Consultation Report

Regulation of Advanced Therapy Products

Department of Health

30 October 2018

Abbreviations

ATMP	Advanced Therapy Medicinal Product (EU)
ATP	Advanced Therapy Product
AP	Authorized Person
DH	Department of Health
EU	European Union
FHB	Food and Health Bureau
GMP	Good Manufacturing Practice
PPB	Pharmacy and Poisons Board
PPO	Pharmacy and Poisons Ordinance
PPR	Pharmacy and Poisons Regulations
Task Force	Task Force on Regulation of Advanced Therapeutic Products in Hong Kong
US	United States

Contents

Executive Summary

1. The public consultation on the Regulation of Advanced Therapy Products ("ATPs") was conducted between 3 April and 2 June 2018. During the consultation period, the Department of Health ("DH") engaged various organisations and stakeholders in the community through briefing sessions and meetings. A total of 127 participants attended the three briefing sessions to express their views and 28 written submissions were received.

2. The Consultation Document issued on 3 April 2018 set out the proposal to include the definitions of ATPs under the definition of pharmaceutical products in the Pharmacy and Poisons Ordinance, Cap. 138 ("PPO"). Accordingly, ATPs would be subject to various requirements on product registration, licensing of manufacturers and distributors, import/export control, approval for clinical trials, labelling, record keeping and adverse event reporting applicable to all pharmaceutical products. In addition, in order to provide sufficient protection to patients, the following specific requirements were proposed taking into account the unique nature of ATPs –

(a) manufacturers are required to comply with guideline/standard on control of cells and tissues for ATPs production and relevant Good Manufacturing Practice ("GMP") guide. Manufacturing would include preparation of ATPs for the purpose of clinical trials or treatment of a particular patient;

(b) the unique donation identifiers/product codes and patient identifiers should be labeled on the ATPs in formats specified by the regulatory authority; and

(c) manufacturers and distributors of ATPs are required to keep additional information such as storage, transport, and the medical practitioner who is responsible for the use of the product to ensure sufficient monitoring and traceability. These records are required to be kept for 30 years.

3. Overall, there were broad support for the proposed regulatory framework of ATPs. The key views received during the public consultation exercise are summarised below –

(a) there was broad support for the proposed regulatory framework of ATPs. Meanwhile, a number of respondents urged the Government to balance different considerations in formulating the framework, including the need for safeguarding public health, the impact on stakeholders, research and industry development, as well as the medical needs of individuals;

(b) there was broad support for the adoption of the EU definition of ATP. Meanwhile, respondents urged for more guidance on the scope of products that will be subject to regulation;

(c) there was general support for the proposed licensing requirement for the manufacturing facilities of ATPs. However, some respondents urged for a more flexible approach to be applied to academic institutions, public hospitals, and production facilities for clinical trials to facilitate the local development of ATPs. Academic respondents expressed difficulties in securing sufficient funding to maintain a full GMP facility for conducting clinical trials on ATPs;

(d) some respondents requested support from the Government in complying with the licensing requirement, including the provision of resources and expert opinions, as well as tailor-made GMP training for key personnel of ATP manufacturers;

(e) there were suggestions that given the unique nature of ATPs, the qualification requirements for AP and other key personnel of ATP manufacturers should be different from the current requirements for conventional pharmaceutical product manufacturers;

(f) there was strong support for the proposed regulation of import/export and registration of ATPs. Some respondents suggested more flexibility in documentation requirements when considering product registration applications, as ATPs are different from conventional pharmaceutical products. Some

urged for clear stipulation of qualifications of personnel administering ATPs;

(g) the proposal for additional labelling requirements specific to ATPs was generally supported;

(h) there was general support regarding the additional record keeping requirements, while some respondents requested for shortening the period from 30 years to 10 years. Some respondents asked for further guidance on the record keeping requirements;

(i) there was general support for the requirement of reporting adverse events related to the use of ATPs; and

(j) some respondents suggested the establishment of an advisory board or a council to support the assessment of applications in relation to ATPs.

