

Consumer Protection of Medical Beauty Services

A New Regulatory Regime



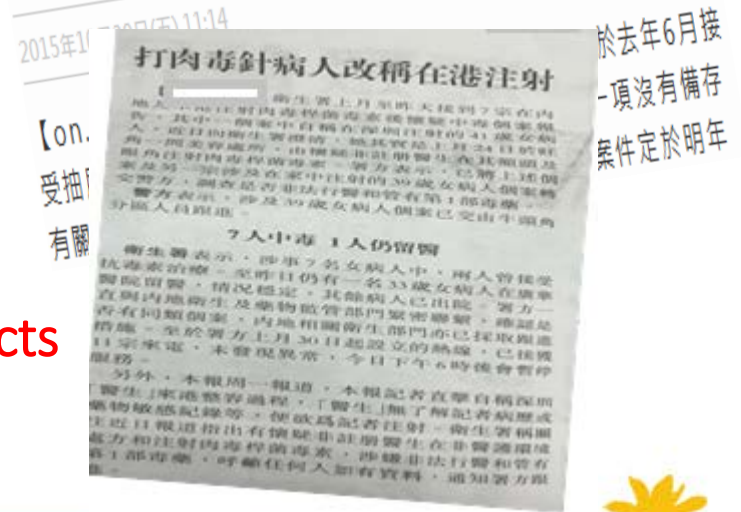
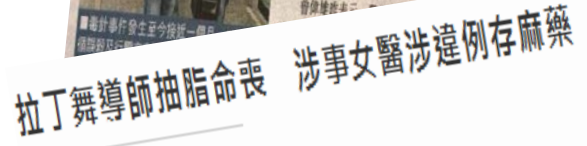
12 December 2016



Fatal/Serious Incidents of Medical Beauty Services

- 2012
 - DR incident: one woman died, three women seriously ill after receiving intravascular infusions
- 2014
 - one woman died after liposuction
- 2016
 - 10 botulism cases after injections, difficulties in standing and walking, swallowing, speaking and breathing

→ Serious consequences and irreversible impacts on consumer health & wellbeing





Complaint Cases

Complaints on medical beauty services*	2015	Jan – Oct 2016
Total	143	202
Service quality	64	82
Sales practices	37	64
Safety issues	27	30
Price disputes	7	6
Others	8	20

Examples:

- Laser treatment by medical practitioner causing injuries
- Injection treatment by non-registered medical practitioners (forwarded to DH)
- Physical damage with ultrasound treatment
- Bait advertising on group buying website
- Misleading prices (discounts on inflated original prices)

→ Poor service quality & questionable sales practices

* Complaint statistics in medical beauty services such as application of high energy and invasive procedures





Objectives of the Study

1. Gauge the level of consumer understanding on the medical beauty services

2. Analyse the key issues of consumer concerns

3. Examine the regulatory regimes in other jurisdictions

4. Assess the manner in which Hong Kong should regulate

5. Make recommendations to enhance consumer protection





Methodology

Local Consultation

- Consultations to 9 organisations including Gov't Depts (DH & CED), Beauty Sector (CPAHK & FBIHK), Medical Professions (HKMA, HKACS, HKCD & HKSDV) & Academics (Division of Clinical Psychology of HKPS)

Regulations in Other Jurisdictions

- Research works and consultations in 7 other jurisdictions (Korea, Mainland China, Singapore, Taiwan, UK, US – California & Florida)

Consumer Research – Three Stages

- Telephone survey of 1,004 users and non-users (Feb – Mar 2016)
- On-street interviews of 602 users (Jun – Jul 2016)
- Focus group discussions of 72 users and non-users (Aug – Sep 2016)

Enquiry Visits – Market Practice

- 30 enquiry visits conducted by the Council staff as consumers
- Covered 9 beauty salons, 13 medical beauty centres, 4 medical beauty clinics and 4 private hospitals (Jun – Aug 2016)





Existing Situation

Lack of specific legislation & competency requirements to govern medical beauty services

Any related law & regulation?

- Only general consumer protection legislations exist
- No specific legislation to govern the industry
 - Control over import, sale & use of related medical devices

Any competency requirement?

- Only 15 high-risk medical beauty procedures
 - Must be performed by medical practitioners/dentists
 - No specific requirement on competency/experience
- Other medical beauty procedures
 - Can be performed by any person





Local Industry's Views

Diverse views on the scope of regulation but shared that a clear definition is needed

What is the definition?

- “Medical beauty service” refers to the improvement of physical appearance with the use of medical means, knowledge or technologies
- HKMA: Need for legal definition on “medical treatment”

How they think about the current classification*?

- Medical profession: **Supported**
- Beauty sector: **Disagreed**; should be differentiated by nature, not by risk (affected by practitioner’s qualification & experience)

Who could perform the service?

- Beauty sector: **Both** beauticians & medical doctors
- HKMA & HKCD: **Only** medical doctors but no need to be specialists

* i.e. The list of medical beauty procedures with potential safety concerns as recommended by the Government’s Working Group on Differentiation between Medical Procedures and Beauty Services





Key Findings

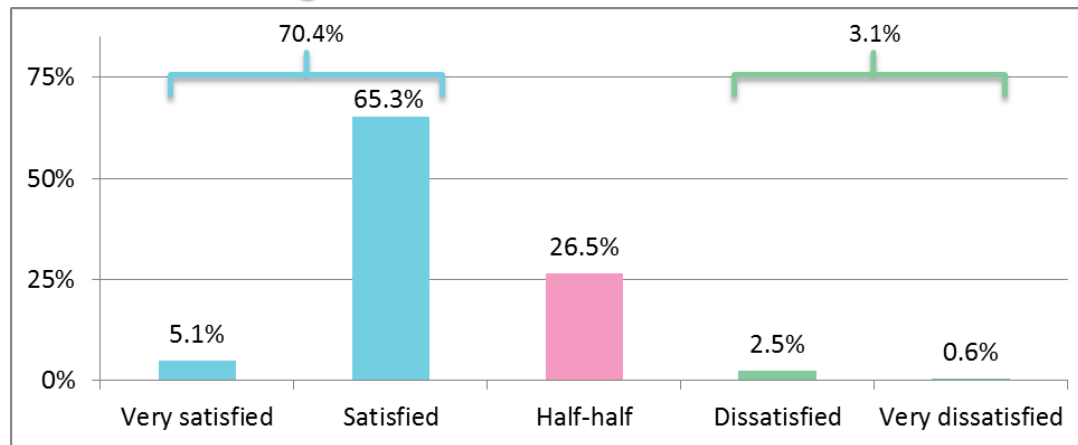
1. Consumer Choice





Satisfaction towards Medical Beauty Services

High consumer satisfaction



Base: All persons who had used medical beauty services (i.e. n = 602; N = 1,015,301)

Why satisfied?

