



# HALAL PHARMACEUTICALS - Regulatory Perspectives

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to all of you who unselfishly dedicated,  
sacrificed your time & resources in  
improving the quality of life of others



**Question 1:** How do you feel if you were given a tablet which was not tested?

# ***Breaking News***



- MALAYSIA: First Malaysian *Halal* Pharmaceutical Standard for Better Healthcare - A First for the World

# Halalan [allowable] & Toyyiban [safe]

## Toy yiban (DCA)

- Quality, Safety & Efficacy
- GMP, Pre & Post Registration requirements, GDP
- Policies etc

Halalan  
(JAKIM)



# DRUG CONTROL AUTHORITY - DCA

## PIHAK BERKUASA KAWALAN DADAH - PBKD

# Regulator's concern ....Pharmaceuticals

## Quality, Safety and Efficacy [Kualiti, Keselamatan dan Keberkesanan]

# *What do we mean ?*

Quality (meet specs, for intended use) and

Safety (Limits for Heavy metals & Microbial counts, no prohibited ingredients, ADR monitored)

Efficacy (proven clinically)





NPCB



Product must  
be first  
registered or  
notified  
with DCA  
[Quality,  
Safety,  
Efficacy -  
already  
evaluated]

JAKIM  
conducts  
HALAL  
Pharma  
Audits



JAKIM issues  
HALAL  
Certificates  
[powers to  
issues or  
revoke  
Certifications]



# Current DCA's Policy on HALAL



Allows HALAL labels on:

- Cosmetics, Traditional Med
  - Health Supplements
    - OTC [2013]  
IV parenterals

*Why?*

- **There is a choice**

**Halal Certification is voluntary**

**Must label if it is from animal source either bovine or porcine**

# Feqah Principles

- To protect life is top priority
- When in *darurat* [emergency or when there is no choice] using of *non-halal* is *harus*
- Continuous quest in search of *halal*



# HALAL Pharmaceuticals: General Guidelines MS 2424 2012

# MS 2424 2012

## Scope

- This Malaysian Standard describes the general guidelines in the manufacturing and handling of *halal* pharmaceuticals. It serves as a **basic requirement for *halal* pharmaceuticals in Malaysia.**

# What is Halal Pharmaceuticals?

Pharmaceutical products that contain ingredients permitted under the *Shariah* law & fulfill the following conditions:

- a) do not contain any parts or products of animals that are **non-*halal*** or any parts or products of animals which are not slaughtered according to *Shariah* law;
- b) do not contain ***najs***

# What is Halal Pharmaceuticals?

- c) **safe** for consumption, non-poisonous, non-intoxicating or non-hazardous to health according to prescribed dosage;
- d) not prepared, processed or manufactured using **equipment contaminated with *najs***;
- e) do not contain any **human parts or its derivatives** that are not permitted by *Shariah* law; and

# What is Halal Pharmaceuticals?

f) during its preparation, processing, handling, packaging, storage and distribution, the *halal* pharmaceutical products are **physically separated** from any other pharmaceutical products that do not meet the requirements stated in items a), b), c), d) or e) or any other items that have been decreed as *non-halal* and *najs* by *Shariah* law.



# *Fundamentals for Halal pharmaceuticals in GMP*

- The requirements describe in the PIC/S GMP Guidelines and PIC/S Annexes are integral part of the standard

Ch. 1. Quality Management System

Ch. 2. Personnel

Ch. 3. Premises and Equipment

Ch. 4. Documentation

Ch. 5. Production

Ch. 6. Quality Control

Ch. 7. Contract Manufacture and Analysis

Ch. 8. Complaint and Product Recall

Ch. 9. Self Inspection

- Annexes 1-20 (specific)

**ELEMENTS OF PIC/S  
GMP**

# *Halal* certificates

- The *halal* certificates shall be issued by the competent authority [JAKIM] in Malaysia
- JAKIM - Dept of Islamic Development of Malaysia
- 71 recognised bodies in 29 countries

# Recognised Halal Bodies in JAPAN

1. **Japan Muslim Association**  
3-4-14, Kohinata, Bunkyo-ku,  
Tokyo 112-8585, Japan  
Chairman Prof. Hideomi MUTO (Tayeb )  
Tel : +81 33947940  
Fax: +81 339479416  
Email : jma@mc.neweb.ne.jp  
TayebM@aol.com
  