4. With general support from the community, the Government will proceed to take forward the proposals along the general direction set out in the Consultation Document. As most of the views received concerned about the need for a clearer regulatory scope and the practical issues in compliance, the Government will provide detailed guidelines on key areas of concern, such as the scope of ATPs under regulation, GMP for ATP manufacturing and labelling requirements. The DH will also work with the Pharmacy and Poisons Board ("PPB") to set out the qualification requirements for AP and other key personnel of ATP manufacturers. We would allow sufficient time for the trade to get prepared before commencing the relevant regulatory measures.

5. We are working on the detailed legislative proposal and our target is to introduce the relevant Amendment Bill to the Legislative Council in 2019.

Chapter 1 The Public Consultation

1.1 The public consultation on the Regulation of Advanced Therapy Products ("ATPs") was conducted between 3 April and 2 June 2018. The Department of Health ("DH") consulted the public on the proposed regulatory framework of the ATPs.

1.2 During the consultation period, DH engaged different organizations and stakeholders in the community through briefing sessions and meetings. Submissions from the public and stakeholders were received in written and electronic form during the consultation period.

General Publicity

1.3 DH publicized the public consultation through the Food and Health Bureau ("FHB"), DH, Drug Office and dedicated Advanced Therapy websites and press release. The Consultation Document is accessible on the websites. In addition, letters were sent to various stakeholders including universities and academia, associations of medical professionals and hospitals, relevant boards and councils, patient groups and industry, beauty and related organisations to invite them to attend the briefing sessions and to submit their views.

Briefings Sessions

1.4 During the consultation period, DH organised three briefing sessions on 20 April, 30 April and 15 May to explain the proposals in detail and to listen to the views expressed by various stakeholders and members of the public. A total of 127 participants attended the sessions, including representatives of universities and academia, associations of medical professionals and pharmacists, public and private hospitals, industry and beauty organisations.

1.5 In addition, another three briefing sessions to licensed wholesalers of pharmaceutical products were held on 17 May and 24 May to introduce the Consultation Document and the proposed regulatory framework for ATP. A total of 393 representatives attended the sessions.

Written Submissions and Opinions Expressed

1.6 DH received a total of 28 submissions on the proposals from individuals and organizations by hand, email, post and facsimile, etc. These included 13 submissions from organisations/institutions (including industry associations), 9 submissions from industry and 6 submissions from individuals. Please see Annex A for a list of all written submissions received (except where the sender requested to remain anonymous or did not want to publish his/her views). Copies of the submissions are available on the Advanced Therapy website, except where the sender requested not to make public the submission. Opinions and comments raised during the briefing sessions were similar to that expressed in the submissions.

Chapter 2 Public Views on Regulation of Advanced Therapy Products

2.1 In the Consultation Document, we consulted the public on the proposed regulatory framework of ATPs and the proposed amendments to the PPO and the Pharmacy and Poisons Regulations, Cap 138A ("PPR"). Having studied the regulatory frameworks for advanced therapies in various overseas jurisdictions, the Government proposed to adopt a similar approach to designate high-risk cell and tissue-based products as ATPs and regulate them as pharmaceutical products under the PPO. Low-risk cells and tissues therapies will be regulated under a separate regulatory framework at a later stage.

2.2 To safeguard public health and facilitate the safe development of innovative medical products, seven elements were proposed to be included in the regulatory framework taking into account international practices.

Area 1 – Scope of regulation and definition of "Advanced Therapy Product"

2.3 Due to the complexity of ATPs, a precise definition for ATPs is needed to clearly define the scope for regulation and differentiate high-risk cell and tissue therapies from low-risk ones. We proposed to adopt the European Union ("EU") definition for ATP (known as advanced therapy medicinal products ("ATMP") in EU Legislation), which includes gene therapy products, somatic cell therapy product and tissue engineered products, the proposed definitions of which were set out in the Consultation Document[1]. We further proposed that the regulation should apply to ATPs intended for use in human only but not that for use in animal, as there is no common model in the regulation of ATP for animal use in overseas jurisdictions.

[1] The proposed definitions are set out in Annex D of the Consultation Document.

How the Public Responded

2.4 There was solid support for the risk-based approach in regulating high-risk cell and tissue-based products as pharmaceutical products under the PPO and the adoption of the EU definitions of ATPs. One respondent opined that cell-based products should be regulated separately from pharmaceutical products. One individual respondent suggested that the ATP regulation should also be extended to products for animal use.