- ✓ Results met consumers' expectation 97.2%
- ✓ Good customer service 1.6%
- ✓ The service providers explained comprehensively 1.1%
- ✓ Others (e.g. reasonable price, the treatment was performed by doctor) 0.9%

Base: All persons who were satisfied with the medical beauty services (i.e. n = 435; N = 714,833)

Why dissatisfied?

- ✗ Results could not meet consumers' expectation 75.3%
- ✗ Felt like unprofessional/being cheated 34.3%
- ✗ Others (e.g. could not use up all purchased treatments before expiry date, impolite & did not perform the treatment well) 32.0%

Base: All persons who were dissatisfied with the medical beauty services (i.e. n = 14; N = 30,914)





Prevalence and Use

- 20.1% aged 15-64 had used medical beauty services*,
female : male = 82.6% : 17.4% , major user group aged 25-44 (52.0%)
- Laser therapy, the most popular medical beauty service ever used, followed by JETPEEL & Radiofrequency

Procedures involving external application of energy (79.0%)	Procedure involving mechanical/chemical exfoliation of skin (33.1%)	Procedures involving skin puncture (15.8%)	Other procedures that may pose safety concerns (10.1%)
Laser therapy (61.8%)	JETPEEL (23.8%)	Microneedle therapy (7.5%)	Colon hydrotherapy (4.3%)
Radiofrequency (21.9%)	Chemical peel (17.3%)	Skin whitening injection (6.7%)	Plastic surgery (2.2%)
Intense pulsed light (18.9%)	Water microjet plus vacuum (4.1%)	Botulinum injection (3.2%)	Hair transplant (2.2%)

* Medical beauty services referred to the listed medical beauty procedures with potential safety concerns as recommended by the Government's Working Group on Differentiation between Medical Procedures and Beauty Services in HK





Usage Pattern

Vast majority of users undertook the service in beauty centres located in Hong Kong, used at least once a month

Purpose

- 74.9% to keep looking young or beautiful
- 11.5% to deal with some bodily problems/to improve self-confidence

Frequency & Payment

- 52.5% used at least once a month
- When purchase the service, spent \$6,600 on average, with most of them (65.6%) being one-off payment

Place & Venue

- 98.8% undertook in HK & in beauty centres (89.3%)
- Few in Mainland China (1.1%), overseas (0.4%) & in clinics (7.6%) or hospitals (2.8%)





Usage Behaviour

Quality as determining factor with information sourced mainly from family, relatives & friends, 2/3 claimed they understood the terms & risks but less on the materials/devices/qualifications of service providers

Determining Factors

- 79.5% 'Guaranteed service quality & safety'
- 59.0% 'Professional qualification of the service providers'
- 55.9% 'Well-equipped equipment & devices'

Source of Information

- 73.4% learned from family, relatives & friends
- 18.7% from online discussion forums/search engines & social media
- Only 1.7% sought advice from medical professionals

