

Overview of Medical Device Regulation in Hong Kong

Department of Health / Electrical & Mechanical
Services Department, Government of the HKSAR

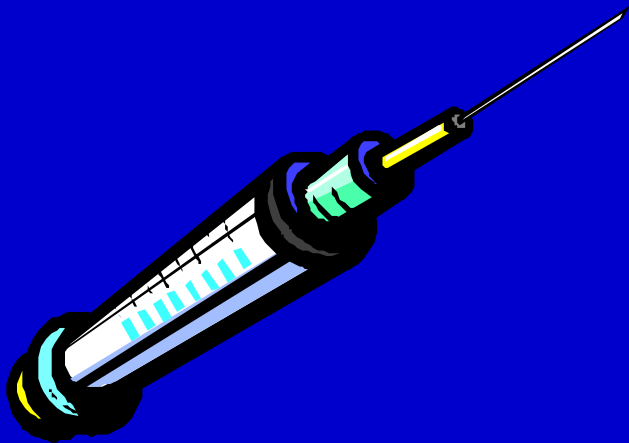
14 May, 2002

Dr. Constance CHAN, AD(HA&P)

Ir. Albert POON, SEE/MDA

Background

No specific legislation for importation
or sale of medical device



Pharmaceutical Products:

Pharmacy and Poisons Ordinance

Radioactive Substances / Irradiating
Apparatus:

Radiation Ordinance

Safe and appropriate treatment for patients: Laws regulating the professionals

Safety and health of employee at work:

Occupational Safety and Health Ordinance

Health claims: Undesirable Medical Advertisement Ordinance



Increasing concerns on:

- Device safety
- Possibility of complications from use of lasers for cosmetic purpose at beauty salons

Current Development

Study underway by the Department of Health

Technical support from the Electrical & Mechanical Services Department

Aim:

To safeguard public health and safety

Principles:

- Control commensurates with device risk level
- Avoid placing unnecessary burden on trade

Reference:

Experience of other countries