2.5 While supporting the need for regulating ATPs, some respondents urged the Government to balance various considerations including the need for safeguarding public health, the impact on stakeholders, research and industry development, as well as the medical need of individuals. One respondent stressed that the regulation should prioritise for cancer patients or patients with known genetic predisposition and diseases. Another respondent suggested that clinical research should be excluded from regulation. A number of submissions stressed that clear regulation is needed before they would consider investment in the manufacturing facilities of ATPs in Hong Kong.

2.6 One of the industry respondents expressed concerns on the difficulty in defining "substantial manipulation", and suggested that in classifying ATPs, focus should be put on the claim of the product. Some suggested that more guidance on the definitions of "substantial manipulation" and "homologous use" should be provided to clarify the scope of regulation.

2.7 One respondent opined that cell culture not exceeding certain passages for banking purpose and mesenchymal stem cell transplant could be considered as low-risk cell therapies. Another suggested preparation of cells from adipose tissues should be regulated. Another respondent opined that allogeneic ATPs and platelet-rich plasma (PRP) for osteoarthritis should be considered as high-risk products while non-systematic injectable ATPs as medium-risk products. One submission suggested that the regulation of medical device combined with cord blood

stem cells may not be required. Another view pointed out that low-risk cell and tissue therapies still carry significant risks and demonstration of the safety, efficacy and quality of these therapies should be required.

Area 2 – To ensure the quality and safety of cells and tissues that used for the production of ATPs

2.8 For ensuring the quality and safety of ATPs, we proposed in the Consultation Document to promulgate the quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells for the production of ATPs and to implement such control via licensing conditions for manufacturers of ATPs.

How the Public Responded

2.9 Respondents generally support the proposal of setting relevant quality and standards for the source cells and tissues. One submission agreed that the cell procurement site should not be required to comply with the full GMP, but should meet relevant standards or accreditation. A respondent expressed that the standards should be assessed on a case-by-case basis by an advisory board or council consisted of expertise in related field. A respondent suggested that the feasibility of using human embryonic stem cells and allowing the sale of umbilical cord blood for research purposes should be explored.

Area 3 – To require all facilities that produce ATPs to obtain a licence and comply with prescribed standards

2.10 Due to the risks and complex nature in the manipulation and preparation of ATP, we proposed in the Consultation Document to regulate all facilities that produce ATPs through a licensing system, under which the facilities need to fully comply with GMP and other standards as set by the regulatory authority. No exemption would be provided for

facilities that produce ATPs on a non-routine basis for the treatment of an individual patient or for the purpose of conducting clinical trial.

How the Public Responded

2.11 There was general support for the proposed licensing requirement for the manufacturing facilities of ATPs. However, some respondents urged for a more flexible approach to be applied to academic institutions, public hospitals, and production facilities for clinical trials to facilitate the local development of ATPs. The respondents also opined that as multiple facilities may be involved during the production of ATPs, it was important to clarify which facilities would be subject to regulation.

2.12 An academic respondent opined that the need to meet GMP requirements should not become a barrier for new technological advancement. One academic institution suggested special exemption for facilities that produce ATPs for first-in-human and phase 1 clinical trials. Academic respondents expressed difficulties in securing sufficient funding to maintain a full GMP facility for conducting clinical trials on ATPs. Some respondents stressed the need for separate and clear guidance for GMP applicable to ATP manufacturing, and urged for extensive communication with academics and industry stakeholders.

2.13 Some submissions requested support from the Government in complying with the licensing requirement, including the provision of resources and expert opinions. Some also requested for tailor-made GMP training for key personnel of ATP manufacturers. One industry respondent suggested DH to arrange inspection to existing ATPs production facilities in Hong Kong to facilitate compliance.

2.14 Some respondents expressed concerns on the qualification requirements for AP and other key personnel. Some suggested that flexibility should be allowed in the qualifications for key personnel. For

instance, pharmacists may not be the most suitable person to be the AP[2] for an ATP manufacturer, and that a medical laboratory technologist or a relevant laboratory staff could also be qualified as a responsible person. There were views that different qualification requirements should be set for AP and other relevant personnel. In addition, there were concerns on the local availability of experts and urged for support from overseas experts and universities on relevant training.

2.15 Most respondents asked for a transitional period and special arrangement to facilitate the trade and researchers to apply for the licence of facilities and to align with the new requirements and GMP. One industry stakeholder suggested that conditional licences may be issued during the transitional period.