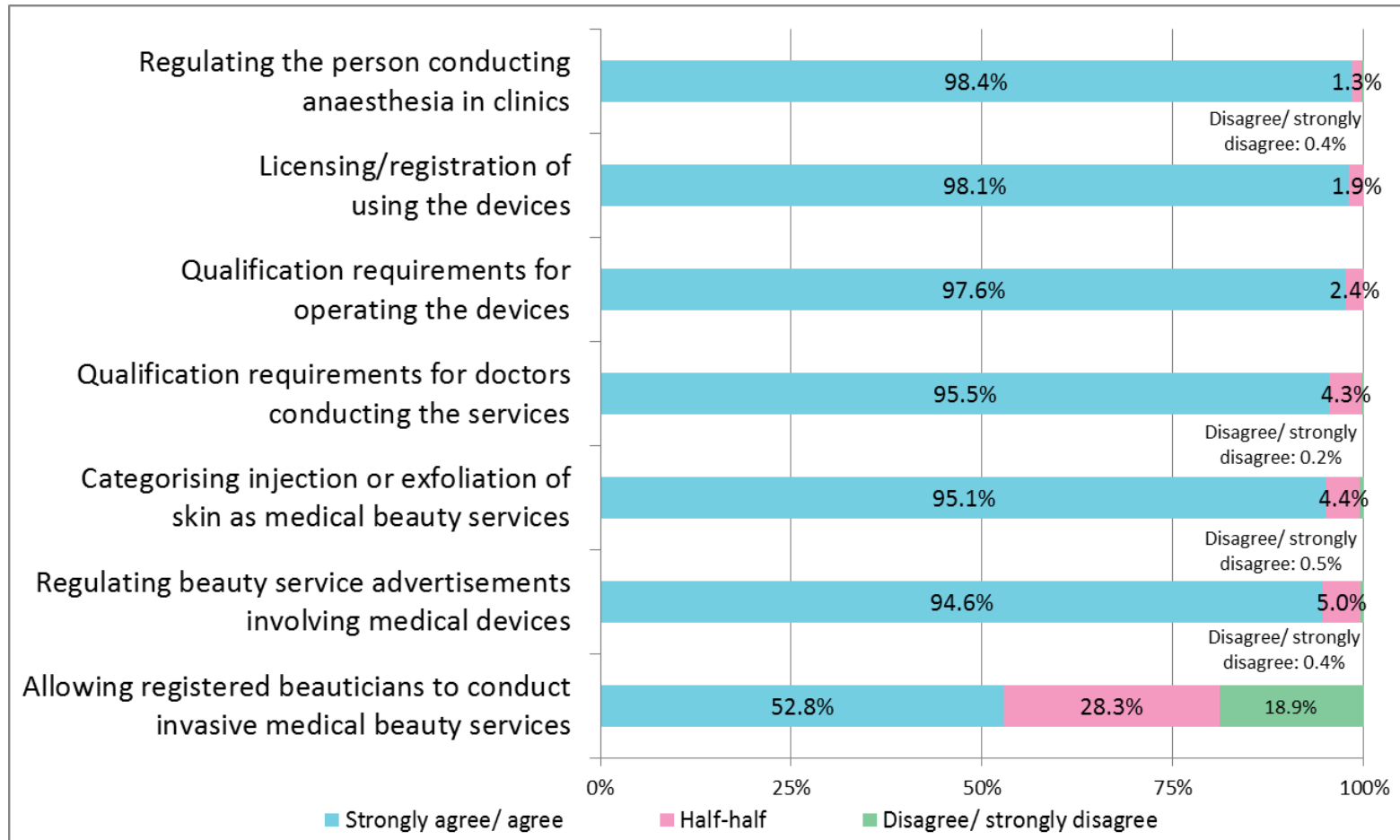
Understanding

- 66.5% claimed they understood the terms & 62.8% potential risks
- 47.6% claimed they understood the medicine, materials/devices used & 46.4% qualifications & experience of service provider





Consumer Views – High Agreement Level towards Legislative Regulations

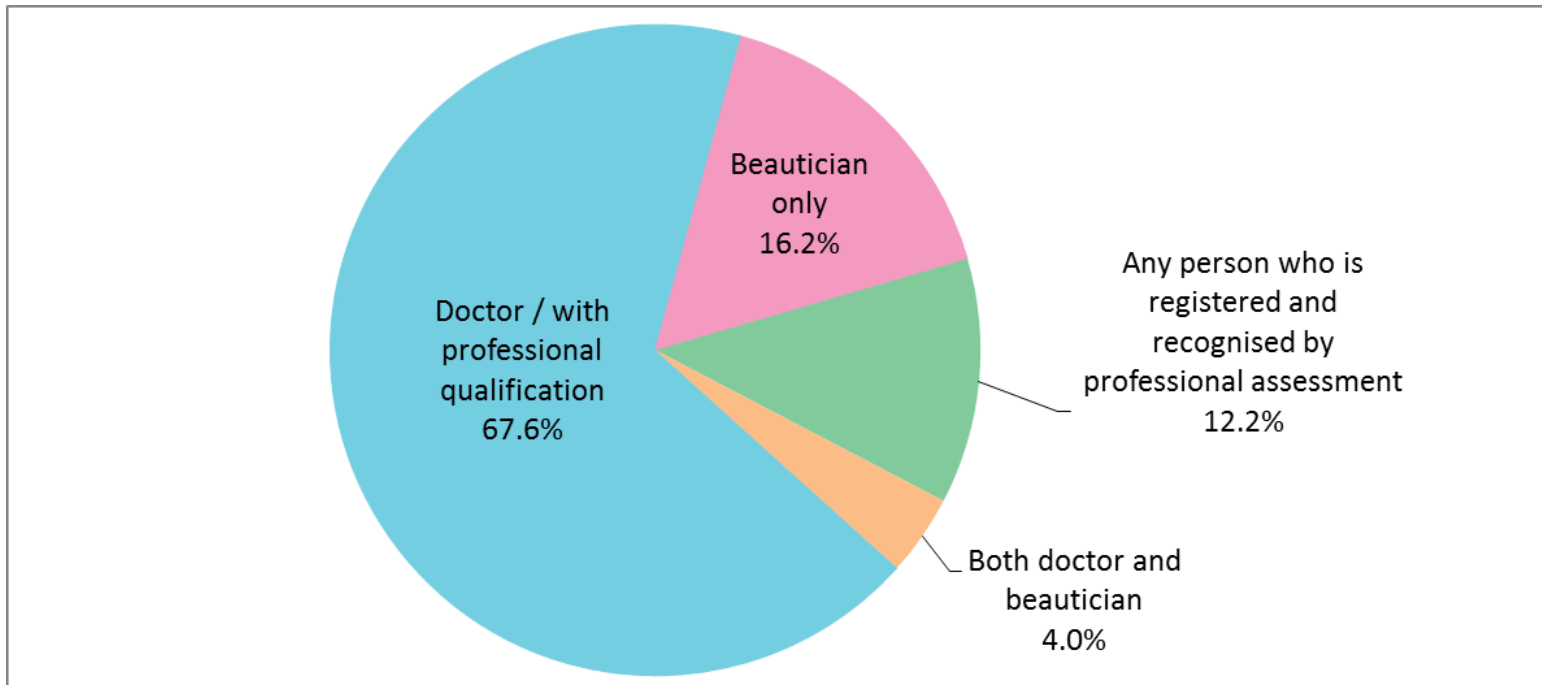


Base: All persons who had used medical beauty services (i.e. n = 602; N = 1,015,301)





Doctors / with professional qualification were most preferred for conducting high risk medical beauty services

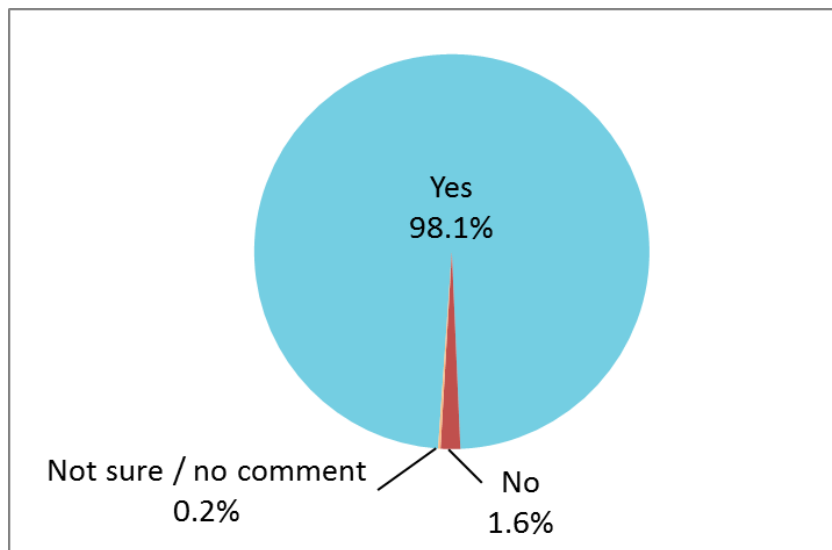


Base: All persons who had used medical beauty services (i.e. n = 602; N = 1,015,301)



