service is provided domestically or non-domestically, pay or free.

Provision of sound broadcasting – Sound Broadcasting Licence is usually limited to broadcasting of commercial free-to-air radio services and analogue radio services.

Telecommunications services

"Telecommunications service" refers to a service for the carrying of communication by means of guided or unguided electromagnetic energy or both. There are four commonly seen types of licences under the existing licensing regime:

Establishment of facility-based telecommunications network – "telecommunications network" means "a system, or series of systems, for carrying communications by means of guided or unguided electromagnetic energy or both". If you intend to provide facility-based public telecommunications services (e.g. establish telecommunications circuits and networks across public street and unleased government land), you will need a Carrier Licence.

Provision of non-facility-based telecommunications services – If you intend to provide public telecommunications services by relying on the fixed or mobile networks established by facility-based operators (i.e. the carrier licensees), you will need a **Services-based Operator Licence** ("**SBO Licence**"). There are many classes and sub-classes of SBO Licences, and it may be difficult at times to identify which SBO Licence you need to obtain. Class 1 and Class 2 SBO Licences are for local voice telephony services. Class 3 contains many sub-classes for specific types of telecommunications services, for example, international value-added network services, mobile virtual network services, teleconferencing services and mobile communication services on board an aircraft.

Provision of radiocommunication services – "radiocommunications" means "telecommunications by means of radio waves;". If you intend to provide public radiocommunications services or to establish, maintain, possess and use the radiocommunications apparatus, you will need a **Public Radiocommunications Service Licence**.

Establishment or maintenance of any means of telecommunications – section 8 of the TO prohibits anyone in Hong Kong or on board any ship, aircraft or space object that is registered or licensed in Hong Kong to, among others, establish or maintain any means of telecommunications. The only way to circumvent this prohibition is to obtain a relevant **Class Licence**. This type of licence will catch the telecommunications operators which do not operate any telecommunications facilities. For example, service providers who simply resell, under their own brand names or service packages, telecommunications services on a wholesale basis from, and operated by, licensed operators, would require a Class Licence for Offer of Telecommunications Services.

Practical tips in applying for a licence

Identify the required type(s) and class(es) of licence – We find several ways helpful to identify the required licences for your contemplated business and operation:

- Start with a thorough read of the detailed licensing guidelines for each type of licence which are available to public on the website of the CA. The guidelines usually contain information on who should apply for the licence, scope of licenced services permitted, application procedures and documentation required.
- After narrowing the possible types and classes of licences you may need, a phone call to the licensing division of the CA can help corroborate your findings and clarify any confusion. Before making the call, we recommend you have a chart detailing your contemplated business and operation in hand such that you will be ready to answer any questions the licensing officer may have. You can make a general enquiry on a "no-name" basis.
- Another useful tool is to conduct a public search of licences held by other companies providing comparable products or services. A list of licensees is available for some (but not all) licences on CA's website, including Carrier licensees and SBO licensees.
- One question that may arise is whether the contemplated telecommunications service is provided in Hong Kong and therefore within the purview of the Hong Kong telecommunications licensing regime. This issue will be even more complicated if the contemplated telecommunications service is to be provided in an aircraft or a vessel which will cross the border. We recommend seeking legal advice if those complications arise as public international laws may be involved.

Prepare to satisfy the licensing conditions – To apply, maintain or renew a licence, it is necessary that all licensing conditions are fulfilled and the fees are paid.

- The CA publishes the sample licence, which contains the standard terms and conditions, for each type of licence on its website. The bodies of the licences are mostly similar so pay more attention to the schedules, which contain the scope of the licenced services, technical particulars and specific requirements to that type of licence.
- We also recommend a thorough read of other documents issued by the CA (such as list of application documents required, code of practice, circular letters, etc.) and prepare supporting documentations well in advance of business launch.
- Beware that the CA periodically reviews and updates the period of validity and licence fees for each type of licence and they are usually in effect immediately upon issuance.

Beware of changes to licensing regime – In the world of rapid technological advancement, the CA's licensing regimes undergo changes from time to time.

