A BILL

To

Provide for the basics for a comprehensive and integrative policy targeting to prevent, diagnose and cure rare diseases as well as to ensure the well-being of persons afflicted with rare disease; to establish a Commission on Rare Disease Policy and an Evaluative Committee on Rare Diseases; to provide for mechanism for the recognition of rare diseases; to provide for a register for rare diseases drugs, treatment or product; to provide for a statutory scheme of subsidy for persons afflicted or suspected to have afflicted with a rare disease; and to provide for connected purposes so as to ensure rights of a person afflicted with rare disease guaranteed under the United Nations Convention on the Rights of Persons with Disabilities can be properly achieved.

Enacted by the Legislative Council.

Part 1
Preliminary

1. Short title

This Ordinance may be cited as the Rare Diseases Ordinance.

2. Object of this Ordinance

Object of this Ordinance is to protect and promote the right to health of persons afflicted with rare disease so timely access to health information and adequate medical care are available fopersons afflicted with rare disease, as with any others; and to provide the premises for a comprehensive and integrative

policy targeting to prevent, diagnose and cure rare diseases as well as to ensure the well-being of persons afflicted with rare disease.

3. Interpretation

(1) In this Ordinance —

Appointed members (委任成員) means,

(a) in respect of the Commission on Rare Diseases Policy , members of the Commission appointed by the Chief Executive under section 5(1);

(b) in respect of the Evaluative Committee on Rare Diseases, members of the Committee appointed by the Chief Executive under section 11(6);

Commission (委員會) means Commission on Rare Diseases Policy established by section 4;

Committee (小組), other than under Part 7, means Evaluative Committee on Rare Diseases established by section 10;

Disposable income (可動用收入) means the net income after various deductions include items such as rent, rates and living expenses, have been made from gross income.

Disposable capital (可動用資產) means the assets of a capital nature, exclude some assets such as the first flat resided in together by the patient's household and the tools of trade owned by the patient's household.

Office-bearer (幹事) has the meaning assigned to it by section 2 of the Societies Ordinance (Cap. 151)

Patients' representative (病人代表) means a person who —

(a) is or was a person afflicted with rare disease; and/or

(b) is an office-bearer of a rare disease concern group; and/or

(c) a care-taker of a person afflicted with rare disease

elected in accordance with the Patients' Representative Election Regulation;

Patients' Representative Election Regulation (《病人代表選舉規例》) means the regulation made under section 29(2)(a);

Rare disease (罕見疾病) means —

(a) Disease or malfunction listed in Schedule 1; and

(b) other diseases or malfunction affecting no more than 1 in 10,000 individuals in Hong Kong and confirmed as such by the Secretary for Food and Health upon recommendation of the Committee;

Rare disease concern group (罕見疾病關注組織) means a society registered under the Societies Ordinance (Cap. 151) with functions or purposes to support persons afflicted with a rare disease or their care-takers;

Rare disease drug (罕見疾病藥物) means any drug used to prevent, diagnose, cure or alleviate a rare disease or its symptoms, registered by the Committee and confirmed as such by the

Secretary for Food and Health in accordance with section 20;

Rare Disease Information System (罕見疾病資料系統) means the information system established and maintained by the Secretary for Food and Health in accordance with section 27;

Rare disease treatment (罕見疾病治療) means any non-drug therapeutic treatment used to prevent, diagnose, cure or alleviate the symptoms, registered by the Committee and confirmed as such by the Secretary for Food and Health in accordance with section 20;

Rare disease product (罕見疾病產品) means any healthcare or nutritional product, other than a drug, including, *inter alia*, diagnostic kits, medical devices and biological products, used to prevent, diagnose, cure or alleviate a rare disease or its symptoms, registered by the Committee and confirmed as such by the Secretary for Food and Health in accordance with section 20;

Registered medical practitioner (註冊醫生) means a person who is registered or who is deemed to be registered in accordance with provisions under the Medical Registration Ordinance (Cap. 161);

Registered pharmacist (註冊藥劑師) means a person registered in the register of pharmaceutical chemists or the register of chemists and druggists under the Pharmacy and Poisons Ordinance (Cap. 138);

Registered social worker (註冊社工) means a person registered in the register of registered social

worker under the the Social Workers Registration Ordinance (Cap. 505);

(2) For a person under the age of 18, his or her parents or legal guardian shall deem to be an authorized person for the purpose of this Ordinance.

(3) For a mentally incapacitated person within the meaning of Mental Health Ordinance (Cap. 136), his or her guardian under that Ordinance shall deem to be an authorized person for the purpose of this Ordinance.

Part 2
Commission on Rare Diseases Policy

4. Establishment and constitution of Commission

(1) A Commission is established to be known as "Commission on Rare Diseases Policy" in English and "罕見疾病政策委員會" in Chinese.

(2) The Commission consists of —

(a) a person, who is not a public officer, nor a member of the Evaluative Committee on Rare Diseases, appointed as the chairperson;

(b) 4 patients' representatives, who is not a public officer, nor a member of the Evaluative Committee on Rare Diseases, elected under the Patients' Representative Election Regulation;

(c) 2 persons elected by the Legislative Council among their own number;

(d) 4 persons,who are not public officers, of whom —

(i) 3 must be medical experts who, in the opinion of the Chief Executive, have knowledge of, or experience in the

research or clinic treatment for rare diseases;

(ii) 1 must be persons who, in the opinion of the Chief Executive, have expertise or experience in medical care, nursing care, healthcare or social care planning for patients;

(iii) 1 must be a registered social worker; and

(e) at least 1, but no more than 2 other members who are public officers.

(3) In any case, members of the Commission must not include more than 2 persons who are also members (including the chairperson) of the Evaluative Committee on Rare Diseases.

5. Appointment, removal, election, or resignation of Commission's members

(1) Persons mentioned under sections 4(2)(a), 4(2)(d) and 4(2)(e) are to be appointed by the Chief Executive.

(2) Persons mentioned under sections 4(2)(a) and 4(2)(d) —

(a) holds office for a period of 5 years from the date of their appointment or for such lesser period as the Chief Executive may appoint;

(b) may be reappointed for not more than one consecutive term;

(c) holds office on any other terms and conditions of appointment that is specified in his or her instrument of appointment;

(d) may resign from office by giving notice in writing to the Chief Executive, taking effect on the date specified in the notice, or if no

date is specified, on the date the Chief Executive receives the notice;

(e) may be removed from office by the Chief Executive if the Chief Executive is satisfied that the member is unable or unfit to carry out the duties of the office due to permanent incapacity or other sufficient cause.