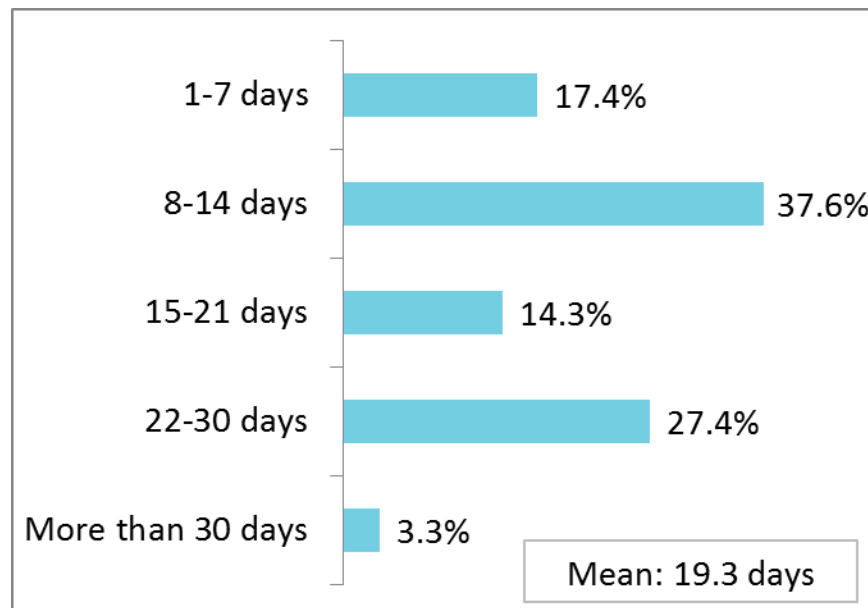
Vast majority agreed with the establishment of a cooling-off period, with strong support of 8-14 days

Whether agreed with the establishment of a cooling-off period



Base: All persons who had used medical beauty services (i.e. n = 602; N = 1,015,301)

Duration of cooling-off period



Base: All persons who agreed with the establishment of a cooling-off period (i.e. n = 592; N = 996,360)



Key Findings

1. Consumer Choice
2. Market Practices



Users Experience

Provision of information

- Materials were provided to facilitate consumers' understanding, 41.3%
- Found the materials believable, 79.5%

Sales tactics

- Being promoted of
 - “Services at trial/discounted price”, 57.7%
 - “Additional/upgraded services”, 29.3%
- Being criticised of “Appearance”, 28.4%

Unfavorable situations

- While undergoing services
 - Asked to pay extra to upgrade/buy other services, 29.8%
 - Cross-sell other services, 29.8%



Council's Observations – Beauty Centres vs Clinics/Hospitals (1)

	Beauty salons/ Medical Beauty Centres	Medical Beauty Clinics/ Private Hospitals
Setting	<ul style="list-style-type: none">• Some centres decorated in “clinic” setting & staff wore white lab coats	<ul style="list-style-type: none">• “clinic”, “hospital” setting
Service provider	<ul style="list-style-type: none">• Titles such as “beauticians”/“consultants”/“therapists”, qualifications not readily known• Centres’ medical doctors not always present, some were reluctant to provide doctor details	<ul style="list-style-type: none">• Medical doctors, some with specialty specified, some did not
Collection of personal information	<ul style="list-style-type: none">• Some collected HKID card no (not doctor-patient relationship) and personal health information	<ul style="list-style-type: none">• Collected HKID card no• Personal health records



Council's Observations – Beauty Centres vs Clinics/Hospitals (2)

	Beauty salons/ Medical Beauty Centres	Medical Beauty Clinics/ Private Hospitals
Provision of information	<ul style="list-style-type: none">• More on promotional information of product/service/treatment, effects & pricing	<ul style="list-style-type: none">• More on nature of product/service/ treatment, potential risks & side-effects
Selling approach	<ul style="list-style-type: none">• Focus on physical appearance• Promoting service to “solve” problem• Modelling effect• Foot-in-the-door techniques• Bait, aggressive selling tactics in some centres	<ul style="list-style-type: none">• Medical consultation (consultation fee was required)



Council's Observations – Beauty Centres vs Clinics/Hospitals (3)

	Beauty salons/ Medical Beauty Centres	Medical Beauty Clinics/ Private Hospitals
Pricing	<ul style="list-style-type: none">• Relatively cheaper• Verbal quotation and commitments (e.g. extension of service expiry date, pre-paid amount transferrable to other service or treatment)• Lobbying and provision of special price offers (“special offer for today”, “trial price”) to make quick purchase decision	<ul style="list-style-type: none">• More expensive• Verbal quotation• Lobbying and provision of special price offers for some clinics



Council's Observations – Beauty Centres vs Clinics/Hospitals (4)

- Other observations
 - Use of **medical devices was common**, however, their effectiveness, safety standards, user requirements, etc were difficult for consumers to ascertain
 - Different treatments (IPL vs laser) to the same fieldworker were suggested by different service providers, consumers rely on **service provider's judgement** on the choice of services or devices
 - Most beauty centre staff (except one case) explained the medical beauty **procedures that are restricted to be performed only by registered medical doctors**