- Just within the last few years, some significant reforms have been made to the licensing regime, for example, the introduction of the Localised Wireless Broadband Service Licence and the Wireless Internet of Things Licence to prepare for the 5G era. As these licences are relatively new, they may give rise to and get unanswered questions as to scope and applicability to novel methods of business.
- You should also be aware that licensing regimes may change without a long grace period. You can expect changes to the licensing regimes if there are new regulatory objectives, introduction of new technologies, etc. The CA is only mandated to conduct public consultation for certain type of licences (such as Carrier Licences) although it will generally operate an even-handed approach to consultation and transitional arrangements.

PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICE REGULATIONS

Regulatory frameworks of pharmaceutical products

A "pharmaceutical product" or "medicine" means any substance, or combination of substances presented as having properties for treating or preventing disease in human beings or animals, that may be used in, or administered to, human beings or animals, either with a view to (a) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or (b) making a medical diagnosis.

Pharmaceutical products are regulated by several pieces of legislation including Pharmacy and Poisons Ordinance (Cap. 138)(the "**PPO**"), Pharmacy and Poisons Regulations (Cap. 138A), Antibiotics Ordinance (Cap. 137), Dangerous Drugs Ordinance (Cap. 134) and Undesirable Medical Advertisement Ordinance (Cap. 231), Public Health and Municipal Services Ordinance (Cap. 132) and Import and Export Ordinance (Cap. 60).

The Drug Office of the Department of Health is the authority responsible for enforcing the legislative provisions for pharmaceutical products. The Pharmacy and Poisons Board of Hong Kong ("**PPB**") is a statutory body established under the PPO to carry out functions including (a) registration and classification of pharmaceutical products, (b) licensing and regulatory control of wholesale dealers and manufacturers of pharmaceutical products, (c) licensing and regulatory control of retail traders of pharmaceutical products, and (d) registration and regulation of pharmacists.

Registration requirement - Subject to certain exceptions, all pharmaceutical products must be registered with the PPB before they can be sold, offered for sale, distributed or possessed for the purpose of sale, distribution or other use in Hong Kong.

Products falling under the following categories do not need to be registered with the PPB:

1. Products containing only proprietary Chinese medicines or Chinese herbal medicines as defined in the Chinese Medicine Ordinance;
2. Drug substances imported by licensed manufacturers solely for the purpose of manufacturing their own pharmaceutical products;
3. Products possessed or used under the direction of a registered medical practitioner or a registered dentist for the treatment of a particular patient;
4. Products imported for re-export only;
5. Products manufactured in Hong Kong for export by the licensed manufacturer only; and
6. Products administered for the purpose of a clinical trial/ medicinal test.

Classification of pharmaceutical products - Depending on the severity of disease the products are intended for and the magnitude of the side effects they can cause, pharmaceutical products are divided into the following three categories:

1. Prescription-only medicines are products which can be supplied by prescription only. Products under this category include antibiotics and dangerous drugs;
2. Pharmacy-only medicines are products which cay be purchased in a pharmacy in the presence and under the supervision of a registered pharmacist, but without the need for a prescription; and
3. Over-the-counter medicines (OTC medicines) are products which can sold in any retail outlet if not containing any poisons (as defined under the Pharmacy and Poisons Regulations) or sold by authorised sellers of poisons and listed sellers of poisons, if containing poisons.

Retailers – there are two types of retailers of pharmaceutical products:

1. Listed sellers of poisons (commonly known as medicine stores) are only permitted to sell OTC medicines; and
2. Authorised sellers of poisons (commonly known as pharmacies or dispensaries) are authorised to sell all three categories of medicines under specific conditions.

Other licensing requirements

Import/export – all imports and exports of pharmaceutical products are subject to import and export licenses issued by the Trade and Industry Department.

Wholesaler Dealer License – required for persons dealing in the wholesale and import/export of poisons and pharmaceutical products.

Wholesale Dealer's License to Supply Dangerous Drugs – required for persons dealing in the wholesale of dangerous drugs.

Antibiotics Permit – required for persons dealing in and to possess antibiotics.

