HALAL PHARMACEUTICAL

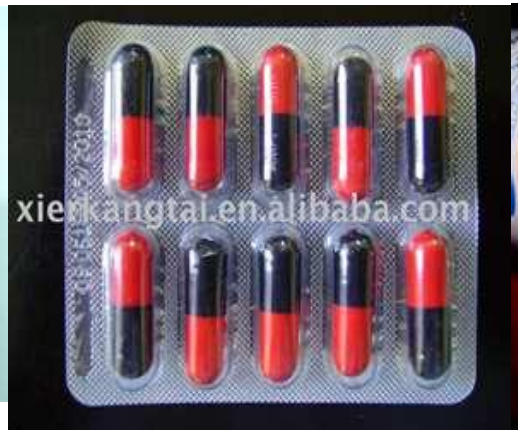
INTERNATIONAL CONFERENCE ON HALAL PHARMACEUTICAL AND HEALTH PRODUCTS ("HALPHARM") 2011

4&5 April 2011, Bintang Ballroom, Level 5, Hotel Cititel Mid Valley, Kuala Lumpur, Malaysia

1.Pharmaceutical:

- finished dosage forms and includes both prescription and non-prescription medicinal products for human use which registered with the Drug Control Authority(DCA), Ministry of Health Malaysia.





2.Halal Pharmaceutical: Definition

Pharmaceutical products that contain ingredient permitted under the Shariah.

1. Do not contain any parts of animals that are not-halal/does not slaughtered according to Shariah;
2. Do not contain any human parts/derivatives;
3. Do not contain najis

4. Safe for consumption/non-poisonous/non-intoxicating/hazardous to health

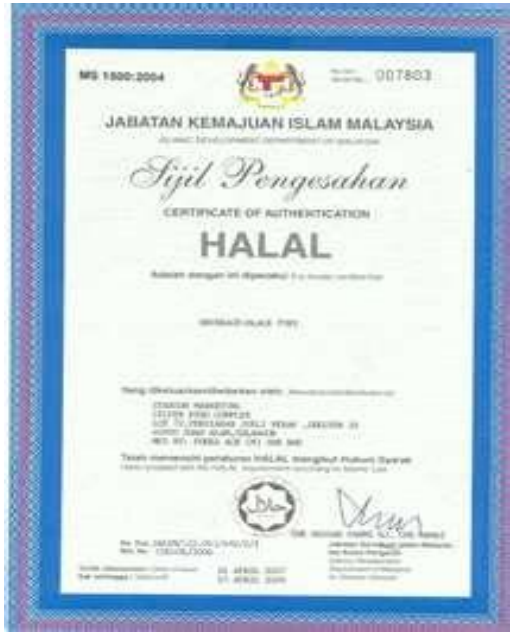
5. Processed using equipments free from najis;

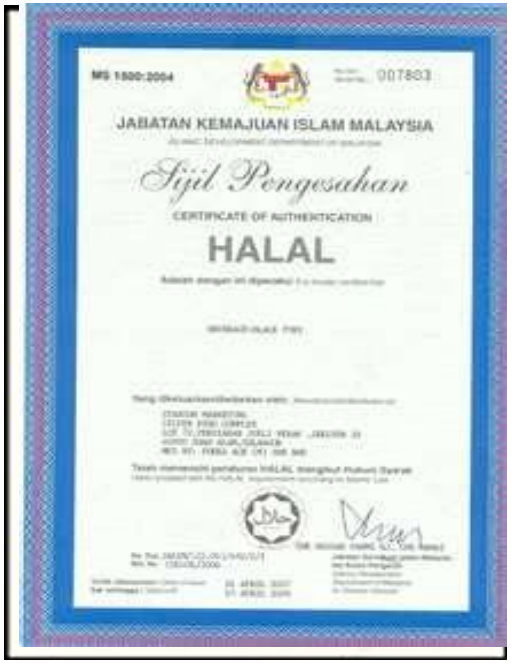
6. Total separation from non-halal items/najis (preparation, handling,storage,distribution)

Source: MS 2424:2010 (P)

Total Compliance to ***MS 2424:2010 & Existing Regulations…***

Halal Certificates from Islamic Development Department of Malaysia (JAKIM)





- ✓ Halal Edible & Pharmaceutical Gelatin
- ✓ Halal Empty Hard Gelatin Capsule

3.Law & Consumer protection

- Malaysia puts country's healthcare industry as one of its top priorities, and continually implements new policies to ensure that the medical sector continue progressing and at the same time to ensure that its people receive the best medical treatment available.