Key Findings

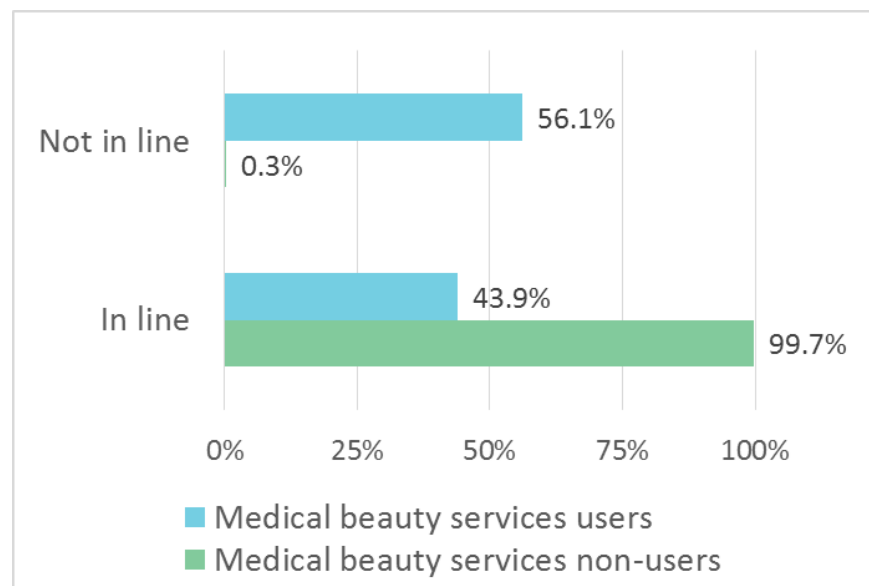
1. Consumer Choice
2. Market Practices
3. Perception and Identification



Different Conceptions of Users or Non-users

20.1% aged 15-64 had used “medical beauty services” (based on the classification of the Government’s working group). Among them:

- 56.1% users claimed that they had not used any medical beauty services when in fact they had used at least one of the listed medical beauty procedures after validation



Base: All persons aged 15-64 (i.e. n = 1,004; N = 5,046,700)

→ conception is not in line with the Government’s categorisation





Perception of Medical Beauty Services Users

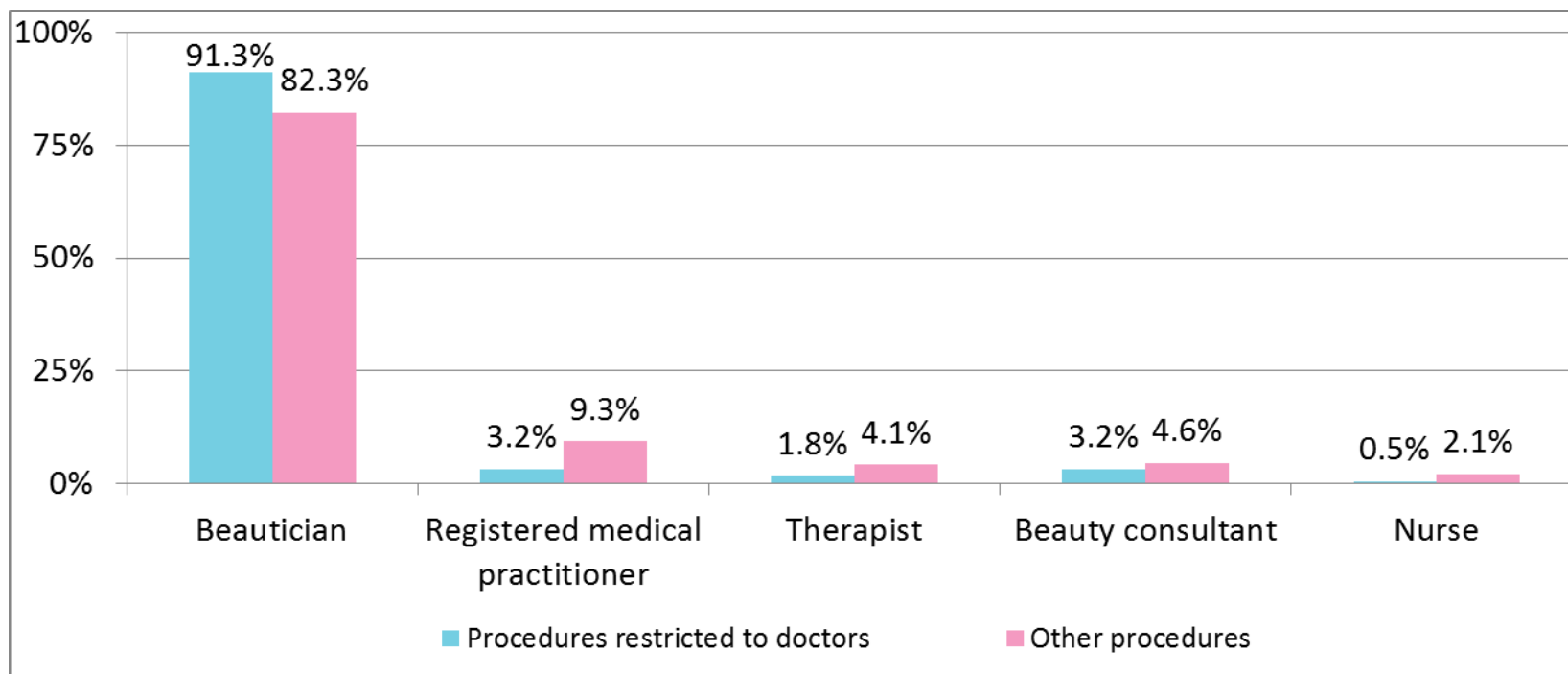
See it as ordinary beauty treatment but not medical beauty procedures

- 45.3% users held **positive** views
 - Effective”, “Trendy” & “Common”
- 81.3% considered the services as **normal beauty treatments**
 - “Not invasive” (32.3%)
 - “Common/Normal” (27.6%)
 - “Can be performed by beautician” (15.5%)
- 17.1% users held **conservative** views
 - “Risky” & “Expensive”
- For other users (17.8%), services to be classified as **medical beauty treatments**
 - “Required to be performed by doctors” (32.5%)
 - “Required to be performed in clinics/hospitals with high technology/advanced devices” (30.7%)



Users Experience

Vast majority said their medical beauty services were performed by beauticians, including those supposedly only performed by registered medical doctors according to current regulation*



* Base on the list of common medical beauty procedures with potential safety concerns as recommended by the Government's Working Group on Differentiation between Medical Procedures and Beauty Services

