

Aims of Medical Devices Regulation

1) ENSURE PUBLIC HEALTH & SAFETY

- Provide an assurance of device quality, safety, efficacy
- Prevent dumping ground for unsafe & defective medical devices
- Timely access to beneficial medical devices

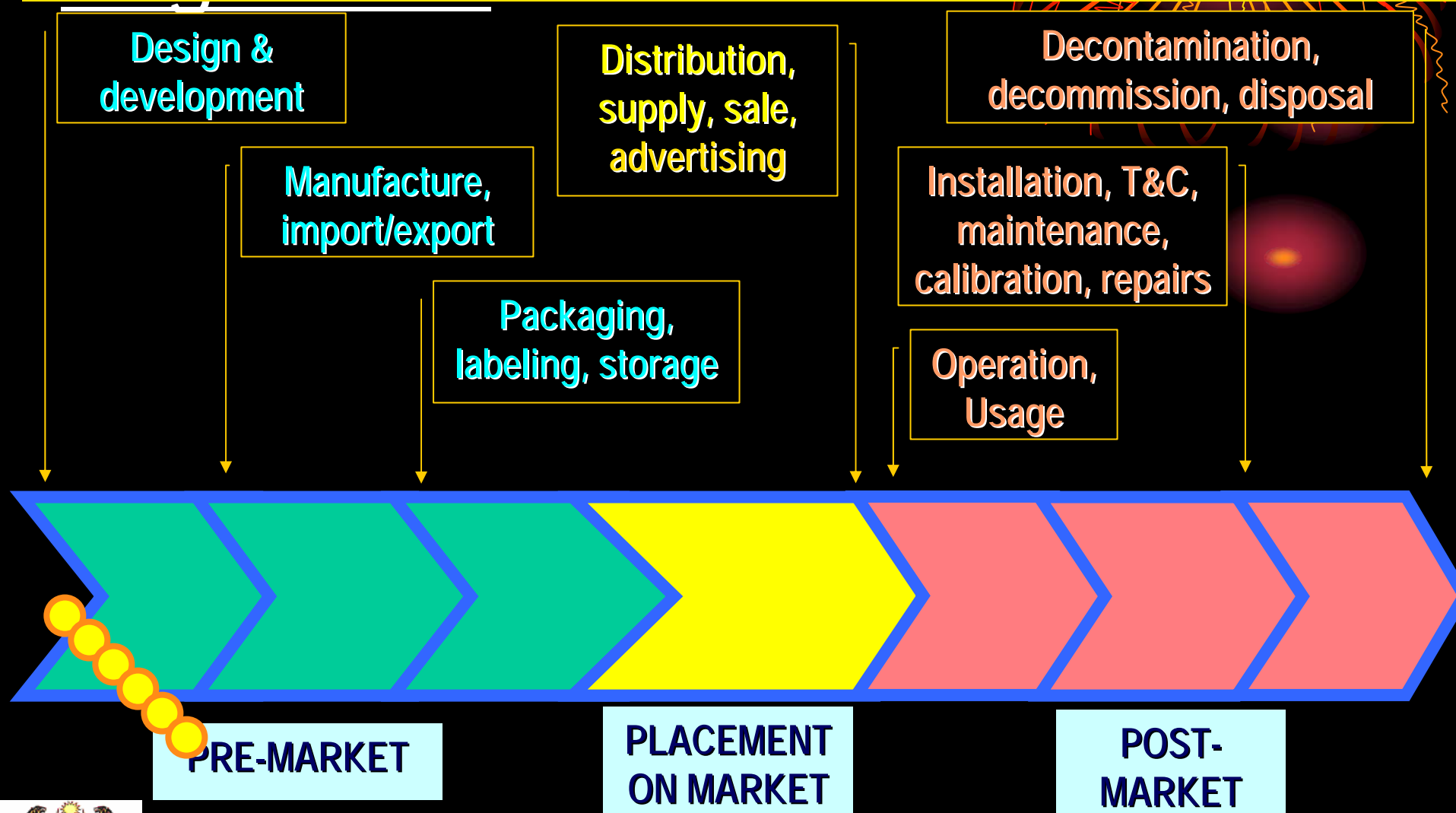
2) INVIGORATE MEDICAL DEVICES INDUSTRY

- Provide conducive environment for manufacturing
- Facilitate trade & export



Scope of regulation:

All phases of medical devices life cycle



Elements Of Medical Devices Regulations

a. Device

b. Activities

c. Personnel



Regulatory Activities



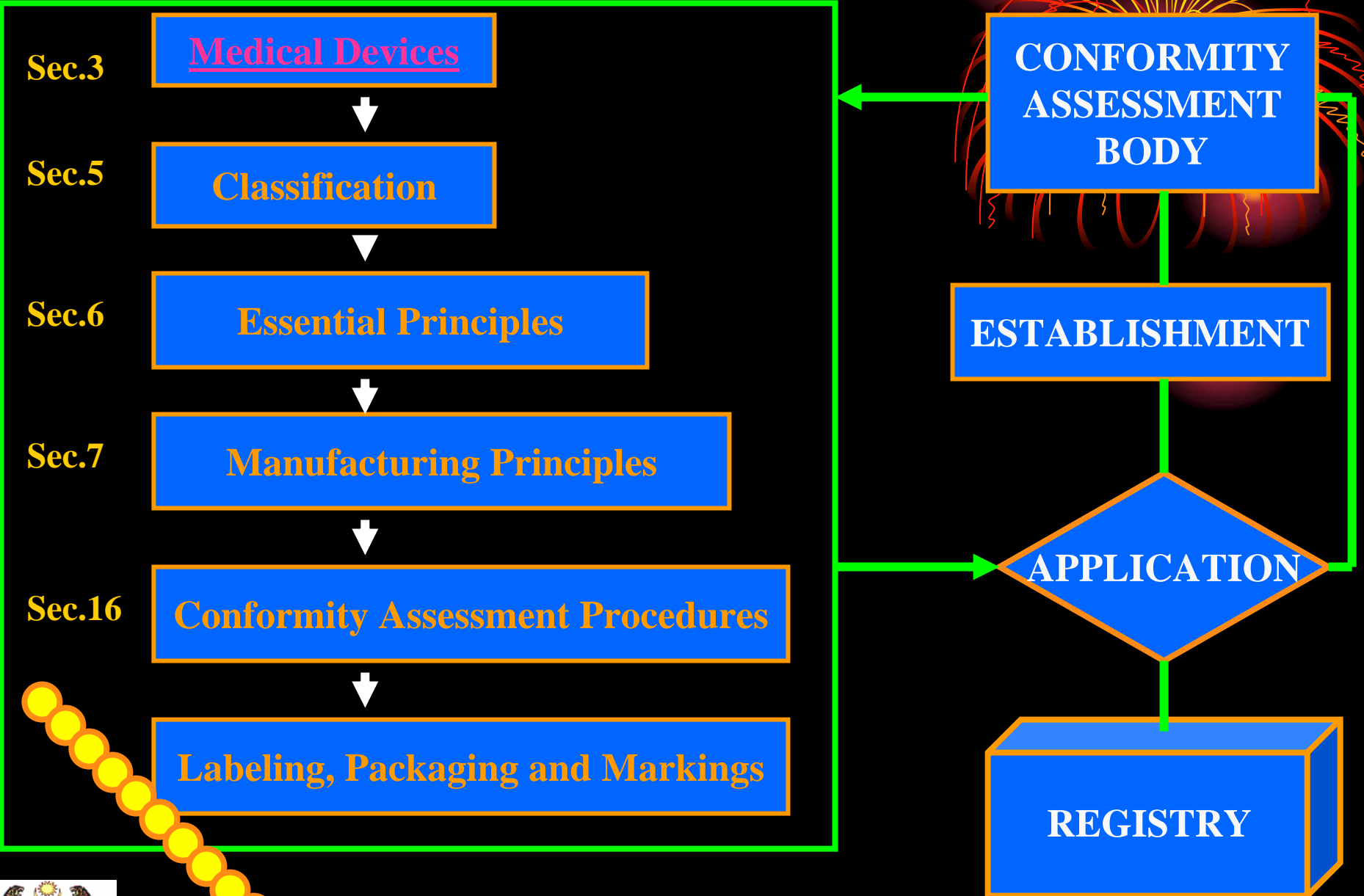