Consumer protection…

- In Malaysia, Pharmaceuticals are regulated by the Drug Control Authority (DCA);
- under the *Control of Drugs and Cosmetics Regulations 1984*;
- The main responsibility of the DCA is to ensure the safety, quality and efficacy of pharmaceuticals in Malaysia

Consumer Protection…

- *Any drug in a pharmaceutical dosage form, intended to be used, or capable or purported or claimed to be capable of being used on humans or any animals, whether internally or externally, for a medicinal purpose* is required to be registered with the DCA.
- This includes products which alleviate, treat or cure diseases, products that diagnose a disease, anesthetics, and products that maintain, modify, prevent, restore or interfere with normal physiological functions.

Exemption…

- The regulation does not apply to diagnostic agents and test kits for laboratory use;
- non-medicated medical and contraceptive devices;
- non-medicated bandages and surgical dressings; and
- instruments, apparatus, syringes, needles, sutures and catheters.

Imported Product and Consumer Protection…

- Due to the concern with counterfeit and unregistered pharmaceuticals in Malaysia, the MOH has issued a *Directive on the Use of the Hologram Security Device ("the Directive").*

✓ The Directive requires all pharmaceutical products, including health supplements, traditional products and over-the-counter (OTC) external personal care products to bear a hologram security label known as Meditag™.

✓The hologram will have a unique serial number, which verifies that the product has been registered with the DCA and the hologram can be traced to the manufacturer or importer of the product.

Implementation:

- This requirement was implemented in two phases.

- 1st January 2005 where all non-parenteral products have been required to be labeled with the hologram label;

- all injectable pharmaceuticals are required to be labeled with the hologram label since Phase 2 began on 1st July 2005.

Exemption…

- The Directive excludes temperature-sensitive products that require cold chain maintenance, such as vaccines and biologicals and cosmetic products from having the hologram labeling.

Consumer protection…

- The hologram should be placed on the front panel of the product label on the outer packaging of the product;
- Each unit of sale requires a hologram;
- customer should be able to see the hologram without opening the box or the container of the product.

Legal Consequences…

- The Directive puts the burden on the manufacturer or the re-packer in the case of products that are imported to Malaysia and packed locally or the importer in ensuring that the hologram label is affixed to the products before they are being marketed in Malaysia.
- However, the labels may also be sent to the overseas manufacturer of the product, affixed overseas, and then imported back to Malaysia.

Legal Consequences…

- companies who's products are still on the shelves without an affixed hologram will not be required to conduct a recall. It is simply up to the customers to decide whether they feel comfortable purchasing products without a hologram. ***(non-retrospective)***
- However, if a manufacturer or importer does not show any attempt to meet the hologram labeling requirements, the MOH can suspend the product registration until the manufacturer or importer complies with the new regulation.

Legal Consequences…

- With the implementation of the “Directive”, selling products which are not affixed with the Meditag™ is an offence and first time individual offenders could face a fine of RM25000 (approximately USD6600) and/or imprisonment of three years and a fine of RM50000 (approximately USD13200) and/or imprisonment of five years for a subsequent offence.
- If the offence was committed by a corporate entity, the entity can be slapped with a fine of RM50,000 (approximately USD13200) for first offence and RM100,000 (approximately USD26400) for a subsequent offence.

Ultimate Goal…

- with the “Directive”, Malaysians are guaranteed to receive genuine patented drugs and their generics and protected from imitation drugs which can be harmful.

4. SAFETY: labelling requirements in respect of pharmaceutical products for the purpose of registration

- **General Labelling Requirements**
- 1. Name of the product.
- 2. Name and quantity of each active ingredient.
- 3. Name and address of the manufacturer.
- 4. Hong Kong registration number of the product.
- 5. Batch Number.
- 6. Expiry date.
- 7. Specific storage conditions, if any.