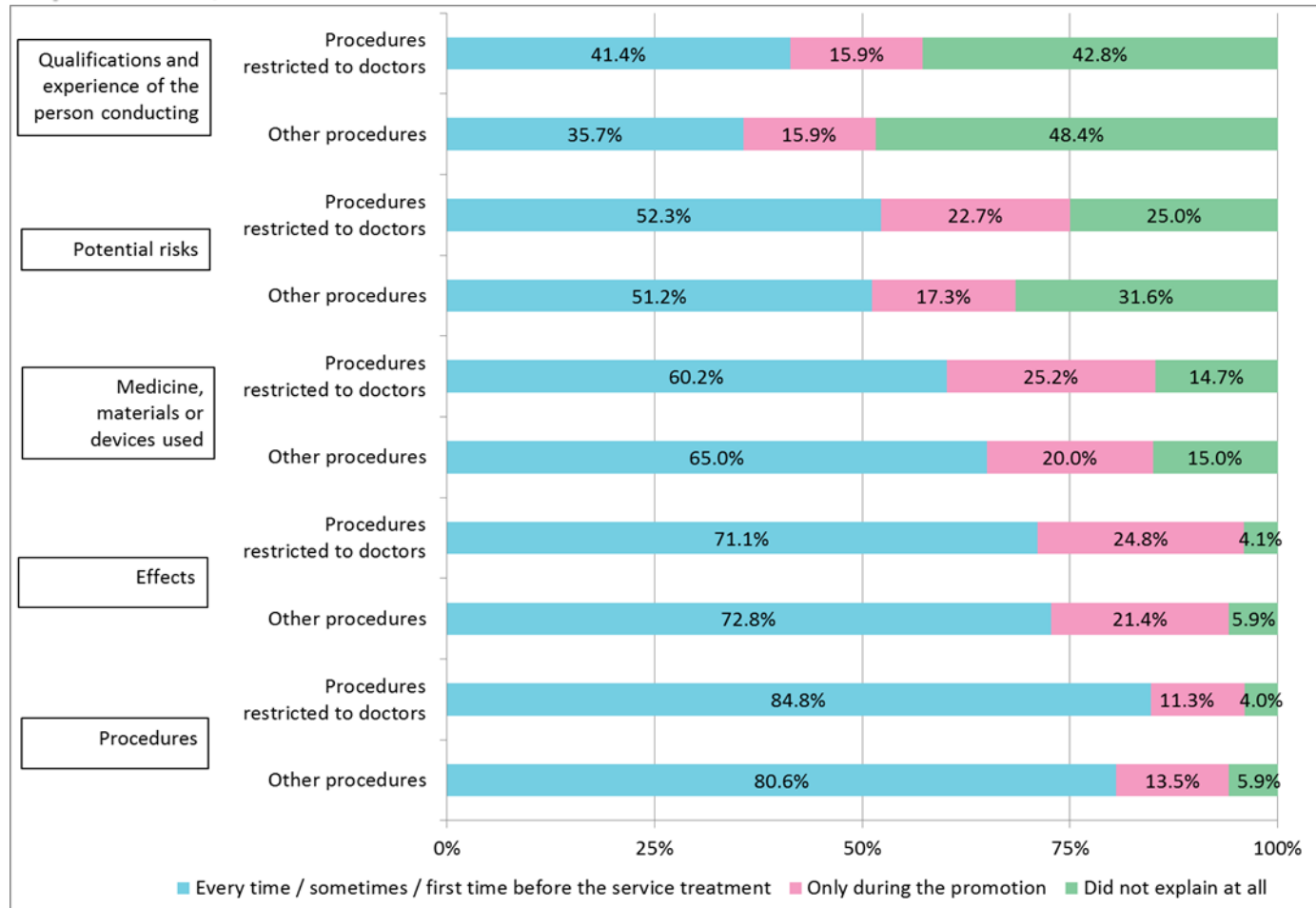
Base: All persons who had used medical beauty services (i.e. n = 602; N = 1,015,301)





Users Experience

Qualifications & experience of the service providers were seldom explained, whether in the restricted or non-restricted cases



Base: All persons who had used medical beauty services (i.e. n = 602; N = 1,015,301)



Key Findings

1. Consumer Choice
2. Market Practice
3. Perception and Identification
4. Regulations in Other Jurisdictions



Key Observations

Provision of “safe” medical beauty service

- An area of concern across all jurisdictions under studied

General consensus

- Service involves the improvement of physical appearance with the use of “medical” means such as surgery, drugs, medical devices or invasive techniques

A common trend

- Specific regulatory regime, registration & licensing, competency standards, and other measures for consumer protection



Benchmarking with Other Jurisdictions

	Hong Kong	Korea	Mainland China	Singapore	Taiwan	United Kingdom	United States (California)	United States (Florida)
Definition of Medical Beauty Service	X	X	✓	X	✓	X	X	X
Regulatory Framework								
- Classification on types of procedures as medical procedures	✓	✓	✓	✓	✓	✓	✓	✓
- Competency requirements of medical practitioners for performing medical beauty procedures	X	X	✓	✓	✓	✓[4]	X	✓
- Preclude non-medical practitioners (beauticians) to perform non-invasive or non-surgical procedures	X	✓	✓	X	X	X	X	X
- Control on use of cosmetic-related medical devices	X[1]	✓	✓	✓	✓	✓[4]	✓	✓
- Control on types of ambulatory facilities in performing medical beauty procedures	X[1]	✓	✓	✓	X	✓	✓	✓
Regulation of the beauty sector								
- Mandated qualification/licensing requirements	X	✓	✓	✓[3]	✓	✓[4]	✓	✓
Consumer Protection								
- Specific advertising restrictions	X[2]	✓	✓	✓	✓	✓	✓	✓
- Information disclosure	X	--	✓	✓	✓	--	--	--
- Cooling off period	X	X	X	✓[3]	X	X[1]	X	X
- Redress mechanism	X	✓	--	--	--	✓	--	--

[1] Under review / consultation; [2] Covered by Trade Descriptions Ordinance; [3] Covered certain aspects only; [4] In progress
-- Information not available