2. **Japan Halal Association (JHA)**  
547-0035 , Osaka Shi Hirano-Ku,  
Nishiwaki 1-1-2 Miyako Sansai  
Tel : 81 6 6704 7080  
Fax : 81 6 6704 9505  
Email : info@jhalal.com

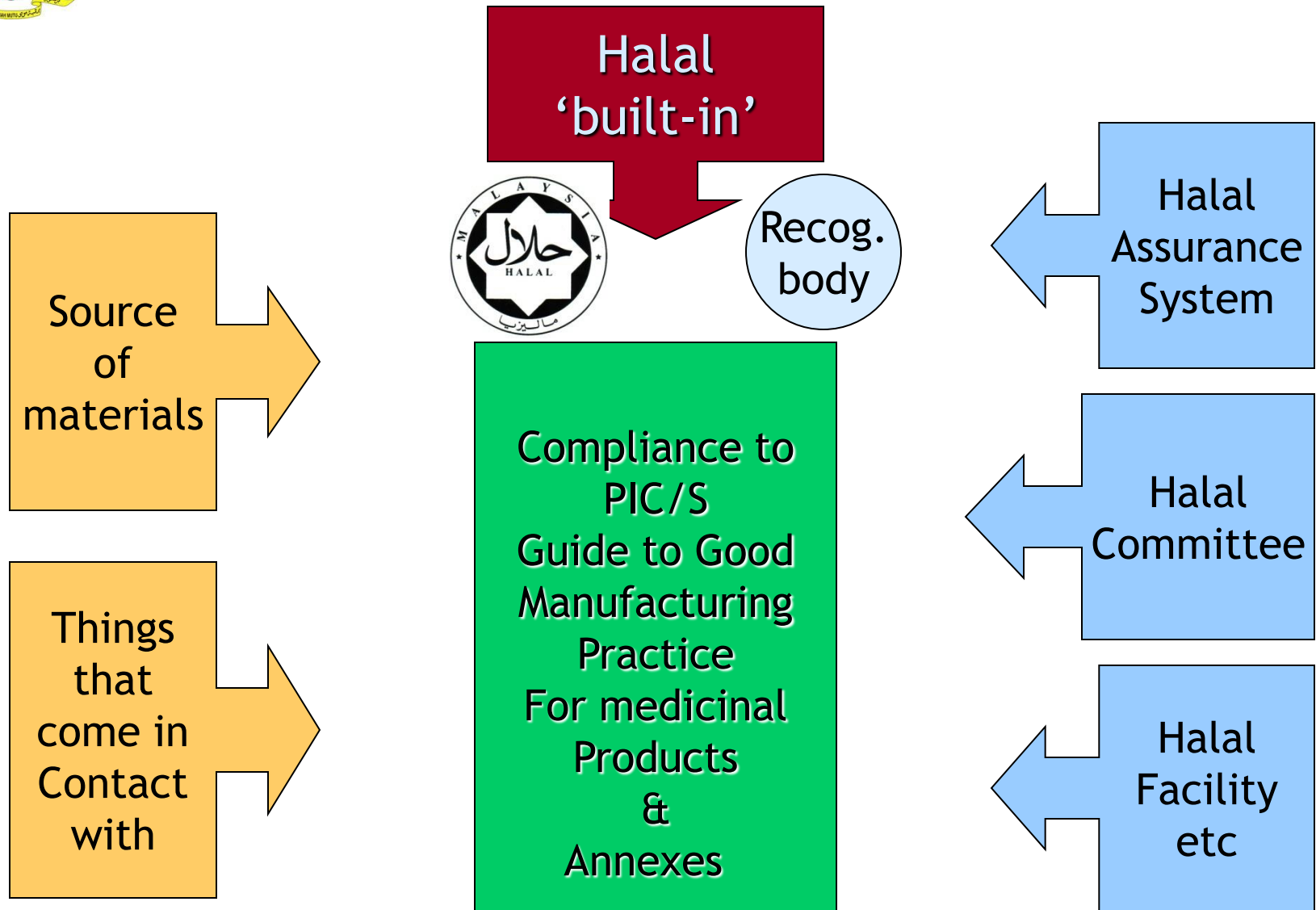


# HALAL BUILT-IN

## Not tested for



NPCB





NPCB

# We compliments each other!



[drtajuddin@bpfk.gov.my](mailto:drtajuddin@bpfk.gov.my)