Labelling requirements…

- **Additional Labelling Requirements for Sterile Products**

- 1. Name and quantity of preservatives, if any.
- 2. Batch number and expiry date (on sales pack and on each ampoule/vial).
-

Labelling requirements…

- **Additional Labelling Requirements for Certain Classes of Products**

- 1. For embrocations, liniments, lotions, liquid antiseptics or other liquid medicines for external application -
-
- “For external use only. 只供外用。”

- 2. For veterinary products -
- “For animal treatment only. 只限醫治禽畜用。”

- 3. For mouthwashes -
- “Not to be swallowed. 不可吞服。”

- 4. For eye-drops -
- “Not to be used one month after opening. 開蓋一個月後不可使用。”

Labelling requirements…

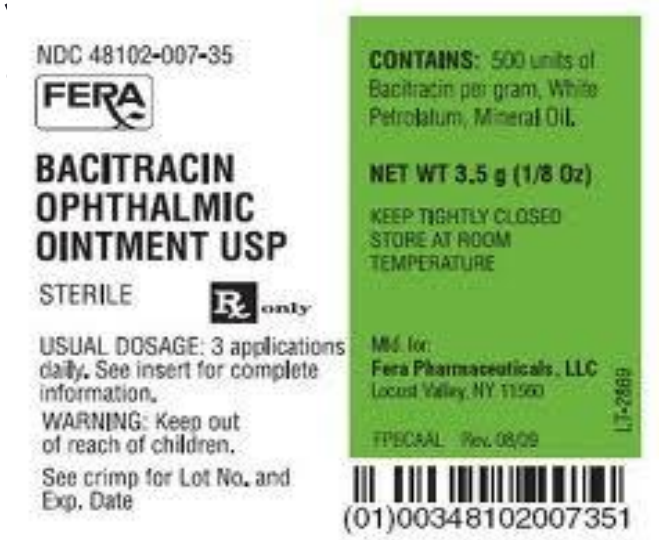
- **Additional Labelling Requirements for Non-poisons and Part II Poisons**

1.Dosage, route and frequency of administration in both English and Chinese.
(For injectable products, words such as “To be used only as directed by a medical practitioner 請遵照醫生指示使用

Labelling/warning requirements…

For medicines containing **Salicylamide** -

- The following is required on the label and/or package insert -
- *"Keep out of reach of children*. This medicine should not be given to children under 16 except on medical advice.
避免兒童誤取。非經醫生指示，十六歲以下兒童不可服用



For medicines containing **Phenylpropanolamine** -

- The maximum daily dose should not exceed 100mg and on the label or in the package insert :-
- (i)“If you are under the care of your doctor or receiving continual prescribed medication or are pregnant then consult your doctor.

假如你是在醫生的照料下或長期服用藥物或懷孕，請徵詢醫生意見。”

- (ii)"Patients with high blood pressure, hyperthyroidism, heart disease or who are receiving monoamine oxidase inhibitors should not take the product. 患有高血壓、甲狀腺素高、心臟病或正接受單氨基酸抑制劑治療的病人不可服用此葯。"

(iii)"The product may aggravate conditions such as diabetes, glaucoma, or prostatic enlargement.此葯可使糖尿病、青光眼和前列腺肥大等病症的病情轉壞。“