(3) For the avoidance of doubt, the appointment or reappointment of persons mentioned under sections 4(2)(a) and 4(2)(d) shall be treated as one term notwithstanding that the term may be for a period of less than 5 years.

(4) Persons under sections 4(2)(e) holds office at the discretion of the Chief Executive.

(5) Persons mentioned under sections 4(2)(b) —

(a) holds office for 5 years from the date of notification in the Gazette of the member's election;

(b) is eligible for re-election;

(c) may resign from office by giving notice in writing to the chairperson of the Commission, taking effect on the date specified in the notice, or if no date is specified, on the date the chairperson of the Commission receives the notice.

(6) Within 3 months before the term of office of a person mentioned in section 4(2)(b) expires, an election must be conducted under the Patients' Representative Election Regulation to elect a patients' representative to succeed that member.

(7) If, before the term of office of a member mentioned in section 4(2)(b) expires, the member resigns or the office otherwise becomes vacant, and—

(a) the unexpired term of the office is not less than six months when the vacancy arises, an election under the Patients' Representative Election Regulation must be conducted as soon as possible to fill the vacancy, and subsection (5) applies to a person so elected; or

(b) the unexpired term of the office is less than six months when the vacancy arises, the Chief Executive must, as soon as possible, on the nomination by the Commission, appoint a person who is not a public officer, to fill the vacancy for the remaining term and represents the interests of rare disease patients, and subsections (2)(c), (d) and (e) applies to a person so appointed.

(8) Persons mentioned under section 4(2)(c) cease to be a member of the Commission if he ceases to be a member of the Legislative Council.

(9) The Chief Executive may appoint another member who is not a public officer to act as chairperson, to carry out all the duties and may exercise all the powers of the office of chairperson —

(a) during a vacancy in the office of chairperson; or

(b) while the chairperson is absent from Hong Kong; or

(c) while the chairperson is, for any other reason, unable or unfit to carry out the duties of the office of chairperson.

(10) Any of the above appointment, removal, election, resignation, or any other arrangement affecting the composition of the Committee must be published in the Gazette.

6. Functions of Commission

(1) The main functions of the Commission include,

(a) to assist the Government in achieving the general principles as set out in Schedule 2;

(b) to advice the Government in the strategic development of the policy concerning rare diseases;

(c) to monitor the implementation of the policy concerning rare diseases;

(d) to monitor the work of the Committee established under section 10 of this Ordinance;

(e) when required by the Chief Executive to do so, to provide to the Chief Executive in Council a report and its recommendations about the policy concerning rare diseases.

(2) The Commission has any other function given to it by other provisions under this Ordinance, or by the Chief Executive in writing.

(3) In performing its functions, the Commission must have regard to the general principles set out in Schedule 2.

7. Power and status of Commission

(1) The Commission has power to do all things, including forming a working committee, that are necessary for, or incidental or conducive to, the performance of its functions.

(2) The Commission may, at any time it thinks fit, issue advice to the Evaluative Committee on Rare Diseases.

(3) The Commission is neither a servant nor an agent of the Government and does not enjoy any status, immunity or privilege of the Government.

8. Meetings of Commission

(1) Meetings of the Commission are to be held at the times and places appointed by the chairperson.

(2) A meeting of the Commission is to be presided by the chairperson.

(3) If the chairperson is absent from any meeting of the Commission, the members present at such meeting must elect from among their number a member to act as chairperson and the person so elected has all the powers of the Chairperson for the purposes of that meeting.

(4) The quorum for a meeting of the Commission is —

(a) the person presiding; plus

(b) not less than half of the other members in office for the time being, including at least 3 members who are not public officers and at least one who is.

(5) Subject to this Ordinance, at meetings of the Commission, all questions must be decided by the votes of a majority of the Commission members (including the presiding chairperson or member) present.

(6) Subject to this Ordinance, the Commission may regulate its own procedure in relation to its meetings.

(7) A vacancy among the members of the Commission or any defect in the appointment must not affect the validity of any proceedings of the Commission.

9. Report of Commission

(1) The Chief Executive must require that a report under section 6(1)(e) to be made at least once in every 3 years. The first report is to be made within 18 months after the commencement this Ordinance.

(2) The Commission's report must include, *inter alia*, an analysis on the status quo of and recommendations on the following matters:

(a) The overall Government policy on the prevention, diagnosis or treatment of rare diseases and for the well-being of persons afflicted with rare disease;

(b) The work of the Commission;

(c) The work of the Committee;

(d) The recognition of rare diseases;

(e) The accessibility, usage, research and development of rare disease drugs, rare disease treatments, or rare disease product;

(f) Operation of information systems related to rare diseases;

(g) International cooperation initiatives for the prevention, diagnosis, treatment, or research of rare diseases.

(3) Before arriving at the recommendation to be included in its report, the Commission may as it thinks fit —

(a) consult any rare disease concern group or any other organization representative of the care-takers of a person afflicted with rare disease or any other person;

(b) issue consultation paper to the public;

(c) consider any submission made to it in the course of its consultations; and

(d) analyse and consider any data derived from, and consider any other information contained in, any research or study.

(4) The Chief Executive must, as soon as practicable and in any case no later than one month after receiving a report made under section 6(1)(e), cause a copy of it to be published.

Part 3
Evaluative Committee on Rare Diseases

10. Establishment and constitution of Committee

(1) A Committee is established under the Commission on Rare Diseases Policy to be known as "Evaluative Committee on Rare Diseases" in English and "罕見疾病評估小組" in Chinese.

(2) The Committee consists of —

(a) a representative from the Commission on Rare Disease Policy who is not a public officer, elected by the Commission's members as the chairperson;

(b) 2 patients' representatives, who is not a public officer, nor a member of the Commission on Rare Disease Policy, elected under the Patients' Representative Election Regulation;

(c) 7 appointed members, who are not public officers, of whom —

(i) at least 2, but not more than 3 must be medical experts who is in the opinion of the Chief Executive, have knowledge of, or experience in the research or clinic treatment for rare diseases;

(ii) at least 2, but not more than 3 must be registered pharmacists who is nominated by the Pharmaceutical Society of Hong Kong;

(iii) 2 must be person who, in the opinion of the Chief Executive, have expertise or experience in medical care, nursing

care, healthcare or social care planning for patients

(iv) 1 must be a registered social worker; and

(d) at least 1, but no more than 2 other members who are public officers.

