MINISTRY OF HEALTH

For a healthier life

# Assessment Framework In Israel
## WCBP January 2018, Dr. Vered Ben Naim

### Applications

"Regular" pathway
Accelerated pathway

### Requirements

Full Dossier
CPP
FDA/EMA assessment reports
Questions & Answers

### Regulation

Pharmacist' Directive & Regulations
IMOH guidelines
ICH & EMA guidelines adoption
FDA & WHO guidelines
EP/ USP/ JP

### Making a Decision

Full Assessment
Advisory Committee
Risk-Balance approach

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# Current Regulation Framework- Advance Therapies

## Legislation

Definition of a Medicinal Product
Cell and Tissues supervision and enforcement

## Hospital Exemption- EU model

In hospitals
Under physician's responsibility
Justification for CL exclusion
Under GMP, Unique Quality standards
Tractability

## GMP

EC Directives & guideline
Flexibility
Risk-based approach
Case by case

## Clinical trials & Licensing

IMOH guidelines
Classification
EMA guidelines
Ad-hoc advisory committee