(iv) "The product should not be used as appetite suppressant.此葯不可作食慾抑制劑使用。“

DEPARTMENT OF HEALTH

PHARMACEUTICAL SERVICE

PHARMACEUTICALS REGISTRATION SECTION

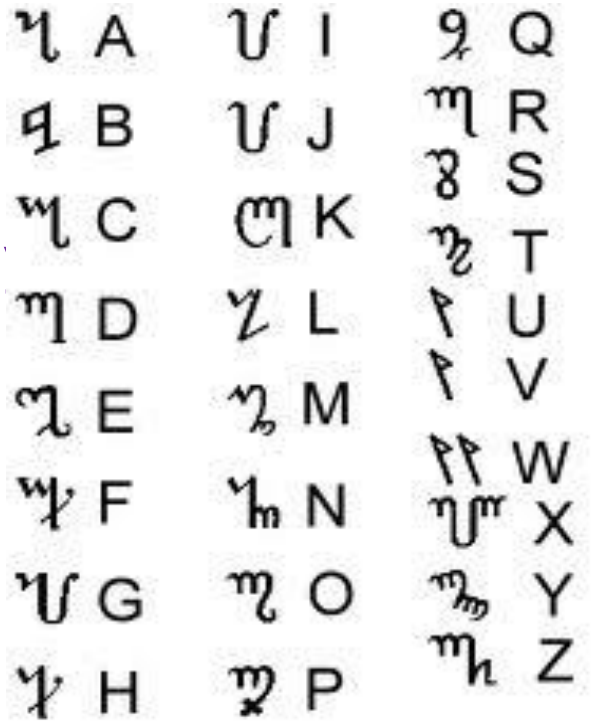
ASEAN COUNTRIES Labelling Requirements

- **1. PHILIPPINES**
- **2. INDONESIA**
- **3. THAILAND**
- **4. SINGAPORE**
- **5. MALAYSIA**
- **6.VIETNAM**
- **7. LAOS**
- **8.CAMBODIA**
- **9. BRUNEI DARUSSALAM**

Example:
LABELING REQUIREMENTS (COUNTRY SPECIFIC) – THAILAND

- According to Drug Acts, these words have to be written in **Thai;**

- Dangerous drug,
- Specially Controlled drug,
- For external use,
- Common Household remed
- Topical use,
- Expiry date.



5.JURISDICTION?

“Food” or “Food Supplement”?

- **Food?**

Food Act (Food Regulations 1985)1983

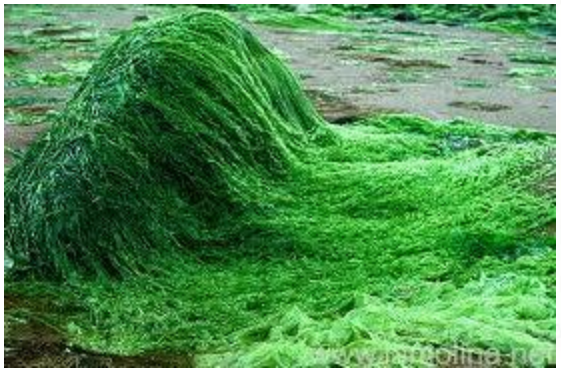
- ✓ **Food Safety and Quality Division(MOH)**

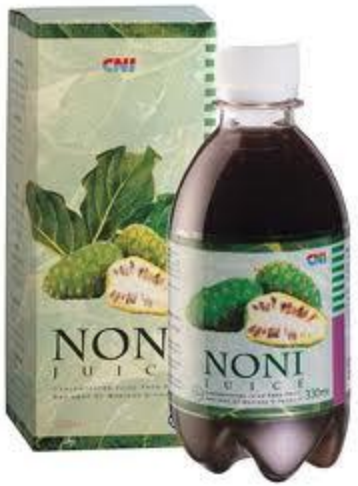
Food Supplement?(which are treated as health supplement)

“food” or “pharmaceutical”?

- Committee for the Classification of Food-Drug Interface Products has developed a classification system to determine whether the launch of a product in question is to be regulated by the Drug Control Authority (“DCA”) of the National Pharmaceutical Control Bureau or the Food Quality Division (“FQD”).

- If a product contains 80% or more of food-based ingredients, singly or in combination, with equal to or less than 20% of biologically active ingredients (such as vitamins, minerals, amino acids), the product is considered as a food product and shall be regulated by the Food Safety and Quality Division
- The governing law will be the Food Act (Food Regulations 1985) 1983





- However,

✓If a product contains less than 80% of food-based ingredients, with more than 20% of the active ingredients, the product is considered as pharmaceutical product and shall be regulated by the DCA.

✓ A product which contains solely natural ingredients that are not traditionally used as food and possesses medicinal value such as alfalfa, spirulina, royal jelly, noni juice, rooibos tea, pegaga tablet and other herbal products, is regulated by the DCA.

labeling requirements specifically provided for health supplement products:

e.g. Obligatory information, warnings or statements

- ✓Registration Number. For e.g. MAL 12345678HN
- ✓ Batch Number
- ✓ Manufacturing Date
- ✓ Expiry Date
- ✓ Route of administration / dose / use instruction
- ✓ Dosage form
- ✓ Pack size
- ✓ Storage condition
- ✓ The words “Keep out of reach of children” or words bearing similar meaning in both Bahasa Malaysia (national language of Malaysia) and English

Ingredients

- ✓Nutrient function claims of the individual vitamins or minerals are allowed. For e.g. Vitamin A helps to maintain growth, vision and tissue development etc.
- ✓Name and strength of active substances
- ✓Name and content of preservative (where present)
- ✓ Name and content of alcohol (where present)
- ✓ Source of ingredients (active, excipient, and/or capsule shell) – derived from animal origin

Grand Guarantee: We promise that this product contains the specified amount of each ingredient as listed in our product facts from the first scoop to the last.