11. Appointment, removal, election, or resignation of Committee's members

(1) Appointment or removal of the chairperson mentioned in section 10(2)(a) is to be decided by the Commission in their meeting by the votes of a two-thirds majority of the Commission members (including the presiding chairperson or member) in office for the time being.

(2) The person elected under subsection (1) ceases to be the chairperson of the Committee if he ceases to be a member of the Commission.

(3) Persons mentioned under section 10(2)(b) —

(a) holds office for 3 years from the date of notification in the Gazette of the member's election;

(b) is eligible for re-election;

(c) may resign from office by giving notice in writing to the chairperson of the Committee, taking effect on the date specified in the notice, or if no date is specified, on the date the chairperson of the Committee receives the notice.

(4) Within 3 months before the term of office of a person mentioned in section 10(2)(b) expires, an election must be conducted under the Patients' Representative Election Regulation to elect a patients' representative to succeed that person.

(5) If, before the term of office of a member mentioned in section 10(2)(b) expires, the member resigns or the office otherwise becomes vacant, and—

(a) the unexpired term of the office is not less than six months when the vacancy arises, an election under the Patients' Representative Election Regulation must be conducted as soon as possible to fill the vacancy, and subsection (3) applies to a person so elected; or

(b) the unexpired term of the office is less than six months when the vacancy arises, the Chief Executive must, as soon as possible, on the nomination by the Committee, appoint a person who is not a public officer, to fill the vacancy for the remaining term and represents the interests of rare disease patients, and subsections (7)(c), (d) and (e) below applies to a person so appointed.

(6) Persons mentioned under sections 10(2)(c) and 10(2)(d) are to be appointed by the Chief Executive.

(7) Persons mentioned under section 10(2)(c)—

(a) holds office for a period of 3 years from the date of their appointment or for such lesser period as the Chief Executive may appoint;

(b) may be reappointed for not more than two consecutive terms;

(c) holds office on any other terms and conditions of appointment that is specified in his or her instrument of appointment;

(d) may resign from office by giving notice in writing to the Chief Executive, taking effect on the date specified in the notice, or if no date is

specified, on the date the Chief Executive receives the notice;

(e) may be removed from office by the Chief Executive if the Chief Executive is satisfied that the member is unable or unfit to carry out the duties of the office due to permanent incapacity or other sufficient cause.

(8) For the avoidance of doubt, the appointment or reappointment of persons mentioned under sections 10(2)(c) shall be treated as one term notwithstanding that the term may be for a period of less than 3 years.

(9) Persons mentioned under section 10(2)(d) holds office at the discretion of the Chief Executive.

(10) The Commission may elect another member of the Commission or the Committee who is not a public officer to act as chairperson of the Committee and to carry out all the duties and may exercise all the powers of the office of chairperson —

(a) while the chairperson is absent from Hong Kong; or

(b) while the chairperson is, for any other reason, unable or unfit to carry out the duties of the office of chairperson

for a period of no more than 6 months.

(11) Any of the above appointment, removal, election, resignation, or any other arrangement affecting the composition of the Committee must be published in the Gazette.

12. Functions of Committee

(1) The main functions of the Committee include,

(a) to assist the Government in achieving the general principles as set out in Schedule 2;

(b) to evaluate any disease or malfunction on its own motion or on application, so as to determine if that disease or malfunction qualifies as a rare disease for the purpose of this Ordinance;

(c) for any disease or malfunction that qualifies as rare disease, to make recommendation to the Food and Health Bureau for its recognition; and

(d) to maintain a register of rare disease drugs, rare disease treatments or rare disease products.

(2) The Committee has any other function given to it by other provisions under this Ordinance, or by the Chief Executive in writing.

(3) In performing its functions, the Committee must have regard to the general principles set out in Schedule 2.

13. Power and status of Committee

(1) The Committee has power to do all things that are necessary for, or incidental or conducive to, the performance of its functions.

(2) The Committee is neither a servant nor an agent of the Government and does not enjoy any status, immunity or privilege of the Government.

14. Meetings of Committee

(1) Meetings of the Commission are to be held at the times and places appointed by the chairperson.

(2) A meeting of the Committee is to be presided by the chairperson.

(3) If the chairperson is absent from any meeting of the Committee, the members present at such meeting must elect from among their number a member to act

as chairperson and the person so elected has all the powers of the Chairperson for the purposes of that meeting.

(4) The quorum for a meeting of the Committee is —

(a) the person presiding; plus

(b) not less than half of the other members in office for the time being, including at least 3 members who are not public officers and at least one who is.

(5) Subject to this Ordinance, at meetings of the Committee, all questions must be decided by the votes of a majority of the Committee members (including the presiding chairperson or member) present.

(6) Subject to this Ordinance, the Committee may regulate its own procedure in relation to its meetings.

(7) A vacancy among the members of the Committee or any defect in their appointment must not affect the validity of any proceedings of the Committee.

Part 4
Recognition of Rare Diseases

15. Interpretation

In this part, ***applicant*** (申請人) includes —

(a) the person afflicted with a disease or malfunction;

(b) the authorized person on behalf of a person mentioned in paragraph (a); and

(c) the registered medical practitioner responsible for the case of the person mentioned in paragraph (a) in respect of that disease or malfunction,

making the application under section 17(1).

16. Recognition of Rare Diseases

(1) The recognition of rare disease shall be evaluated by the Evaluative Committee on Rare Diseases on its own motion or on application, and confirmed by the Food and Health Bureau upon the Committee's recommendation.

(2) Subject to subsection (3) and section 18, the Committee is to make a recommendation for a disease or malfunction to be recognised as rare disease if, and only if —

(a) it is clinically definable; and

(b) it affects no more than one in 10,000 individuals in Hong Kong.

(3) Where a disease or malfunction satisfies subsection (2)(a) but not (2)(b) because of the lack of any applicable clinical data concerning the Hong Kong population, the Committee is entitled to —

(a) analyse and consider any data or situation concerning the same disease or malfunction in other countries; and

(b) recommend the disease or malfunction to be provisionally recognised as rare disease for a specified term of not more than 5 years

if it is satisfied that —

(i) the disease or malfunction is identifiable with reasonable diagnostic precision;

(ii) the disease or malfunction appears to have a significantly low prevalence rate; and

(iii) relevant medical experience or studies provide evidence that the disease or malfunction causes, in the absence of effective treatment, a significant reduction in age-specific life expectancy or developmental disorders for the person afflict with that disease or malfunction.

(4) Upon receiving recommendations from the Committee, the Food and Health Bureau must, as soon as practicable and in any case not later than one month, confirm the recommended disease or malfunction as rare disease by notice in the Gazette.