Current Situation in Hong Kong

No regulatory framework

- Absence of definition of medical beauty service
- Absence of competency requirements of medical practitioners for performing medical beauty procedures
- Non-medical practitioners performing non-invasive, non-surgical medical beauty procedures
- Absence of control on use of cosmetic-related medical devices
- Absence of control on types of ambulatory facilities in performing medical beauty procedures

No consumer protection measures

- No specific advertising control
- No mandatory information disclosure
- No mandatory cooling-off period
- No specific redress mechanism



Recommendations



9 Recommendations on Medical Beauty Services

Regulatory Approach

1. Definition of Medical Beauty Services
 2. Licensing Requirement
 3. Competency Requirements
4. Registries & Reporting Mechanisms

Other Aspects under a Licensing Regime

5. Independent, Evidence-based Advice
 6. Consent Process
 7. Advertising Code
 8. Cooling-off Period
9. Resolution & Redress Mechanism



1. Definition of Medical Beauty Services

- Introduction of relevant legislation to enhance clarity in defining the term
 - Clearly define the various procedures, e.g. the types of surgeries, drugs & devices commonly used
 - Set the boundaries for regulating the behavior of all persons undertaking the services
 - Help to educate consumers on the definition & the risks involved



2. Licensing Requirement

- A clearly identifiable “licensing” framework is preferred
 - Rather than a “piecemeal” approach to regulate “devices”, “drugs” & “procedures” which may results in confusion
 - Other specific operating codes to safeguard the interests of consumer health and the wider interests of the Hong Kong economy



3. Competency Requirements

- Specify the necessary skills & expertise of the medical beauty service providers, who to perform the service safely to recognised standard
 - Competency standards set for different services by classifying the types of surgeries, drugs, devices commonly used in medical beauty services
 - Access to related info on qualification & experience by public means with mechanisms for regular updates



4. Registries and Reporting Mechanisms

- Establish a “Registry” for medical beauty devices, and formal reporting mechanisms of adverse incidents
 - Provide oversight and pre-market controls (prior to the use of devices) to safeguard public health
 - Appropriate licensing conditions and sanctions to provide incentives to report adverse incidents



5. Independent, Evidence-based Advice

- Develop an evidence-based information service providing standardised information on medical beauty services, drugs & devices that are prevalent in the market
 - For impartiality & convenience, the information should ideally be disseminated in an accessible form by the Government, or through any proposed industry licensing regime



6. Consent Process

- Specify the need of written consent before the medical beauty service is undertaken
 - Include an acknowledgement that relevant complications, side effects or remedial action might arise
 - Prohibit any action that is construed as persuading consumers to undergo subsequent procedures, when a consumer is in the course of treatment



7. Advertising Code

- Measures should be imposed to restrict the manner in which some advertising claims are made in the medical beauty service market
 - Code on advertisement to regulate the way in which the services are promoted

8. Cooling-off Period

- Legislative cooling-off period for medical beauty services
 - Give right to consumers who are enticed into purchasing medical beauty services, or having made a prepayment, the right to withdraw within a reasonable time frame



9. Resolution and Redress Mechanism

- Development of a specialist mediation agency by collective efforts of the medical beauty industry
 - Give consumers a feasible & practical choice to resolve their disputes with service providers



Way Forward

- Safety issues & questionable sales practices in medical beauty services are public concerns
- The Council urges the Government, beauty & medical sectors, & relevant stakeholders to consider the 9 recommendations for better consumer protection





Supplementary Information



Table 1 Categorisation and recommendation of the 35 medical beauty procedures with potential safety concerns by the Working Group on Differentiation between Medical Procedures and Beauty Services in Hong Kong*

Item	Procedure		Perform by medical practitioners /dentists	Deliberate within the regulatory framework for medical devices
Procedures Involving skin puncture 涉及皮膚穿刺的程序				
1.	Dermal filler injection	皮下填充劑注射	✓	
2.	Botulinum toxin A injection	A型肉毒桿菌毒素注射	✓	
3.	Autologous platelet-rich plasma	自體高濃度血小板血清	✓	
4.	Autologous cellular therapy	自體細胞療程	✓	
5.	Cryo-crystallised Growth Factor	冰釋細胞複製再生療程	✓	
6.	Skin whitening injection	美白針注射	✓	
7.	Injection lipolysis	減肥針注射	✓	
8.	Mesotherapy	中胚層療法	✓	
9.	Microneedle therapy	微針療程		✓
10.	Tattooing	紋身	Exempted	
11.	Body piercing	穿環	Exempted	
Procedures Involving external application of energy 涉及體外能量源的程序				
12.	Laser (Class 3B and 4)	激光(第3B類/4類)		✓
13.	Radiofrequency	射頻		✓
14.	Intense pulsed light (IPL)	強烈脈衝光		✓
15.	Extracorporeal shock wave	體外衝擊波		✓
16.	Ultrasound for lipolysis (high intensity focused ultrasound and non-thermal ultrasound)	消脂用途的超聲波 (高強度聚焦超聲波和 非熱能性超聲波能量)		✓
17.	Cryolipolysis	冷凍溶脂術		✓
18.	High voltage pulsed current	高壓脈衝電流		✓
19.	Plasma	等離子		✓
20.	Lighting emitting diode phototherapy	發光二極管光線療法		✓
21.	Infrared light	紅外線		✓
22.	Micro-current therapy	微電流		✓
23.	Cryoelectrophoresis	低溫電泳導入術		✓
24.	Electroporation / Iontophoresis	電穿孔導入術/離子導入術		✓
25.	Pulsed magnetic field therapy	脈衝磁療		✓
26.	Microwave application	微波應用		✓
Procedures involving mechanical / chemical exfoliation of the skin 涉及以機械或化學方法進行皮膚剝脫的程序				
27.	Microdermabrasion	微晶磨皮	✓	
28.	Chemical peel	化學剝脫	✓	
29.	JETPEEL	水磨嫩膚	✓	
30.	Water microjet plus vacuum	水鑽嫩膚加真空療程	✓	
Other procedures that may pose safety concerns 其他有機會引起安全關注的美容程序				
31.	Colon hydrotherapy	洗腸		✓
32.	Hyperbaric oxygen therapy	高壓氧氣治療	✓	
33.	Jet injector	氣壓槍	✓	
34.	Dental bleaching	漂牙	✓	
35.	Suction massage	吸力按摩	Not required	