ACTIVE INGREDIENTS:	PER 1 DOSE:
GLUCOSAMINE HCL (SHELLFISH SOURCE)	5,000 mg
VITAMIN C	5,000 mg
METHIONINE	3,000 mg
MANGANESE GLUCONATE	250 mg
ZINC GLUCONATE	200 mg
LYSINE	200 mg
NIACINAMIDE	150 mg
CITRUS BIOFLAVONOIDS	100 mg
YUCCA	100 mg
PROLINE	80 mg
COPPER GLUCONATE	50 mg
INACTIVE INGREDIENTS:	
Maltodextrin	
STORAGE:	
Store in a cool, dry place. Keep lid closed for maximum freshness. Follow label directions.	

Supplement Facts

Service Size: 1 Power Cell™ .35 oz (10g)

	Amount Per Serving	% Daily Value
Calories	38	
Calories from Fat	3	
Total Fat	0.3 g	0.4%†
Total Carbohydrates	5.6 g	1.8%†
Dietary Fiber	0.8 g	3.2%†
Sugars	4.4 g	*
Protein	2.6 g	
Vitamin C	1 mg	0.2%†
Vitamin B2	0.6 mg	35.2%†
Vitamin B3	6 mg	30%†
Vitamin B5 (Pantothenic Acid)	4 mg	40%†
Vitamin B6	2 mg	100%†
Vitamin B12	2 mcg	33.4%†

6.*FATWA* and Drug Administration

1. Hukum Penggunaan Vaksin Meningitis Menveo

- Muzakarah Jawatankuasa Fatwa Majlis Kebangsaan Bagi Hal Ehwal Ugama Islam Malaysia Kali Ke-94 yang bersidang pada 20 - 22 April 2011 telah membincangkan Hukum Penggunaan Vaksin Meningitis Menveo. Muzakarah telah memutuskan seperti berikut:

- Setelah mendengar taklimat dan penjelasan daripada Biro Pengawalan Farmaseutikal Kebangsaan (BPFK) dan meneliti keterangan, hujah-hujah serta pandangan yang dikemukakan, Muzakarah mengambil perhatian bahawa proses penghasilan Vaksin Menveo keluaran Syarikat Novartis Vaccines adalah sama sepertimana penghasilan Vaksin Mencevax keluaran Syarikat Glaxo Smith Kline (GSK).

- Sehubungan itu, Muzakarah bersetuju memutuskan bahawa pada dasarnya hukum penggunaan vaksin Menveo adalah **harus atas dasar dharurah** sama seperti vaksin Mencevax yang telah diputuskan pada Muzakarah kali ke-53 bertarikh 27 November 2002 kerana sehingga kini masih belum ada mana-mana vaksin meningococcal meningitis yang dihasilkan 100% halal dan suci daripada awal hingga akhir proses penghasilannya.

- Walaubagaimanapun untuk maslahah umat Islam, Muzakarah berpandangan di antara kedua-dua vaksin ini, **keutamaan adalah kepada vaksin Mencevex** yang telah digunakan sekian lama dan telah terjamin dari segi keberkesanan dan keselamatan kepada pengguna. Manakala vaksin Menveo masih baru di pasaran dan pemonitoran kesan jangka panjang masih berterusan.

- Muzakarah juga berpandangan bahawa **Sijil Halal tidak wajar diberikan** kepada vaksin Menveo kerana penentuan harus adalah atas dasar ***dharurah*** dan proses penghasilannya tidak mematuhi piawaian pensijilan halal Malaysia.

2.Meningococcal Meningitis Vaccination for Muslims

- **Decision:**
  The 53rd Muzakarah (Conference) of the Fatwa Committee of the National Council for Islamic Religious Affairs Malaysia held on 27th November 2002 has discussed Meningococcal Meningitis vaccination for Muslims:
- The Committee has decided that meningococcal meningitis mencevax vaccine extracted from cow sources is permissible;
- However, meningococcal meningitis monumune vaccine that contains pig sources is forbidden.