License for Manufacturer – required for persons dealing in the manufacture of pharmaceutical products.

License for Manufacturer (secondary packaging) – required for personal dealing in the manufacturing of secondary packaging for pharmaceutical products.

License to Manufacture Dangerous Drugs – required for persons dealing in the manufacture of dangerous drugs.

Practical Tips

When deciding whether a product requires registration as a pharmaceutical product, both the (a) indication and use, and (b) product ingredients are important factors for consideration. In practice, if a personal care product contains a poison product which is in Part 1 of the Poisons List under the Pharmacy and Poisons Regulations, the product will likely be required to be registered, regardless of whether the product is "medicinal" in nature or not. The Drug Office has published useful guidance materials for the pharmaceutical trade, such as the Guidance Notes on Registration of Pharmaceutical Products, and the Guidance Notes on Classification of Products as "Pharmaceutical Products" under the PPO.

Regulatory framework of medical device

Currently, there is no specific legislative control over the manufacture, importation and sale of medical devices in Hong Kong. Pending the enactment of any statutory controls, Hong Kong currently adopts a voluntary administrative system for medical devices, namely the Medical Device Administrative Control System ("**MDACS**") which allows listing of medical devices (except for class I devices) upon satisfying the conformity assessment requirements.

The MDACS, which is administered by the Medical Device Control Office of the Department of Health ("**MDCO**"), consists of a number of administrative control measures including the following:

1. **Listing System** – the MDCO maintains (a) the list of medical devices (excluding class I medical device) that have been shown to conform to accepted standards of safety and efficacy, and (b) other lists of local manufacturers, distributors, and conformity assessment bodies;
2. **Requirements of a local responsible person ("LRP")** – an overseas manufacturer who wishes to list its medical device on the MDACS, must appoint an LRP if the manufacturer has no registered place of business in Hong Kong. The LRP has numerous obligations including: a liaison role with users, importers, the public and authorities; maintaining distribution records and tracking system for certain high-risk medical devices; handling complaints; product alerts; modifications; recalls and advertisements; and
3. **Adverse incident reporting system** – which requires LRP to report to MDCO any adverse incidence concerning a listed medical device that has occurred in Hong Kong.

Classification of Medical Devices

The MDACS adopts the risk-based classification rules promulgated by the Global Harmonization Task Force, which classifies medical devices (other than *in vitro* diagnostic medical devices) into four classes (Class I, II, III and IV) with class I as low risk to class IV as high risk. Apart from class I medical devices, and certain type of devices which are expressly excluded, all other types of medical devices can be listed on the MDACS.

Upcoming reform

There are ongoing discussions about the implementation of a statutory regulation framework for medical devices. The regulation will comprise of (a) pre-market control of the medical devices to ensure safety, quality, performance and efficacy of the device, and (b) post-market control to ensure swift control measures against defective and unsafe medical devices. In relation to the pre-market control, the regulation will impose (a) mandatory registration requirements for Class II- IV general medical devices, and Class B-D *in vitro* diagnostic medical devices, and (b) registration and licensing requirements for traders of medical devices. For the medical devices which have been listed on the MDACS, there may be certain exemptions available to ensure a smooth transition of the MDACS to the statutory regime. As such, it would be beneficial for the medical device trade to list its medical devices with the MDACS to take advantage of the exemption measures. While there have been no announcements as to the actual implementation of the statutory framework, our understanding is that the legislature is at the stage of finalising the relevant legislation.

PUBLIC PERFORMANCE LICENSING

Songs and films are usually made up of several elements of copyright works created by different people, which are copyright works protected under the Copyright Ordinance (Cap. 528) (the "**CO**"). For example, a music video is a combination of melody (as a musical work), lyrics (as a literary work), sound recording and audio-visual recording, all of which could be created by different people (the copyright owners).

Under the CO, copyright owners have the exclusive right in relation to the performance, playing or showing of copyright works in public. Performing, playing or showing songs, music or movies in public places requires a licence to be obtained from copyright owners or the relevant copyright licensing bodies.