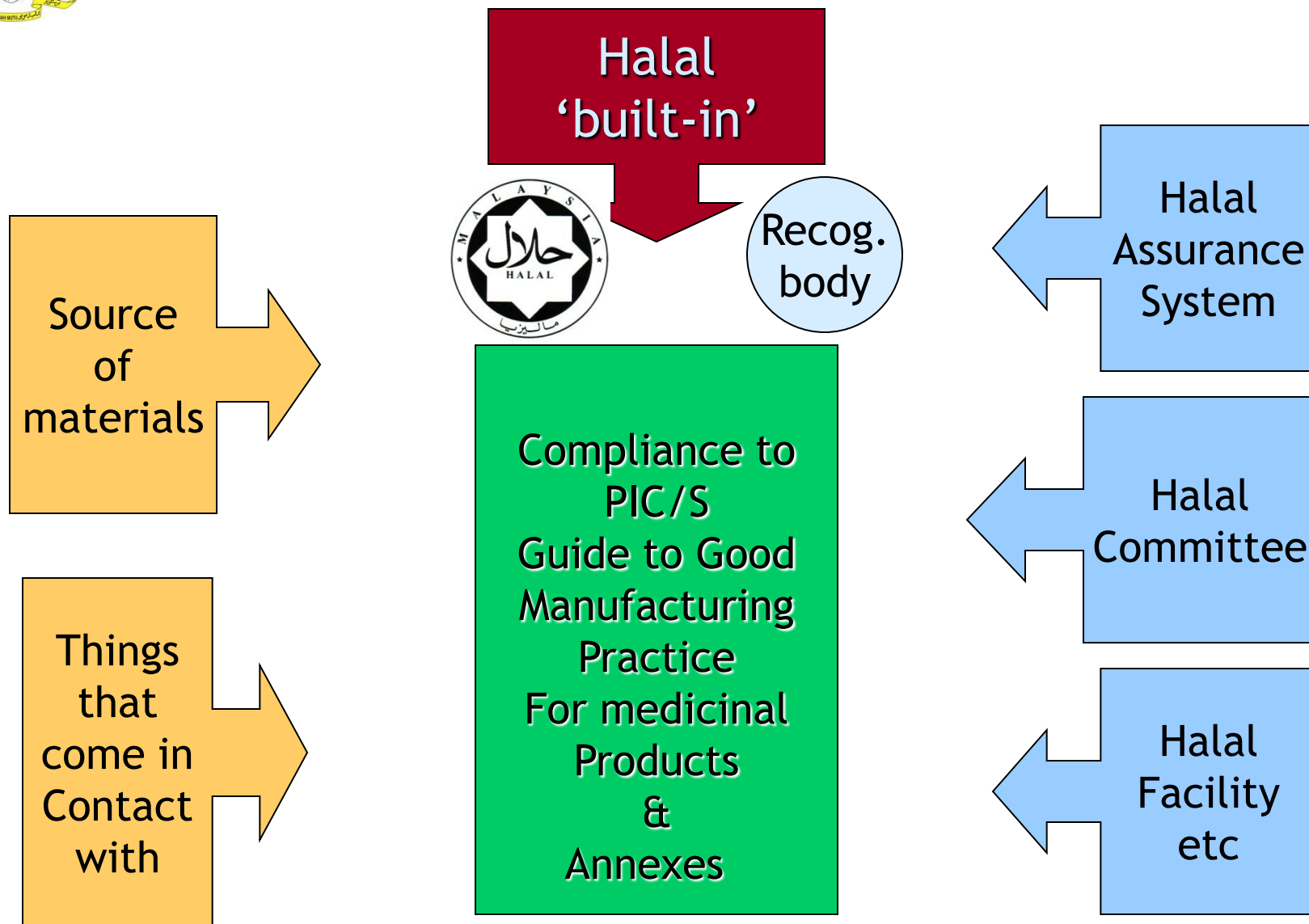


*Terima  
kasih*





# *Take Home Message*





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