Area 4 – To require approval prior to import/export, marketing and clinical trial of ATPs

2.16 In line with the current control for pharmaceutical products, we proposed that approval should be obtained prior to import/export, marketing and clinical trial of ATPs. We also proposed that the current exemption under the PPR to possess and use pharmaceutical product for the purpose of treatment by a registered medical practitioner or a registered dentist of a particular patient continues to apply.

How the Public Responded

2.17 There was strong support for the proposed requirements in relation to import/export and marketing of the ATPs.

[2] At present, an AP of a licenced manufacturer of pharmaceutical products must be a registered pharmacist in Hong Kong.

2.18 There was a suggestion to set up expert committees for ethics approval and evaluation of registration application. Industry stakeholders urged for more flexibility in documentation requirements when considering applications for product registration and change of registered particulars, as ATPs are different from conventional pharmaceutical products. Flexibility in handling of recall was also requested.

2.19 Some respondents expressed concerns on the administration of ATPs and suggested the need to define the qualification of personnel who can administer different categories of ATPs. A respondent opined that the administration of ATPs should be considered as a high-risk medical procedure and that systemic administration should only be conducted in hospitals or regulated facilitates. Another respondent recommended that medical practitioners should be required to receive training before using ATPs.

2.20 An academic respondent proposed that application for clinical trial certificate should be considered on a case-by-case basis taking into account the special nature of ATPs. Some respondents asked for a clear guidance for application for clinical trial certificate in relation to ATPs.

Area 5 – To provide specific labelling requirements for ATPs

2.21 To ensure traceability and avoid mistakenly mixing up of ATPs, we proposed additional labelling requirements specific to ATPs, including unique donation identifiers/ product codes and for autologous products, patient identifiers and a statement like “for autologous use only”. These should be labelled on the immediate packaging of ATPs in formats specified by the PPB.

How the Public Responded

2.22 The proposal for labelling requirements specific to ATPs was generally supported. An industry respondent raised concern about putting all the proposed information on the immediate packaging of the ATPs. An industry stakeholder suggested that overseas standards on labelling of ATPs should be adopted.

Area 6 – To provide specific record keeping requirements for ATPs

2.23 To facilitate the monitoring of long-term safety and efficacy of ATPs, as well as product tracing and recall, we have made reference to the EU and proposed to require the manufacturers and/or product registration holders to keep record on all starting and raw materials, production process, packaging, storage, transport, and the medical practitioner who is responsible for the use of the product. The above records were proposed to be kept for at least 30 years after the expiry date of the product, in line with the EU practice. Provisions on handling of the records during situations like insolvency or transfer of licence would also be stipulated.

How the Public Responded

2.24 Responses received were generally supportive regarding the additional record keeping requirements. An academic institution raised concern about the difficulties in the long-term follow-up of subjects of small-scale clinical trials, and considered that keeping records without follow-up data may not be useful. Another academic institution opined that keeping record for 30 years may be unnecessarily long for some patients, e.g. cancer patients, and also urged for the exemption of record keeping requirements for named patient use on a non-routine basis. Some suggested shortening the record keeping period from 30 years to 10 years. One respondent suggested the record keeping period should be counted from the date of use, instead of the expiry date of the product. Some

respondents requested for further guidance on record keeping requirements and clarification of acceptability of electronic record.

Area 7 – To require suppliers of ATPs to report adverse events related to the use of ATPs

2.25 As the experience of using ATPs is still very limited, monitoring the efficacy and adverse reactions of ATPs after use by the manufacturers and/or registration holders is crucial. Similar requirements on adverse reactions reporting are already in place for pharmaceutical products as registration and licensing conditions. We proposed that the same requirements should also apply to ATPs.

How the Public Responded

2.26 There was general support for the requirement of reporting adverse events related to the use of ATPs. More guidance on the long-term pharmacovigilance on ATP was requested.

Other Issues

2.27 Some respondents pointed out the need to ensure DH to secure sufficient manpower to deal with various aspects of ATP regulation.

2.28 In addition, there were suggestions that an advisory board or council should be established to support the assessment and evaluation of applications in relation to ATPs and medical device experts should be included in the Task Force on Regulation of Advanced Therapeutic Products in Hong Kong ("Task Force").

