

Regulation of Gene Therapy Products and Gametes Research in Hong Kong

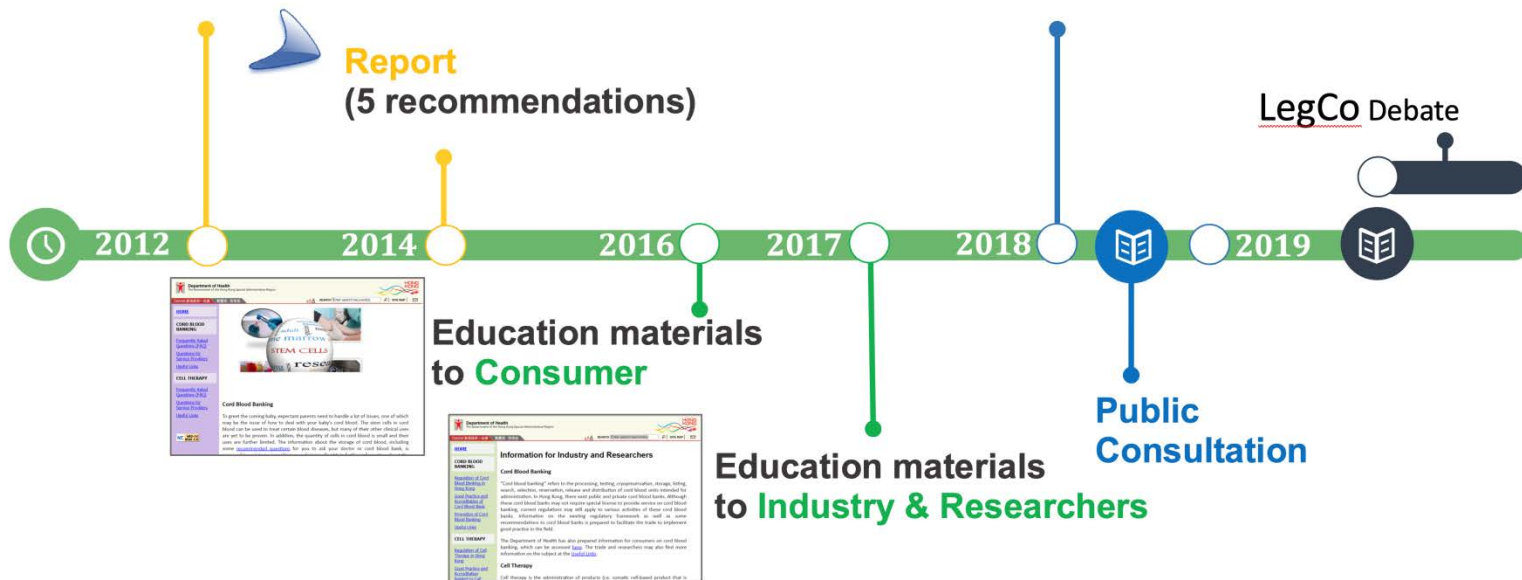
Lot Chan
Department of Health



Advanced Therapy Products

**Working Group on
Regulation of Premises Processing Health
Products for Advanced Therapies**

**Task Force on
Regulation of Advanced
Therapeutic Products in HK**



Advanced Therapy Products

- Somatic cell therapy products
- Tissue-engineered products
- Gene therapy products



Gene therapy products

- Contains an active substance which contains or consists of a **recombinant nucleic acid** used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence



Pharmacy and Poisons Ordinance

- Good Manufacturing Practice
- Clinical trial certificate
- Registration (marketing authorization)
- Import/export control



Human Reproductive Technology Ordinance

- Embryo researches involving creation or cloning of embryo, combining human and non-human gametes or embryos, and replacement of the nucleus are prohibited
- Other embryo research requires a licence from the Council on Human Reproductive Technology



Gametes/embryos for research

人類生殖科技管理局

Council on Human Reproductive Technology



English

繁體

简体

Code of Practice on Reproductive Technology and Embryo Research

Council on Human Reproductive Technology
January 2013

(Softcopy of this Code is available at <http://www.chrt.org.hk>)



COP provisions on Genetic Manipulation

- Research must first be approved by **ethics committee**
- May only be undertaken for **preventive, diagnostic or therapeutic purposes**



COP provisions on Genetic Manipulation (cont'd)

- Not aims to introduce any **modification in the genome** of any descendants
- **Germ-line gene therapy** should not be performed



THANK YOU