How to obtain a copyright licence for public performance of a song?

Who: As shown above, since a song embraces several copyright works from different copyright owners, separate "public performance" licences granted by different copyright owners may be required.

Where: Most copyright owners have appointed copyright licensing bodies to administer the rights of performance, playing or showing their songs and music in public on their behalf.

In the local music industry, major copyright licensing bodies include:

(i) Composers and Authors Society of Hong Kong (also commonly known as "**CASH**") (https://www.cash.org.hk/home), which represents a group of composers and authors and grants licences for public performance of music and song; and

(ii) Phonographic Performance (South East Asia) Limited ("**PP(SEA)L**") (http://www.ppseal.com) and Hong Kong Recording Industry Alliance Limited ("**HKRIA**") (https://www.hkria.com/en/index.aspx), which represent different music record companies and grant licences for playing/showing sound and audio-visual recordings in public.

How: In general, licences for public performances are subject to payment of royalties or licensing fees. If you want to have live performance of the music or songs without playing any sound or audio-visual components, you only require a licence from CASH. However, if your performance involves the showing of any sound or audio-visual recordings, you may also need to obtain a public performance licence from HKRIA and PP(SEA)L.

If you wish to play music recordings in your business premises, you will need to obtain a licence form the relevant copyright licensing agents. There are different types of licence depending on how the music recordings are used. Please check with the relevant licensing agents for specific licensing requirements.

Exemption:

According to section 76 of the CO, you don't need to apply for licences for performing, showing or playing music-related copyright works (other than showing or playing a broadcast or a cable programme) as part of the activities of, or for the benefit of, a club, society or other organization if the following two conditions are met:-

a) the main objects of that club, society or organization are charitable or are otherwise concerned with the advancement of religion, education or social welfare; and

b) the proceeds of any charges for admission to the place where the music-related copyright work to be performed, shown or played are applied solely for purpose of that club, society or organisation.

How to obtain a copyright licence for public performance of a film?

The CO requires users to apply for licences for playing or showing a film in public venues.

Who: Similar to music and songs, a film embraces different copyright works from different copyright owners. You should beware that the sound-track accompanying a film, is treated as part of the film, so you should also obtain a licence for playing the film sound-track which accompanies the film.

Where: One of the major copyright licensing bodies in the movie industry is Motion Picture Licensing Company (Hong Kong) Limited (MPLC) ((http://www.mplc.com.hk). MPLC acts on behalf of the major film and television producers by administering public performance rights for their films and cable programmes in various non-theatrical markets and granting licences for public performance.

How: You should enquire with MPLC (for films and other programmes administered by MPLC) or the relevant copyright owners for obtaining a licence to cover the public performance.

Exemption:

The exemption as mentioned above for music and songs also applies as an exemption for playing or showing a film in public.

Under the CO, if you are playing or showing a film, broadcast or cable programme before an audience consisting wholly or mainly of teachers or pupils at an educational establishment for the purposes of giving or receiving instruction, you may not need to apply for a licence. It is worth noting that, the act in question should not conflict with a normal exploitation of the work by the copyright owner and should not unreasonably prejudice the legitimate interests of the copyright owner.

Practical tips

Who is liable to obtain the licenses?

The person who wishes to play the copyright work in public muat obtain the public performance license. This could be the shop owner, the operator of a live performance venue or the person performing the copyright work in public.

Who do I obtain the license from?

We suggest first approaching the licensing bodies in Hong Kong as they represent most of the production houses in the market. For works created by independent authors, you should contact the author directly. But note, you many need to obtain a license from more than one licensing body. If you are playing a CD in the shop premises, you may need a license from CASH for a public performance license granted by the composers and authors, as well as a license from HKRIA or PPSEAL for playing the sound recordings.

What type of license do I need?

Once you have identified the appropriate licensing body, you need to consider the type of license required. The licensing bodies provide different types of licensing regime depending on how the copyright works are used. For example, an annual licensing plan is available for unlimited playing or showing of copyright works at a fixed premises, or a one-time license for performance of copyright works at an event.

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