17. Application for the Recognition of a Rare Disease

(1) A person afflicted with a disease or malfunction that is not yet recognized as rare disease, or an authorized person on his or her behalf, may together with a registered medical practitioner responsible for his or her case in respect of that disease or malfunction, make an application to the Committee for the recognition of that disease or malfunction as a rare disease.

(2) All application must be dealt with expeditiously as is practicable and no later than 3 months from the date the application is received. Where there is a good reason why it is impracticable to do so, the Committee must, before the expiration of the 3-month period, deliver to the applicant a written notice specifying the time would be required to process the application with the reason why it is impracticable to process his or her application within 3 months. In any case, a decision must be reached no later than 6 months from the date the application is received.

(3) The Committee must notify the applicant in writing of any decision reached upon the application. If the application is declined, the notification must state the grounds for the refusal to recognize the disease or malfunction as rare disease.

(4) If the Committee has made a decision to not recommend a disease or malfunction to be recognized as rare disease, because it has failed to fulfil any of

the conditions specified in section 16(2), that decision shall stand, if the Committee deems appropriate, for a maximum of 2 years and the Committee need not accept any application of recognition in respect of that disease or malfunction until the time of 2 years or a specified shorter period expires.

(5) Nothing in this section shall be construed as restricting or otherwise affecting a person's power under section 29 to apply for a review of decision.

18. Written statement of non-recommendation

(1) Where the Committee is satisfied that there are compelling reasons not to recognise a disease or malfunction satisfying all conditions under section 16(2) as rare disease, it may submit a written statement of non-recommendation to the Commission specifying that the disease or malfunction is not recommended to be recognised as a rare disease notwithstanding that the disease or malfunction has satisfied the conditions specified under section 16(2).

(2) The written statement must set out the grounds for the non-recommendation and accompanied by such relevant information and evidence as the Commission may require.

(3) Upon receiving the written statement, the Commission may decide —

(a) if it is satisfied that the reason given by the Committee is compelling, the disease or malfunction is not to be recommended to the Food and Health Bureau for its recognition until —

(i) conditions specified by the Commission is satisfied; or

(ii) the Committee is satisfied that there is no longer any compelling reason not to recognise the disease or malfunction,

whichever first occurs.

(b) if it is of view that the reason given by the Committee is not compelling, the disease or malfunction is to be recommended to the Food and Health Bureau. In this case, the Committee must act accordingly.

(4) If the written statement is submitted in response to an application made under section 17(1),

(a) the written statement must be delivered to the applicant together with, or in lieu of the written notice as required under section 17(3); and

(b) the Commission's decision in subsection (3) must be delivered in writing to the applicant as soon as practicable.

(5) Nothing in this section shall be construed as restricting or otherwise affecting a person's right under section 17(1) to make an application for the recognition of a disease or malfunction as rare disease. If an application under section 17(1) is made for a disease or malfunction that the Committee has submitted a written statement and the decision of non-recommendation is confirmed by the Commission in accordance with subsection (3)(a), the Committee is required to review the application and —

(a) recommend the disease or malfunction to the Food and Health Bureau for its recognition as a rare disease if the disease or malfunction still satisfies the conditions under section 16(2) and —

(i) conditions specified by the Commission pursuant to subsection (3)(a)(i) (if any) are satisfied; or

(ii) the Committee is satisfied that there is no longer any compelling reason to not recognise the disease or malfunction; or

(b) in any other cases, decide that the decision of non-recommendation shall stand; and

notify the applicant in writing of any decision reached upon the application.

(6) In any case, the Committee must review the non-recommendation of the disease or malfunction at least every 2 years.

(7) The Commission has the power to discharge any conditions it specified pursuant to subsection (3)(a)(i), or to alter it to a less stringent condition

Part 5
Rare disease drugs, rare disease treatments and rare disease products

19. Interpretation

In this part, ***interested party*** (有利害關係的人) means a manufacturer, importer, seller, supplier, provider or distributor of a relevant rare disease drug, treatment, or product.

20. Registration of rare disease drugs, rare disease treatments or rare disease products

(1) The Committee is responsible for maintaining a register of rare disease drugs, rare disease treatments or rare disease products.

(2) When a drug, treatment or product have indications for the cure or alleviation of a rare disease or its symptoms, the Committee may, on its own motion or on application by —

(a) the person afflicted with a relevant rare disease or malfunction, or the authorized person on his or her behalf

(b) an interested party,

register that drug, treatment or product as a rare disease drug, rare disease treatment or rare disease product.

(3) Before any drug, treatment or product is registered as a rare disease drug, rare disease treatment or rare disease product, the Committee must be satisfied as to its safety, quality and effectiveness.

(4) In evaluating the safety, quality and effectiveness of a drug, treatment or product, the Committee is empowered to consult any expert it deems fit.

(5) The Committee must notify the applicant in writing of any decision reached upon an application as soon as practicable. If the application is declined, the notification must state the grounds for the refusal.

(6) Any registration takes effect upon the confirmation by the Secretary for Food and Health. The confirmation must take place no later than a month upon receiving a written notice from the Committee.

(7) Nothing in this section affects operation of any other Ordinances that provides for the registration, licensing or other requirements for the lawful manufacturing, importation, provision, or distribution of any drugs, treatments or products.

21. Removal from register

(1) Subject to subsection (2), the Committee, with the Commission's consent, is entitled to remove any drug, treatment or product from the register if it is satisfied that—

(a) the relevant drug, treatment or product is defective in its safety, quality or effectiveness;

(b) the removal of that drug, treatment or product from the register would not result in any serious adverse impact on any person afflicted, or suspected to have afflicted with rare disease; and

(c) any relevant interested party is afforded opportunity to be heard by the Committee.

(2) The requirement under subsection (2)(c) may be exempted in life- or health-dangering situations.

(3) Any removal from register takes effect upon the confirmation by the Secretary for Food and Health.

Part 6
Subsidies

22. Provision of subsidy for rare disease drugs and rare disease treatment

(1) The Government is responsible for launching and maintaining a scheme to subsidize the expenses on rare disease drug or rare disease treatment of a person afflicted with rare disease.

(2) The said scheme must, on application, provide the person afflicted with rare disease a subsidy of an amount to be decided by the Committee with reference to the following descriptions or principles —

(a) The said scheme must endeavour ensure the provision of safe, quality, effective and affordable rare disease drugs and rare disease treatment to a person afflicted with rare disease, whereas cost-efficiency shall not be the foremost concern.