3. The Ruling of Botulinum Toxin Type A (BTA) Injection

Decision:

- The 73rd Muzakarah (Conference) of the Fatwa Committee of the National Council for Islamic Religious Affairs Malaysia held on 4th -6th April 2006 has discussed the ruling on botulinum toxin Type A (BTA) injection. The Committee has decided that:

- 1. After conducting careful examination on international and local research together with evidences brought by fatawa committee in some Muslim countries, it is concluded that botulinum toxin Type A or commercially known as botox does contain doubtful substances, najis (impure) and it is forbidden. Amongst the doubtful substances are pig extracts.

- 2. Botulinum toxin Type A injection or its commercial name botox can cause long and short term negative side effects to the users and it can be manipulated for scam.

- 3. On the bases of the statement above, the committee has concluded that the botulinum toxin Type A injection or its trade name, botox is forbidden;

- **4. However, the botulinum toxin Type A injection is permissible for medical purposes, on the condition that it is used for *darura* case (emergency), urgent need and conducted by a certified specialist. (Necessity/Pressing need)**

4.The Ruling on Using Biothrax Vaccine and Rotateq Vaccine that Used Pig Sources in its Production Process

- **Decision:**
- The 81st Muzakarah (Conference) of the Fatwa Committee National Council of Islamic Religious Affairs Malaysia held on 31st March 2006 has discussed the ruling of using biothrax vaccine and rotateq vaccine that used pig sources in its production process. The Committee has decided that the usage of Biothrax vaccine and RotaTeg are not permitted because:

- 1. No urgent need at the moment

- 2. There are alternative substances or medicines besides using pig sources in the production of the said vaccines

3. There is no concrete proof stating that people in the country are in dire need of such vaccine.

5. The Rulling on Using Human Papilloma Virus Vaccine (HPV)

- Muzakarah Jawatankuasa Fatwa Majlis Kebangsaan Bagi Hal Ehwal Ugama Islam Malaysia Kali Ke-92 yang bersidang pada 15 - 17 Disember 2010 telah membincangkan Hukum Pengambilan Vaksin Human Papilloma Virus (HPV). Muzakarah telah membuat keputusan seperti berikut:

- Setelah mendengar taklimat daripada pihak Biro Pengawalan Farmaseutikal Kebangsaan serta pandangan dan hujah-hujah yang dikemukakan, Muzakarah berpandangan bahawa Islam menggesa umatnya supaya menjaga kesihatan kerana penjagaan kesihatan seseorang individu akan menentukan tahap dan mutu kesihatan masyarakat secara umumya. Pemberian vaksin merupakan jalan pencegahan awal yang diambil oleh pihak Kerajaan dalam usaha mengelakkan penyebaran virus di kalangan wanita.

- Sehubungan itu, Muzakarah bersetuju memutuskan bahawa pengambilan Vaksin Human Papilloma Virus (HPV) yang telah dipastikan tiada unsur meragukan dalam kandungannya dan tidak mendatangkan kemudharatan adalah diharuskan bagi mencegah penyakit kanser pangkal rahim (servik) di kalangan wanita.

- Muzakarah juga memutuskan bahawa pemvaksinan ini hendaklah tidak mengandungi unsur-unsur eksploitasi terhadap pengguna atau digunakan untuk tujuan yang bercanggah dengan syarak.

6.The Ruling on Using Ink for Cancer Treatment

- **Decision:**

- The 90th Muzakarah (Conference) of the Fatwa Committee National Council of Islamic Religious Affairs Malaysia held on 1st March 2010 has discussed the ruling on using ink for cancer treatment. The Committee has decided that cancer treatment using Holbein drawing ink which is najis free is permissible and the patient can take the ablution as usual because the ink is only inserted underneath the skin.
- Penggunaan tandaan berdakwat untuk pesakit kanser ini adalah berbeza daripada tatoo yang diharamkan oleh Islam kerana tatoo dicacah ke dalam lapisan kulit dan ia kekal selama-lamanya, manakala tandaan berdakwat ini hanya dicucuk dengan menggunakan jarum kurang dari 1mm .

