



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 concernPharmaceuticals

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*



NPCB

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

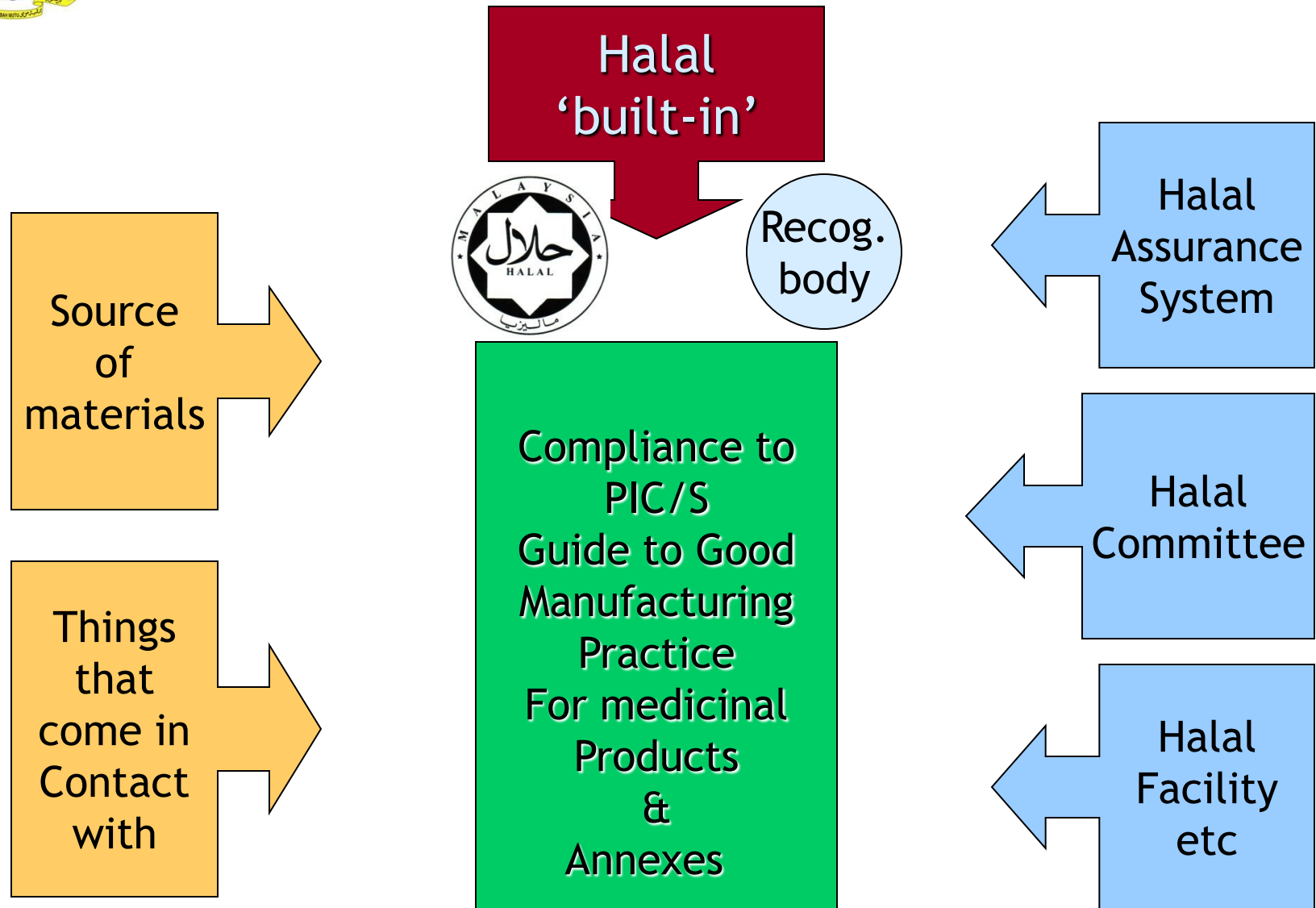
1. **Japan Muslim Association**
3-4-14, Kohinata, Bunkyo-ku,
Tokyo 112-8585, Japan
Chairman Prof. Hideomi MUTO (Tayeb)
Tel : +81 33947940
Fax: +81 339479416
Email : jma@mc.newweb.ne.jp
TayebM@aol.com

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

We compliments each other!