(b) The said scheme shall be progressive in nature, with reference to the affordability of the relevant persons.

(c) In considering the affordability of the relevant persons, (only?) their disposable income and disposable asset should be taken into account.

(d) The relevant persons shall not be liable for expenses on rare disease drug or rare disease treatment for more than a reasonable portion of his or her and his or her spouse's disposable income and disposable asset.

(e) The relevant persons, with a low-income, shall be exempted from making any contribution to the expenses on rare disease drug or rare disease treatment.

(3) The Committee may, on approving a subsidy to be granted under the said scheme, invite the person afflicted with rare disease to participate in domestic clinical trials or the evaluation of effectiveness of the rare disease drug or rare disease treatment and reasonably adjust the amount of subsidy in subsequent applications by the same applicant for the same item with a view to encourage such participation.

(4) All application must be dealt with expeditiously as is practicable and no later than 3 months from the date the application is received. Where there is a good reason why it is impracticable to do so, the Committee must, before the expiration of the 3-month period,

deliver to the applicant a written notice specifying the time would be required to process the application with the reason why it is impracticable to process his or her application within 3 months. In any case, a decision must be reached no later than 6 months from the date the application is received.

(5) The Committee must notify the applicant in writing of any decision reached upon the application as soon as practicable, with the calculation or reasoning of the Committee in its determination of the amount of the subsidy, or the refusal to grant any subsidy.

(6) ***Relevant persons*** (有關人士) under subsection (2) means —

(a) in respect of an application made for the benefit of a person afflicted with rare disease over the age of 18, that person and his or her spouse (if any);

(b) in respect of an application made for the benefit of a person afflicted with rare disease under the age of 18, … (should there be any different? I'm not sure) (e.g. discounting the patient but only the 同住父母?)

(7) The said scheme shall come into operation within 18 months after the commencement this Ordinance.

23. Provision of other subsidies

(1) The Government shall be responsible for providing a person afflicted, or suspected to have afflicted with a rare disease with subsidies for cost incurred, or expected to be incurred for —

(a) any examinations, tests or check-up for the identification or diagnosis of a rare disease;

(b) any pre-marital or pre-natal check-up for the identification or diagnosis of a rare disease with implication on his or her next generation;

(c) any rare disease products;

(d) any medical or nutritional counselling necessary for the diagnosis, treatment or alleviation of the rare disease or its symptoms;

(e) home use equipment and appliances for the maintenance of his or her life or daily living; and

(f) overseas diagnosis or treatment that cannot be competently performed domestically.

(2) Nothing in this Ordinance prevents the Government, the Commission or the Committee from launching or administering any other schemes of subsidy for the healthcare and social care of patients with rare disease or otherwise connected to the purpose of the prevention, early diagnosis and treatment of rare diseases, parallel to the scheme prescribed under section 22.

Part 7
Appeals and Reviews

24. Appealing decision of Evaluative Committee on Rare Diseases

(1) Any relevant applicants may, by application, appeal to the Commission regarding —

(a) a decision of the Evaluative Committee on Rare Diseases in respect of an application made under section 17(1), including situation stipulated in section 18(5);

(b) a decision of the Evaluative Committee on Rare Diseases in respect of an application made under section 20(2); or

(c) a decision of the Evaluative Committee on Rare Diseases in respect of the amount of subsidy granted, or refusal to grant a subsidy under the scheme of subsidy prescribed in section 22.

(2) Upon receiving an application made under subsection (1), the Commission must, within 1 months from receiving the application, decide —

(a) that the decision made by the Evaluative Committee on Rare Diseases shall stand, if the Commission is satisfied that the decision is in all circumstances reasonable, and accords with provisions under this Ordinance and the general principles set out in Schedule 2; or

(b) that the decision made by the Evaluative Committee on Rare Diseases is to be reviewed by a panel appointed by the Commission in accordance with section 26, if the Commission considered that the decision is ill-reasoned or otherwise deviates from provisions under this Ordinance or the general principles set out in Schedule 2.

25. Request for application to be evaluated by panel appointed by the Commission

(1) Where the Evaluative Committee on Rare Diseases fails to meet any requirements stipulated in section 17(2) or section 22(4), an applicant may, on application to the Commission, request his or her application to be evaluated by a panel appointed by the Commission in accordance with section 25.

(2) Upon receiving an application under subsection (1), the Commission must, within 1 month from receiving the application —

(a) if the Commission concludes that the Evaluative Committee on Rare Diseases has met the requirements stipulated in section 17(2) or section 22(4), dismiss the application;

(b) if the Commission concludes that the Evaluative Committee on Rare Diseases has failed to meet the requirements stipulated in section 17(2) or section 22(4) but is capable of handling the application without prejudice to the applicant, direct the Evaluative Committee on Rare Diseases to complete the processing of the application within a month; or

(c) if the Commission concludes that the Evaluative Committee on Rare Diseases has failed to meet the requirements stipulated in section 17(2) or section 22(4) and considered that it is not desirable for the application to be handled by the Evaluative Committee on Rare Diseases, decide that the application is to be evaluated by a panel appointed by the Commission.

26. Panel to be appointed by the Commission

(1) Within 1 month from deciding that a decision of the Evaluative Committee on Rare Diseases or an application is to be reviewed or evaluated by a panel appointed by the Commission, the Commission must appoint a panel consist of —

(a) a member of the Commission acting as the chairperson of the panel;

(b) a patients' representatives elected to the Commission or Evaluative Committee on Rare Diseases;

(c) 2 medical experts who are not public officers and have knowledge of, or experience in the research or clinic treatment for rare diseases;

(d) 2 registered pharmacists who is not a public officer, nominated by the Pharmaceutical Society of Hong Kong;

(e) a person who, in the opinion of the Commission, have expertise or experience in medical care, nursing care, healthcare or social care planning for patients;

(iii) a registered social worker; and

(f) at least 1, but no more than 2 members who are public officers.

(2) When conducting the review or evaluation, the panel shall assume the duties and power of the Evaluative Committee on Rare Diseases connected with the purpose of processing the relevant application.

(3) Subject to subsection (4), a decision of the panel, upon confirmation by the Commission, has the same legal effect as if it is a decision made by the Evaluative Committee on Rare Diseases.

(4) A decision of the panel is final and conclusive. No appeal shall be brought under section 24.

Part 8
Rare Disease Information System

27. Rare Disease Information System

(1) The Secretary for Food and Health must establish and maintain a Rare Disease Information System.