● **Pre - Market**

● **Placement On Market**

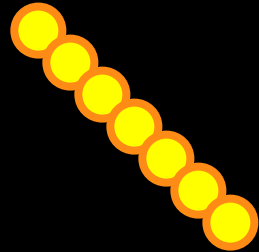
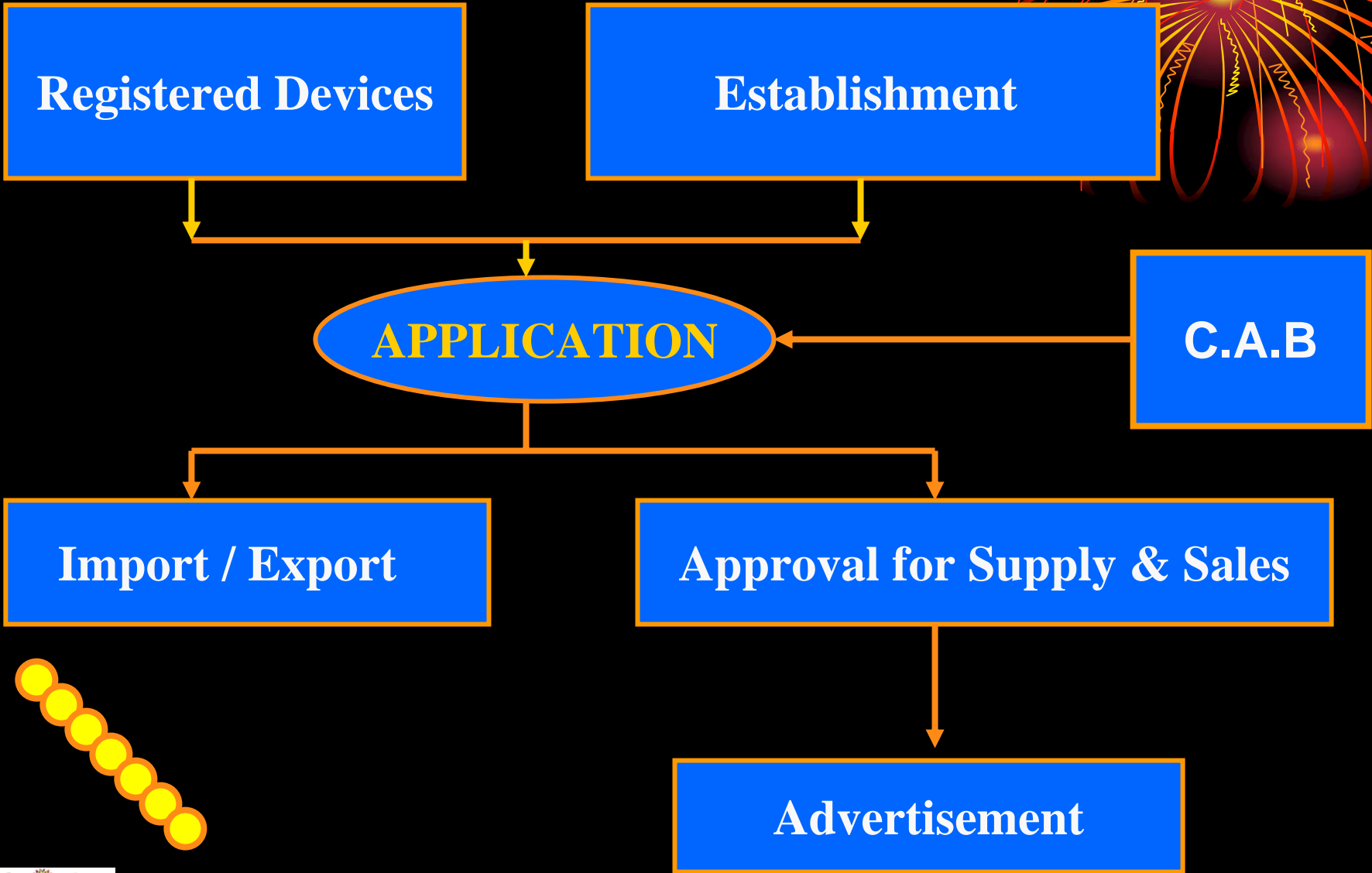
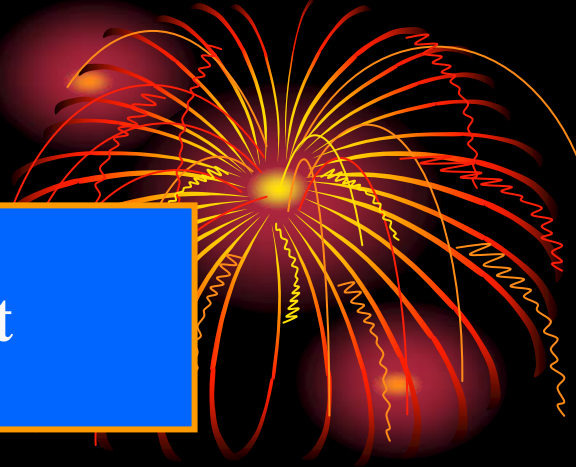
● **Post - Market**