Chapter 3 Conclusion and Way Forward

Conclusion from the Public Consultation

3.1 Overall, there were broad support for the proposed regulatory framework of ATPs. The key views received during the public consultation exercise are summarised below –

(a) there was broad support for the proposed regulatory framework of ATPs. Meanwhile, a number of respondents urged the Government to balance different considerations in formulating the framework, including the need for safeguarding public health, the impact on stakeholders, research and industry development, as well as the medical needs of individuals;

(b) there was broad support for the adoption of the EU definition of ATP. Meanwhile, respondents urged for more guidance on the scope of products that will be subject to regulation;

(c) there was general support for the proposed licensing requirement for the manufacturing facilities of ATPs. However, some respondents urged for a more flexible approach to be applied to academic institutions, public hospitals, and production facilities for clinical trials to facilitate the local development of ATPs. Academic respondents expressed difficulties in securing sufficient funding to maintain a full GMP facility for conducting clinical trials on ATPs;

(d) some respondents requested support from the Government in complying with the licensing requirement, including the provision of resources and expert opinions, as well as tailor-made GMP training for key personnel of ATP manufacturers;

(e) there were suggestions that given the unique nature of ATPs, the qualification requirements for AP and other key personnel of ATP manufacturers should be different from the current requirements for conventional pharmaceutical product manufacturers;

(f) there was strong support for the proposed regulation of import/export and registration of ATPs. Some respondents suggested more flexibility in documentation requirements when considering product registration applications, as ATPs are different from conventional pharmaceutical products. Some urged for clear stipulation of qualifications of personnel administering ATPs;

(g) the proposal for additional labelling requirements specific to ATPs was generally supported;

(h) there was general support regarding the additional record keeping requirements, while some respondents requested for shortening the period from 30 years to 10 years. Some respondents asked for further guidance on the record keeping requirements;

(i) there was general support for the requirement of reporting adverse events related to the use of ATPs; and

(j) some respondents suggested the establishment of an advisory board or a council to support the assessment of applications in relation to ATPs.

Way Forward for Regulation of Advanced Therapy Products

3.2 With general support from the community, the Government will proceed to take forward the proposals along the directions set out in the Consultation Document. The Government is committed to striking a proper balance between safeguarding public health and development of innovative medical products. Responses to key comments raised during the public consultation are summarised below.

Scope of regulation [3.1(a) to (b)]

3.3 As substantial manipulation such as culturing, expansion, differentiation and activation of cells or tissues may introduce contamination and/or lead to selection of subpopulations of cells with genetic mutations (which may contribute to oncogenic transformation), we maintained the principle that products subjected to substantial manipulation should be regulated. Similarly, non-homologous use of ATPs, i.e. cells or tissues not to be used for the same essential functions in the recipient and the donor, are complex and many are still under research. This raises increased safety and effectiveness concerns[3], as the behaviour of these ATPs in the body is less predictable. As such, we would maintain our proposal that cell-based products which have been subject to substantial manipulation or intended for non-homologous use would be regulated.

3.4 The proposed scope of regulation is in line with the regulatory approach in various jurisdictions, including the EU, the United States ("US"), Singapore, Japan and Korea. Such international convergence of the regulatory framework for ATP in Hong Kong with other jurisdictions is vital for innovation and technology development in the industry and academic sector and efficient trading. Meanwhile, there are limited reference models for the regulation of ATPs for animal use internationally. As such, the issue would be considered at the later stage when there is more experience to enable international consensus.

3.5 In response to the request for guidance in the interpretation of the scope of ATPs under regulation, the DH will prepare and issue guidance with examples to assist stakeholders in understanding which products are regulated.

[3] US FDA (2017). Guidance for Industry and Food and Drug Administration Staff – Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use, available at: https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/cellularandgenetherapy/ucm585403.pdf

Licensing of manufacturers [3.1(c) to (e)]

3.6 The quality of ATPs is important to ensure patient safety. Due to their specific and complex nature, the preparation of the ATPs may introduce the microbial and other contamination which may cause serious harm to the patients. There is a strong need from public health perspective to require all manufacturing facilities to obtain a licence and comply with GMP requirements.