(2) The Rare Disease Information System must include, *inter alia*, —

(a) an updated list of all rare diseases;

(b) data on the prevalence of rare diseases and demographic information of persons afflicted;

(c) data on the use of rare disease drugs, rare disease treatments or rare disease products.

(3) All information contained in the system, unless public interest requires otherwise, must be accessible by the members of the public at all reasonable times free of charge.

(4) Public access required under subsection (3) may be achieved by —

(a) publication through the Internet or a similar electronic network; and

(b) in any other manner the Secretary for Food and Health considers appropriate.

28. Information not to be reported in Rare Disease Information System

(1) Confidential and private information of a person afflicted with rare disease must not be reported in the Rare Disease Information System.

(2) In any case, personnel in possession of any confidential and private information of a person afflicted with rare disease must not disclose, and must

not be required to disclosure, any such information without legitimate cause or consent of that person.

(3) Confidential and private information in subsection (1) includes, *inter alia*, name, number of the Hong Kong identity card number or other identification documents, address, contact information of the person afflicted with rare disease or his or her care-takers.

(4) Confidential and private information in subsection (1) does not includes demographic information such as the age, sex, race of the person afflicted with rare disease.

Part 9
Miscellaneous

29. Power to make regulations

(1) Subject to this Ordinance, the Chief Executive in Council may by regulation provide for—

(a) details of the scheme prescribed under section 22;

(b) details of any other scheme for provision of subsidies described under section 23.

(2) Subject to this Ordinance, the Secretary for Food and Health may by regulation provide for—

(a) the procedure and other matters in relation to an election of patients' representative under sections 4(2)(b) or 10(2)(b), including the qualifications of candidates, the eligibility requirements for electors and subscribers for a nomination paper, the particulars of any system of voting and counting, the determination of election results and questioning of the results;

(b) the procedure and other matters in relation to the reporting of relevant information by medical personnel or institutions for the purpose of the Rare Disease Information System prescribed under section 27;

(3) Subject to this Ordinance, the Commission may by regulation provide for —

(a) the procedure to be followed in relation to any application made to the Commission under this Ordinance;

(b) certificates, forms or other documents required for any application made to the Commission under this Ordinance;

(c) any fee required to be paid for any application made under this Ordinance.

(4) The Committee may by regulation provide for—

(a) the procedure to be followed in relation to any application made to the Committee under this Ordinance;

(b) certificates, forms or other documents required for any application made to the Committee under this Ordinance.

(5) Any regulation in relation to subsection (3)(c) must not be made or amended unless the prior consent of the Secretary for Food and Health has been obtained and the fee prescribed therein must obtain approval from the Legislative Council.

(6) Any regulation in subsection (4) must not be made or amended unless the prior consent of the Commission.

Schedule 1
List of Rare Diseases

(In alphabetical order)

1. α1- Antitrypsin deficiency
2. 1α-hydroxylase deficiency
3. 3-hydroxy-3-methyl-glutaric acidemia
4. 3-methylcrotonyl-CoA carboxylase deficiency
5. Aarskog-Scott syndrome
6. Achondroplasia
7. Adrenocorticotropic hormone (ACTH) resistance
8. Adrenoleukodystrophy
9. Aicardi-Goutieres syndrome
10. Alagille syndrome
11. Alexander disease
12. Alsrtom syndrome
13. Amino acid metabolic disorders
14. Amyotrophic lateral sclerosis (ALS)
15. Andersen-Tawil syndrome
16. Angelman syndrome
17. Apert syndrome
18. Aromatic L-amino acid decarboxylase deficiency
19. Asphyxiating thoracic dystrophy
20. Ataxia-telangiectasia
21. Atypical hemolytic uremic syndrome
22. Autosomal recessive polycystic kidney disease
23. Bardet-Biedl syndrome
24. Barth syndrome
25. Bartter’s syndrome
26. Becker muscular dystrophy
27. Beckwith Wiedemann syndrome
28. Beta-Ketothiolase deficiency
29. Biotinidase Deficiency
30. Branchio-oto-renal syndrome

31. Bruton’s agammaglobulinemia
32. Campomelic dysplasia with autosomal sex reversal
33. Carbohydrate deficiency glycoprotein syndrome
34. Cardiofaciocutaneous (CFC) syndrome
35. Primary carnitine deficiency syndrome
36. Central core disease
37. Cerebro-costo-mandibular syndrome
38. Cerebrotendinous xanthomatosis
39. Charcot-Marie-Tooth Disease
40. CHARGE Syndrome
41. Chronic infantile neurologic cutaneous articular (CINCA) syndrome
42. Chronic primary granulomatous disease
43. Citrullinemia
44. Cleidocraninal dysplasia
45. Cobalamin C defect
46. Cockayne syndrome
47. Collodion baby
48. Complement component 8 deficiency
49. Congenital adrenal hypoplasia
50. Congenital central hypoventilation syndrome
51. Congenital generalized lipodystrophy
52. Congenital hyper IgE syndrome
53. Congenital insensitivity to pain with anhidrosis (CIPA)
54. Congenital interstitial cell of Cajal hyperplasia with neuronal intestinal dysplasia
55. Congenital muscular dystrophy
56. Congenital urea cycle disorders
57. Conradi-Hunermann syndrome
58. Cornelia de Lange syndrome
59. Crouzon syndrome
60. Cystic fibrosis
61. Cystinosis
62. Darier’s disease

63. DiGeorge’s syndrome
64. Duchenne muscular dystrophy
65. Dyskeratosis Congenita
66. Ectodermal Dysplasias
67. Ehlers Danlos syndrome IV
68. Epidermolytic ichthyosis
69. Fabry disease
70. Facioscapulohumeral muscular dystrophy
71. Familial amyloidotic polyneuropathy
72. Familial hyperchylomicronemia
73. Fatty acid oxidation defect
74. Fibrodysplasia ossificans progressiva
75. Fraser syndrome
76. Freeman-Sheldon syndrome
77. Fucosidosis
78. Galactosemia
79. Gaucher’s disease
80. Globoid cell leukodystrophy (Krabbe’s disease)
81. Glucose transporter type 1 (GLUT1) deficiency syndrome
82. Glutaric aciduria type I or II
83. Glycogen storage disease
84. GM1/GM2 gangliosidosis
85. Hallerman-Streiff syndrome
86. Harlequin ichthyosis
87. Hereditary epidermolysis bullosa
88. Hereditary hemorrhagic telangiectasia
89. Hereditary spastic paraplegia
90. Hereditary tyrosinemia
91. Histidinemia
92. Holt-Oram syndrome
93. Homocystinuria
94. Homozygous familial hypercholesterolemia
95. Homozygous protein C deficiency
96. Huntington's disease (Huntington's chorea)