7.Ruling on Using Clexane and Fraxiparine Medicines

- **Decision:**
- The 87th Muzakarah (Conference) of the Fatwa Committee National Council of Islamic Religious Affairs Malaysia held on 23rd-25th June 2009 has discussed the ruling on using clexane and fraxiparine medicines. The Committee has decided that:
- Islam prohibits using medicine derived from unlawful sources as a cure, except in a situation where there is no other lawful sources and the amount used according to the prescribed dosage only. The haram based medicine is only permitted to be used limitedly. The permissibility (of using haram based medicine) is annulled when the halal alternative is found.
- Thus, as regards to clexane and fraxiparine that are urgently needed by patients who are in critical condition to prevent sudden clotting of the blood, the Committee has decided that the medicines are forbidden. It is due to the **availability of alternative medicine namely arixtra that is produced from lawful sources which has the same function and efficiency as clexane and fraxiparine (**MAL 20034441A).

8.Rubella Immunization

- **Decision:**

The 21st Muzakarah (Conference) of the Fatwa Committee of the National Council for Islamic Religious Affairs Malaysia held on 12th September 1988 has discussed rubella immunization. The Committee has decided that the rubella vaccine provided by Malaysian Ministry of Health is not najis (ritually impure) and the injection is permitted to prevent rubella

9.The View of Islam Regarding Measles, Tuberculosis, Diphtheria, Tetanus and Polio Immunizations

- **Decision:**

- The 24th Muzakarah (Conference) of the Fatwa Committee of the National Council for Islamic Religious Affairs Malaysia held on 5th -6th June 1989 has discussed the view of Islam regarding measles, tuberculosis, diphtheria, tetanus and polio immunizations. The Committee has decided that such immunizations are permissible in Islam.

10.Hepatitis-B Immunization

- The 22nd Muzakarah (Conference) of the Fatwa Committee of the National Council for Islamic Religious Affairs Malaysia held on 24th November 1988 has discussed Hepatitis-B immunization. The Committee has decided that the vaccine of Hepatitis B extracted from yeast is not najis (ritually impure) and permitted to be used due to the fact that yeast is (ritually) pure.

11. Use of Gelatin in Medicine

- The 8th Muzakarah (Conference) of the Fatwa Committee of the National Council for Islamic Religious Affairs Malaysia held on 24th -25th September 1984 has discussed gelatin in medicine. The Committee decided that gelatine in medicine is permissible because of necessity *(darura).* If there is any other alternative substance that can prevent medicine from easily deteriorating, hence the gelatin is no longer permitted.

12. Use of Alcohol in Medicine

Decision:

- The 7th Muzakarah (Conference) of the Fatwa Committee of the National Council for Islamic Religious Affairs Malaysia held on 11th -12th April 1984 has discussed alcohol from Islamic point of view. The Committee has decided that:

- ✓ All liquor contains alcohol, but not all alcohol is liquor. Alcohol produced from liquor process is regarded as najis (ritually impure) but not alcohol produced from other than liquor process. Both types however are prohibited to be consumed.

- ✓ Soft drink produced in the same way of liquor production and contains either little amount of alcohol or the alcohol has been distilled is prohibited to be consumed

- ✓ Soft drink produced not to become liquor or intoxicants item and produced not in the same process of liquor is lawful

- ✓ Tapai (fermented rice) is lawful to be eaten

- ✓ Alcohol produced as by product in food process is not najis and can be consumed