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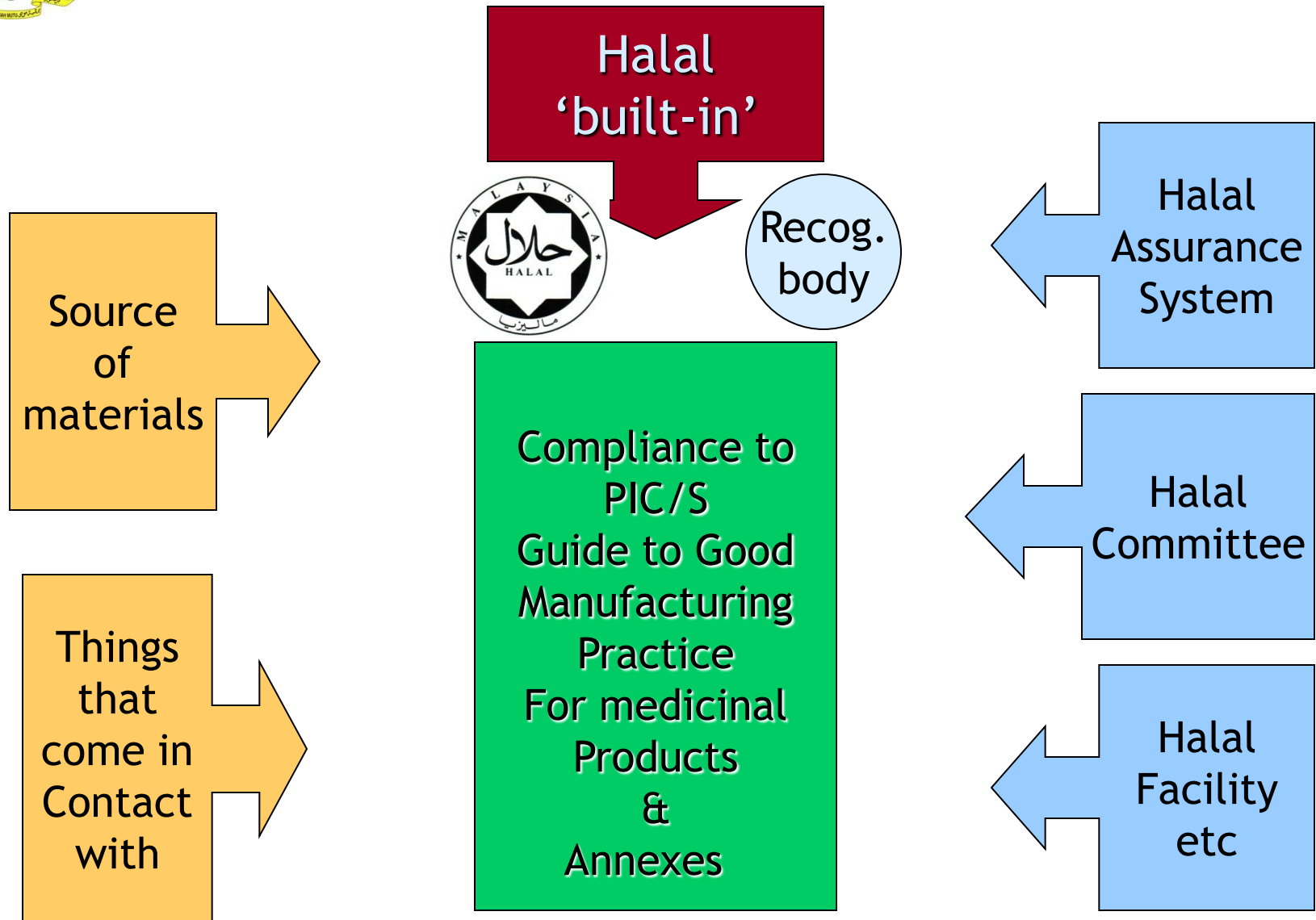




*Terima
kasih*



Take Home Message





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