3.7 The DH is committed to providing various support to the academia and industry stakeholders including the provision of relevant guidance and standards in a timely manner. We noted that some overseas jurisdictions promulgated separate GMP guide for the production of ATPs. The regulatory authority will review these standards and provide separate GMP guidelines for ATP manufacturing. Briefing and training sessions would also be arranged for trade and stakeholders. The DH will continue to approach potential applicants for the manufacturing licence for ATPs and encourage them to engage with the DH for early advice.

3.8 It is true that ATP manufacturing is different from the manufacturing of conventional medicines and the qualification and experience requirements for AP and other key personnel should be different. The DH is working with the PPB on this area and will inform the trade and stakeholders the requirements in due course.

Control of import/export, marketing and clinical trial of ATPs [3.1(f)]

3.9 We would provide detailed guidelines on application for product registration, change of registered particulars and clinical trials that are relevant to ATPs. To meet the special medical need of patients, the use of unregistered ATP for the purpose of treatment by a registered medical practitioner or a registered dentist of a particular patient should continue to be allowed under the existing regulatory framework.

Record-keeping [3.1(h)]

3.10 In response to the concern expressed by some correspondents on the long follow-up period for clinical trials, it should be noted that the proposed requirement only requires the ATP manufacturers and distributors to keep manufacturing and distribution records of ATPs. Such requirement does not extend to clinicians or clinical trial investigators in relation to their treatment or study records.

3.11 Having considered the rapid developments of the field and current lack of knowledge in the long-term effects of ATPs, we maintain the view that such records should be kept for at least 30 years, in line with the EU practice. As the records would most likely be in electronic format, guidance on how to maintain such records would be promulgated to assist the trade.

Others [3.1 (g), (i) and (j)]

3.12 We would provide detailed guidelines on the labelling requirements for ATPs.

3.13 The suggestion to set up an expert group to advice on the regulation of ATPs would be forwarded to the PPB for consideration.

3.14 We would allow sufficient time for the trade to get prepared before commencing the relevant regulatory measures.

Implementation of the Proposals in the Consultation Document

3.15 To take forward the proposals set out in the Consultation Document and the proposed refinement, we will take steps to iron out the details of the new regulatory regime in collaboration with various

Government departments and stakeholders. The Task Force will continue to give advice on the guidance and standards applied to the regulation of ATPs.

3.16 Our target is to introduce the relevant Amendment Bill to the Legislative Council in 2019.

Vote of Thanks

3.17 We would like to take this opportunity to express our sincere thanks to all members of the community for their support and contribution to the public consultation exercise. Their invaluable comments and suggestions put to us during the consultation has helped us better understand public expectations and provided us a foundation of taking forward the regulation of ATPs with refinements and enhancements.

Annex A

List of Written Submissions Received in Public Consultation

Submissions from Organizations / Institutions (including Industry Associations)

Serial No.	Name
(O)01	Cell Therapy Laboratory of Li Ka Shing Institute of Health Sciences, Faculty of Medicine, The Chinese University of Hong Kong
(O)02	Hong Kong Biotechnology Organization
(O)03	Hong Kong College of Radiologists
(O)04	Hong Kong Dental Association
(O)05	Hong Kong Medical and Healthcare Device Industries Association
(O)06	Hong Kong Regenerative Medicine Association Limited
(O)07	Hong Kong Science & Technology Parks Corporation
(O)08	Hospital Authority
(O)09	International Society for Stem Cell Research
(O)10	Li Ka Shing Faculty of Medicine, The University of Hong Kong
(O)11	The Hong Kong Association of the Pharmaceutical Industry
(O)12	The Hong Kong Institute of Biotechnology Limited
(O)13	香港美容業總會

Submissions from Industry

Serial No.	Name
(IND)01	BioCell Technology Limited
(IND)02	Bioscience Institute Limited
(IND)03	Dendreon HK Limited
(IND)04	Gilead Sciences Hong Kong Limited
(IND)05	Hong Kong Stem Cell Centre
(IND)06	Living Tissues Company Limited
(IND)07	Mononuclear Therapeutics
(IND)08	Pfizer
(IND)09	ProStemCell Limited

Submissions from Individuals

Serial No.	Name
(I)01	A University Principal Investigator
(I)02	Dr. KK Chan and Dr. TL Chan
(I)03	Prof. MH Zheng
(I)04	Steven
(I)05	Mr. Cheung
(I)06	陳先生