97. Hutchinson Gilford progeria syndrome
98. Hyper-IgM syndrome
99. Hyperlysinemia
100. Hypermethioninemia
101. Hyperornithinemia-hyperammon 270.6 emia-homocitrullinuria syndrome*Hyperprolinemia*
102. Hypophosphatasia
103. Idiopathic infantile arterial calcification
104. Inborn errors of bile acid synthesis
105. Incontinentia pigmenti
106. Infantile lysosomal acid lipase deficiency
107. Interferon γ receptor 1 deficiency
108. IPEX Syndrome
109. Isovaleric academia
110. Joubert syndrome
111. Kabuki syndrome
112. Kallmann syndrome
113. Kearns-Sayre syndrome
114. 甘迺迪氏症 [Proper English term?]
115. Kenny-Caffey syndrome
116. Laron syndrome
117. Larsen syndrome
118. Lchthyosis, lamellar recessive
119. Leigh's disease
120. Lesch-Nyhan syndrome
121. Limb-girdle muscular dystrophy type 2A, 2B, or 2D
122. Lowe syndrome
123. Maple syrup urine disease
124. Marfan syndrome
125. McCune-Albright syndrome
126. Mcleod syndrome
127. Medium-chain acyl-coenzyme A dehydrogenase deficiency
128. MELAS syndrome
129. Meleda disease

130. Menkes syndrome
131. Metachromatic Leukodystrophy (MLD)
132. Methyl CpG binding protein 2 duplication syndrome
133. Methylmalonic acidemia
134. Miller Dieker syndrome
135. Mitochondrial defect
136. Mitochondrial neurogastrointestinal encephalopathy syndrome
137. Moebius syndrome
138. Molybdenum cofactor deficiency
139. Mucolipidosis
140. Mucopolysaccharidoses
141. Multiminicore disease
142. Multiple carboxylase deficiency
143. Multiple epiphyseal dysplasia
144. Multiple pterygium syndrome
145. Multiple sclerosis
146. Multiple sulfatase deficiency
147. Myelofibrosis
148. Myotonic dystrophy
149. Myotubular myopathy
150. Nager syndrome
151. Nail-Patella syndrome
152. Nemaline Rod Myopathy
153. Netherton Syndrome
154. Neurofibromatosis type II
155. Neuronal ceroid lipofuscinosis
156. Niemann-Pick disease
157. Nitroacetylglutamate (NAG) synthetase deficiency
158. Nonketotic hyperglycinemia
159. Occult Macular Dystrophy
160. Organic acidemias
161. Ornithine transcarbamylase deficiency
162. Osteogenesis imperfecta
163. Osteopetrosis

164. Oto-Palato-Digital syndrome
165. PAH type PKU combine with sucrase-isomaltase deficiency
166. Pantothenate kinase associated neurodegeneration (PKAN)
167. Paroxysmal nocturnal hemoglobinuria
168. Pelizaeus-Merzbacher disease
169. Permanent neonatal diabetes mellitus
170. Persistent hyperinsulinemic hypoglycemia of infancy (PHHI)
171. Peters-Plus syndrome
172. Pfeiffer syndrome
173. Phenylketonuria
174. Pompe Disease
175. Porphyria
176. Prader-Willi syndrome
177. Primary Paget disease
178. Primary pulmonary hypertension (PPH)
179. Progressive intrahepatic cholestasis
180. Propionic academia
181. Proteus syndrome
182. Pseudoachondroplastic dysplasia
183. Pseudohypoparathyroidism
184. Pyruvate dehydrogenase deficiency
185. Rett syndrome
186. Rhizomelic chondrodysplasia punctata
187. Robinow syndrome
188. Rubinstein-Taybi syndrome
189. Schwartz Jampel syndrome
190. Severe combined immunodeficiency
191. Short-chain acyl-CoA dehydrogenase deficiency
192. Sialidosis
193. Sitosterolemia
194. Smith-Lemli-Opitz syndrome
195. Spinal muscular atrophy
196. Spinocerebellar ataxia
197. Split-hand/ Split-foot malformation

198. Stargardt’s disease
199. Stiffperson syndrome
200. Sulfite oxidase deficiency
201. Tetrahydrobiopterin deficiency
202. Thalassemia major
203. Thrombasthenia
204. Treacher Collins Syndrome
205. Tricho-hepato-enteric syndrome
206. Trimethylaminuria
207. Tuberous sclerosis complex
208. Tyrosine hydroxylase deficiency
209. Urea cycle defects
210. Unna-Thost type palmoplantar keratoderma
211. Von Hippel–Lindau disease
212. WAGR syndrome
213. Waardenburg syndrome
214. White-Sutton syndrome
215. Williams Syndrome
216. Wilson disease
217. Wiskott- Aldrich Syndrome
218. Wolfram syndrome
219. X-linked hypophosphatemic rickets
220. Zellweger syndrome

Schedule 2
General Principles

1. It is in the public interest to provide a comprehensive and integrative policy targeting to prevent, diagnose and cure rare diseases and to ensure the well-being of persons afflicted with rare disease.

2. As the United Nations Convention on the Rights of Persons with Disabilities recognised, persons afflicted, or suspected to have been afflicted with a rare disease shall enjoy the highest attainable standard of physical and mental health and have the right to access timely and quality medical services as with any others.

3. Will, dignity and privacy of any persons having, or suspected to have a rare disease shall at all-time be respected.

4. The Government is responsible for providing a comprehensive and integrative policy targeting to prevent, diagnose and cure rare diseases and to ensure the well-being of persons afflicted with rare disease.

5. The Secretary for Food and Health is principally responsible for policies related to rare disease. All other relevant government departments shall assist in the full implementation of such policies, general principles herein and this Ordinance. Each relevant Government department, as well as the Government as a whole is responsible for allotting budget for the implementation of such policies, general principles herein and this Ordinance.

6. The Government shall take steps to assure the access of timely and quality medical services for persons having, or suspected to have a rare disease.

7. The Government shall institutionalize a comprehensive and integrative pre-natal and newborn screening system that will facilitate early identification of rare disease affecting the foetus, infants or an expecting mother.

8. Upon identification of a person afflicted with rare disease, the Government shall, other than medical assistance, endeavour to provide also support in psychological and social terms as the patient and his or her care-takers may need. The Secretary for Labour and Welfare shall be principally responsible for the provisions of such support.