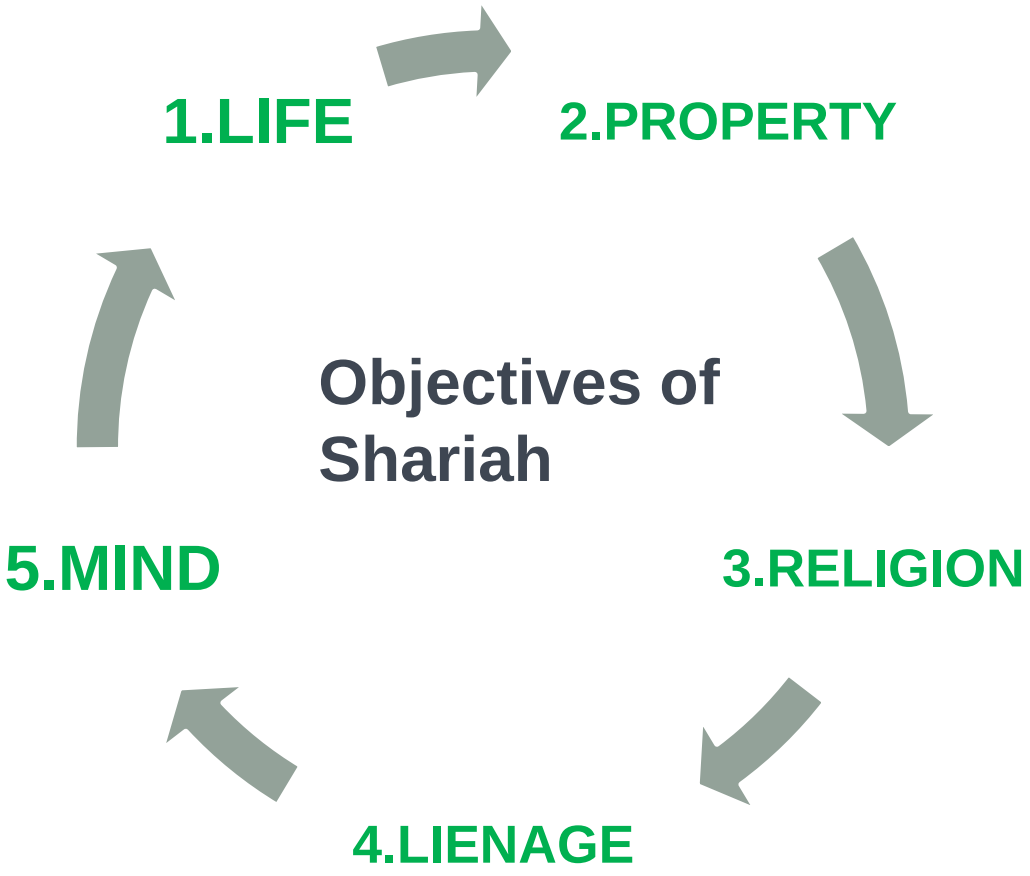
- ✓ ***Medicines and fragrances containing alcohol are permissible***

13.Injection of Highly Purified Insulin Derived From Pig

- **Decision:**

The 6th Muzakarah (Conference) of the Fatwa Committee of the National Council for Islamic Religious Affairs Malaysia held on 10th October 1983 has discussed injection of Highly purified insulin derived from pig. The Committee has decided that injecting highly purified insulin derived from najis mughallaza (grave impure item that is pig) as medication for diabetics is permissible on the basis of *emergency (Darurah)*. The ruling is applicable to the person who administers the injection.

Dharurah/Necessity?



7.*FATWA* and Its Relevancy

- **Peruntukan Mengenai Fatwa Dalam Undang-Undang**

✓Di dalam Akta Pentadbiran Undang-Undang Islam (Wilayah-Wilayah Persekutuan) 1993 [Akta 505], peruntukan mengenai fatwa dijelaskan di bawah Seksyen 34 iaitu:

- ✓ **Maksud Fatwa** iaitu pendapat atas apa-apa persoalan yang belum diselesaikan atau yang menimbulkan pertikaian mengenai atau berhubung dengan Hukum Syarak;
- ✓ **Mengenai bila sesuatu fatwa itu boleh dibuat**, iaitu apabila diperintahkan oleh Yang di-Pertuan Agong, atau atas permintaan orang ramai melalui surat yang dihantar kepada Mufti, atau dibuat atas kehendak Mufti itu sendiri;
- ✓ Sesuatu pernyataan yang dibuat oleh Mufti hanya boleh diambil sebagai fatwa jika pernyataan itu disiarkan dalam **warta** berhubung dengan Hukum Syarak;

- ✓Sesuatu fatwa yang telah disiarkan dalam **warta (gazette)** hendaklah dipatuhi oleh semua umat Islam yang berada di negeri itu, kecuali amalan peribadi yang dibenarkan mengikut Hukum Syarak; dan

- ✓Fatwa yang diwartakan merupakan sebahagian daripada undang-undang yang perlu diikuti oleh semua Mahkamah Syariah bagi negeri itu ***(binding)***

Acknowledgement:

- NPCB/Ministry of Health
- Jabatan Kemajuan Islam Malaysia
- Department of Standard Malaysia
- *www.Mirandah.com*
- *www.lexmundi.com*

THANK YOU