Local Consultation

Views on Medical Beauty Services: from Gov't Depts, Beauty Sector, Medical Professions & Academics

- Department of Health (DH)
- Customs and Excise Department (CED)
- The Cosmetic & Perfumery Association of Hong Kong (CPAHK)
- Federation of Beauty Industry H.K. (FBIHK)
- The Hong Kong Medical Association (HKMA)
- Hong Kong Association of Cosmetic Surgery (HKACS)
- Hong Kong College of Dermatologists (HKCD)
- The Hong Kong Society of Dermatology and Venereology (HKSDV)
- The Division of Clinical Psychology of the Hong Kong Psychological Society (DCP-HKPS)

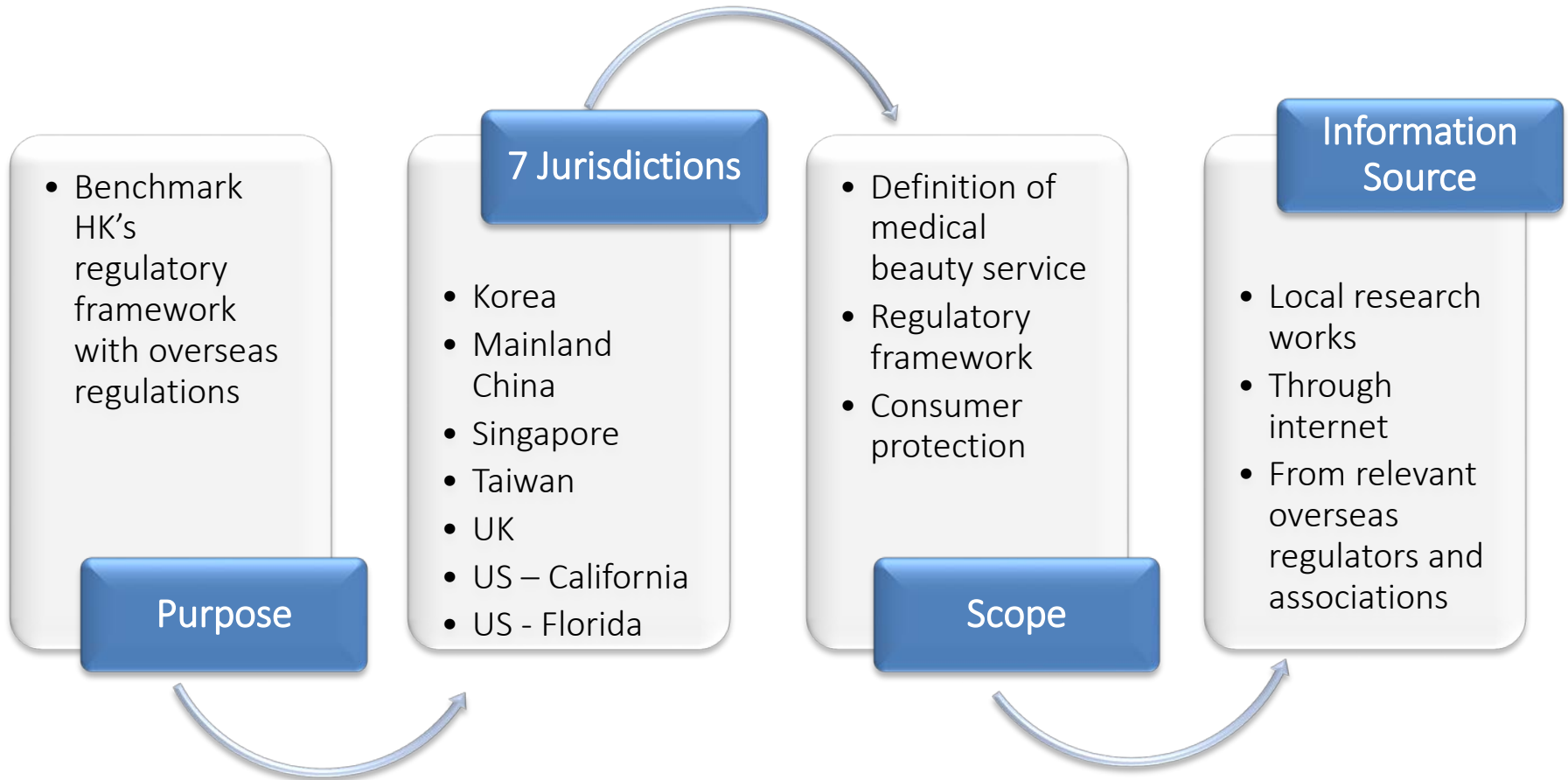
Exchange of Policy Views: Food and Health Bureau (FHB), DH

Advice on Issues:

- Customs and Excise Department (enforcement issue)
- Office of the Privacy Commissioner for Personal Data (consumer privacy)
- Commerce and Economic Development Bureau (cooling-off period)



Regulations in Other Jurisdictions





Consumer Research – Three Stages

Stage 1: Telephone surveys



Purpose

- Prevalence on the use of local/non-local medical beauty service
- Profile of users & non-users as sampling framework for on-street interviews

Period

- 22 Feb - 23 Mar 2016

Respondent

- 1,004 persons aged 15-64

Stage 2: On-street interviews



Purpose

- Consumers' perception & use
- Determining factors in choosing service & provider
- Primary concerns
- Views on regulations

Period & Location

- 16 Jun – 7 Jul 2016
- 15 locations (HK, Kln & NT)

Respondent

602 persons aged 15-64 with medical beauty service experience

Stage 3: Focus group discussions



Purpose

- Direct personal experiences of users
- Perceptions of non-users

Period

- 23 Aug - 8 Sept 2016

Respondent

- 6 focus groups, total 72 respondents



Enquiry Visits – Market Practice

Objectives

- * Information Provision
- * Sales practices
- * Differences between services & providers

Coverage 30 enquiry visits

- *9 beauty salons
- *13 medical beauty centres
- *4 medical beauty clinics
- *4 private hospitals

Period

20 Jun - 18
Aug 2016

Case categories

- *Laser therapy
- *Botox injection
- *Group buying
- *Claims