PRE MARKET

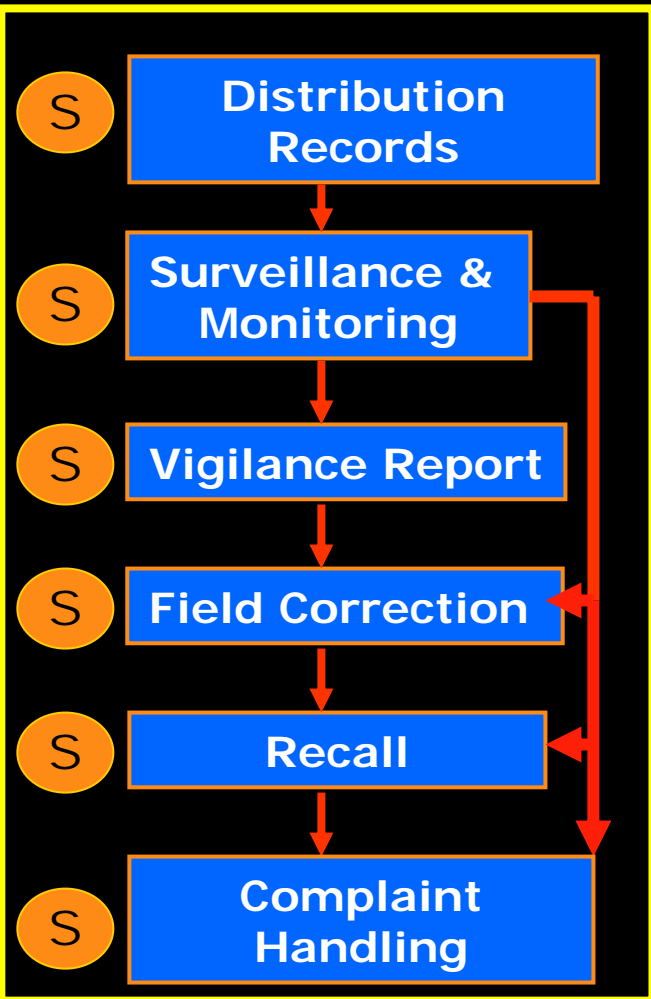


PLACEMENT ON MARKET

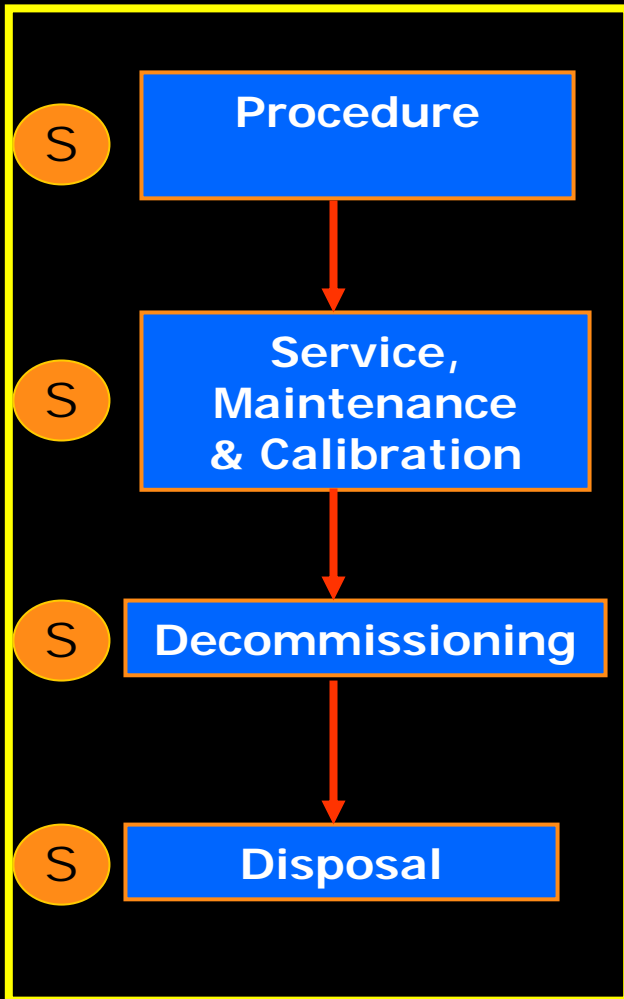


POST MARKET

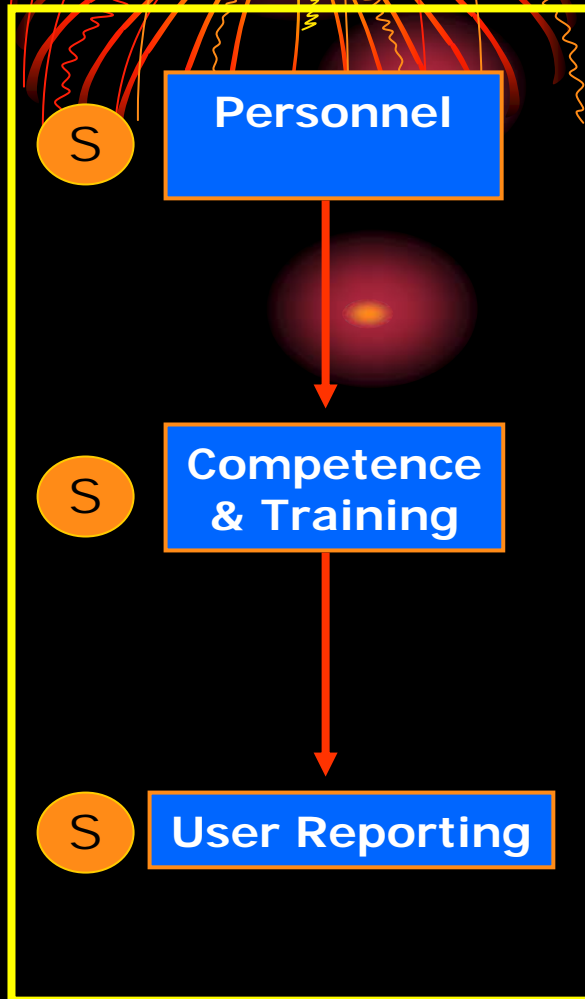
Establishment



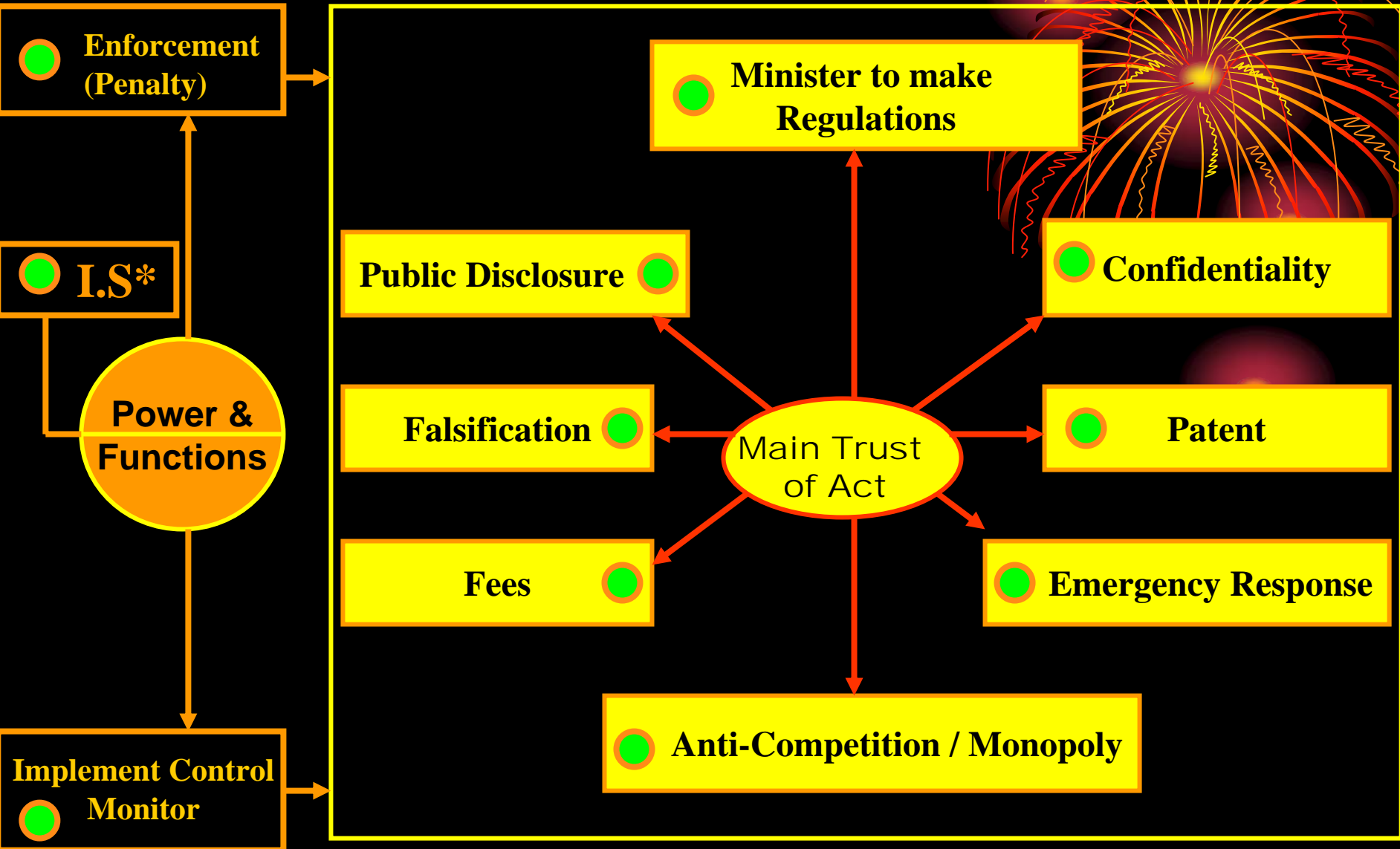
Usage & Operation



User



PROSECUTION