9. The Government shall institutionalize a comprehensive and integrative scheme that provides a persons afflicted with rare disease, his or her family and care-takers, information, consultations and advices including, *inter alia*, the possible short-term, medium-term or long-term impacts on the person's physical health, daily living, growth, development, the possible implications on the person's on reproduction, the possible effects on the person's offsprings, any accommodations or assistance may be necessary, as well as methods to acquire the necessary advice, care and assistance from government agencies or non-governmental organisations.

10. The Government shall endeavour to encourage the research and development, manufacturing, importation and provision of effective and affordable rare disease drugs, treatments and products by providing regulatory and fiscal incentives.

11. The Government shall endeavour to encourage individuals and institutions to actively participate in clinical or academic researches as well as international cooperation projects for the prevention, early diagnosis and treatment of rare diseases by providing regulatory and fiscal incentives.

12. The Government shall endeavour to develop a sustainable system that provides sufficient number of local specialists for the prevention, early diagnosis and treatment of rare diseases by investing in human capital development in relevant fields.

13. The Government shall endeavour to support rare disease concern groups and activities aiming at awareness-raising, capacity-building, exchange of information, social network enrichment and outreach to isolated patients or their care-takers.

14. The Government shall endeavour to coordinate non-government organizations at both the international and domestic levels, the private sector, schools, academic institutions, organizations for healthcare professionals, and mass media to organize educational and public awareness activities on rare diseases.

Explanatory Memorandum

The object of this Bill protect and promote the right to health of persons afflicted with rare disease so timely access to health information and adequate medical care are available for persons afflicted with rare disease, as with any others; and to provide the premises for a comprehensive and integrative policy targeting to prevent, diagnose and cure rare diseases as well as to ensure the well-being of persons afflicted with rare disease so that rights of a person afflicted with rare disease guaranteed under the United Nations Convention on the Rights of Persons with Disabilities can be properly achieved.

The Bill has 9 parts with 29 clauses.

2. Clause 1 sets out the short title.

3. Clause 2 sets out the object of this Ordinance.

4. Clause 3 provides the definitions for the interpretation of the Ordinance.

5. Clause 4 establishes a "Commission on Rare Diseases Policy" and provides for its constitution.

6. Clause 5 provides for the appointment, removal, election or resignation of the members of the Commission.

7. Clauses 6 and 7 state the functions, power and status of the Commission.

8. Clause 8 regulates the manner in which meetings of the Commission is to be conducted.

9. Clause 9 enables the Chief Executive to specify the timeline within which the Commission must report to him/her and to provide for contents of the report.

10. Clause 10 establishes an "Evaluative Committee on Rare Diseases" under the Commission on Rare Diseases Policy and provides for its constitution.

11. Clause 11 provides for the appointment, removal, election or resignation of the members of the Committee.

12. Clauses 12 and 13 state the functions, power and status of the Committee.

13. Clause 14 regulates the manner in which meetings of the Committee is to be conducted.

14. Clause 15 contains the definition of "applicant" for the interpretation of Part 4 to the Ordinance.

15. Clause 16 provides for the recognition of a disease or malfunction as rare disease.

16. Clause 17 enables a person afflicted with a disease or malfunction that is not yet recognized as rare disease, or an authorized person on his or her behalf, to apply to the Committee for the recognition of that disease or malfunction as a rare disease together with a registered medical practitioner responsible for his or her case in respect of that disease or malfunction. This clause also provides for the actions to be taken by the Committee in handling the application.

17. Clause 18 enables the Commission to submit a written statement of non-recommendation to the Commission specifying that a disease or malfunction is not recommended to be recognised as a rare disease notwithstanding that it has satisfied the prescribed conditions when there is a compelling reason to do so and for the Commission to make a decision as to whether that disease or malfunction is to be recommended.

18. Clause 19 provides the definition of "interested party" for the interpretation of Part 5 to the Ordinance.

19. Clause 20 requires the Committee to maintain a register of rare disease drugs, rare disease treatments or rare disease products, and provides for such registration.

20. Clause 21 provides for the removal of a rare disease drugs, rare disease treatments or rare disease products from the register.

21. Clause 22 requires the Government to launch and administer a statutory scheme of subsidy to subsidize costs a person afflicted incurred for a rare disease drugs or rare disease treatments with the amount of subsidy to be determined by the Committee with reference in sub-clause (2). This clause also provides for the actions to be taken by the Committee in handling the relevant application.

22. Clause 23(1) makes the Government responsible for the provision of subsidies for cost incurred, or expected to be incurred for items listed thereunder.

23. Clause 23(2) allows the Government, the Commission or the Committee to launch or administer other schemes of subsidy parallel to the scheme prescribed under Clause 22.

24. Clause 24 provides for the right to appeal to the Commission of the decision of the Evaluative Committee on Rare Diseases by application and provides for the actions to be taken by the Commission in handling the application.

25. Clause 25 provides for the right to apply to the Commission for an application to be reviewed by a panel appointed by the Commission where the Evaluative Committee on Rare Diseases has failed to meet the requirement under clause 17(2) or clause 22(4).

26. Clause 26 empowers the Commission to appoint a panel for the purposes under Clause 24 or Clause 25 and provides for the constitution of the said panel.

27. Clause 27 requires the Secretary for Food and Health to establish and maintain a Rare Disease Information System and provides for free public access to the system.

28. Clause 28 stipulates that confidential and private information of a person afflicted with rare disease is not to be reported in the Rare Disease Information System, nor should be disclose without legitimate cause or consent of the patient.

29. Clause 29(1) empowers the Chief Executive in Council, to make regulations as to the details of the scheme of subsidy prescribed in Clause 22 or other schemes of subsidy described in Clause 23.

30. Clause 29(2) empowers Secretary for Food and Health to make regulations for the election of patient's representative to the Commission or Committee, and the procedure for medical personnel or institutions to report relevant information for the purpose of Clause 27.

31. Clause 29(3) empowers the Commission to make regulations as to the application procedure, form of application or any document required for an application made to the Commission under this Ordinance, as well as fee charged for any application made under this Ordinance. Clause 29(5) stipulates that no regulations as to fee charged for any application made under this Ordinance may be made or amend with the prior consent of the Secretary for Food and Health and the prescribed fee must have the approval of the Legislative Council.

32. Clause 29(4) empowers the Committee to make regulations as to the application procedure, form of application or any document required made to the Committee. Clause 29(6) stipulates that no such regulations may be made without prior consent of the Commission.