**I.S = Institution Structure*

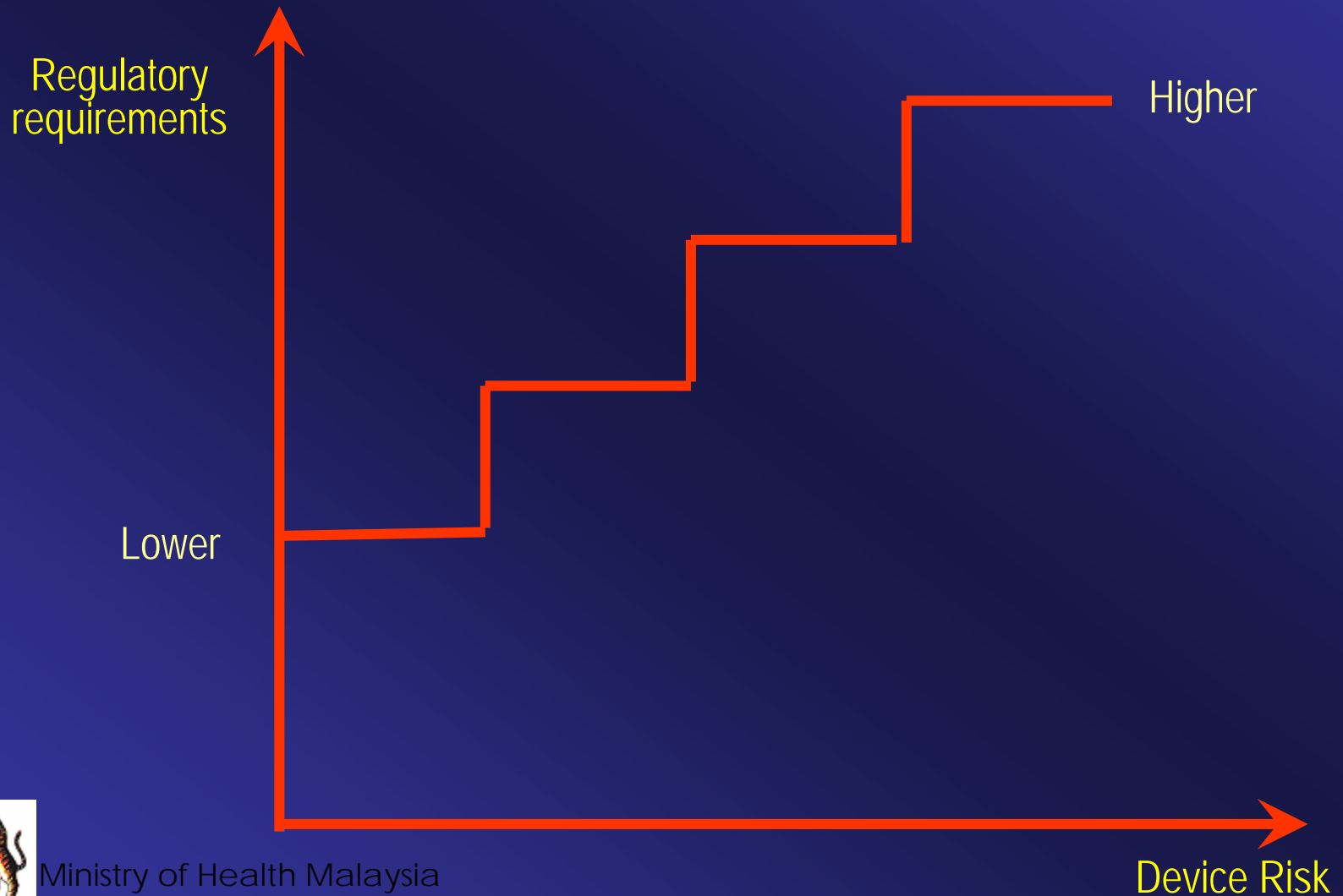




“Medical device” means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

- a) intended by the manufacturer to be used, alone or in combination, for **human beings** for one or more of the specific purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease, compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of medical devices, providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body, and
- b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Risk-based Regulatory Control



Medical Devices Classification

<i>Class</i>	<i>Risk Level</i>	<i>Device examples</i>
A	Low	Simple surgical instruments/ tongue depressor
B	Low- Moderate	Hypodermic needles/suction equipment
C	High- Moderate	Lung ventilator/orthopaedic implants
D	High	Heart valve/implantable defibrillator



Conformity Assessment

