National Regulatory Conference 2015

4 August 2015

Report on ASEAN Harmonisation and Malaysian Regulatory Updates

Tan Ann Ling

Director of Regulatory Pharmacy

Presentation Outline

- ASEAN Harmonisation Updates
  - Pharmaceutical Products (PPWG)
  - Traditional Medicines & Health Supplement (TMHS)
- Malaysian Regulatory Updates
- Future Plans

Changes in Top Management of NPCB

Director
Regulatory Pharmacy
Mr. Tan Ann Ling

Dep. Director
Centre for Organisational Development
Mdm. Siti Aida Abdullah

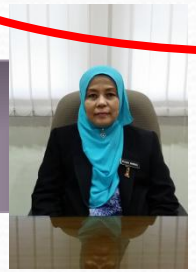
Dep. Director
Centre for Quality Control
Dr. Tajuddin Akasah

Dep. Director
Centre for Post Registration Of Products
Ms. Sameerah Shaikh Abd Rahman

Dep. Director
Centre for Compliance & Licensing
Mr. Muhammad Lukmani Ibrahim

Dep. Director
Centre for Investigational New Product
Dr. Kamaruzaman Saleh

Dep. Director
Centre for Product Registration
Mdm. Anis Talib



Head of
Centre for Administration
Mdm. Pesah Ahmad

PPWG Updates

ASEAN Sectoral Mutual Recognition Arrangements (MRA) for Bioequivalence Study Reports

- Currently 3rd. Draft MRA
- Timeframe for finalization of the BE MRA:
  - National consultation on 3rd Draft until 31 July 2015
  - Workshop and Inter-Sessional Meeting and finalisation of 4th. Draft: 24-27 August 2015
  - Endorsed of 4th Draft by PPWG : December 2015
  - Legal review at national & ASEAN level : Jan-Mac. 2016
  - Submission to ACCSQ and SEOM for endorsement : April 2016
  - Signing by ASEAN Economic Minister : 2nd. half 2016.

PPWG Updates

Main Components of BE MRA

- Accreditation of BE Centres in ASEAN Countries
  - Inspection Format
  - Panel of Experts
  - Experts from AMS
- BE Study Reports
  - ASEAN BE Guidelines
  - Accepted & Evaluated by individual AMS
- Proposed Date of Implementation: 2020

PPWG Updates

- **ASEAN GMP MRA – Impact on Malaysia**
  - Thailand accepted in ASEAN GMP MRA: 12 March 2015
  - Presently 4 members : Indonesia, Malaysia, Singapore & Thailand
  - GMP Inspection Reports by Thai FDA recognised : 12 March 2015
  - Conditional renewal of registration of products from Thailand:
    - Commitment letter by Thai FDA to do GMP inspection within 6 months
    - GMP inspection report/certificate submitted to NPCB before 1 October 2015
    - Failure to provide GMP certificate ⟶ Suspension of registration
- **ACTD/ACTR for Biologics**
  - In process of development
  - Status quo on flexibility on using ICH CTD format

PPWG Updates

- **Single Dossier Project**
  - Project is being reviewed -> scope, mechanism etc
  - Independent body – WHO
    - Country assessment
- **Country Specific Requirements**
  - Vietnam will revise survey template and circulate to Member States, APC and APRIA for comments

TMHS-PWG Updates

- **The following guidelines have been adopted:**
  - ASEAN Guiding Principles for the use of Additives and Excipients
  - ASEAN Guidelines on Limits of Contaminants
  - ASEAN Guidelines for Minimising the Risk of Transmission of Transmissible Spongiform Encephalopathies
  - ASEAN Guidelines on Stability and Shelf-Life
  - ASEAN Guidelines on Claims and Claims Substantiation
  - ASEAN Guiding Principles on Safety Substantiation
- **Still in discussion stage:**
  - ASEAN Guiding principles for Inclusion into or Exclusion from the Negative List of substances for TMHS

TMHS-PWG Updates

Development of an ASEAN Regulatory Framework for TMHS : Key activities and timelines

i. National consultation completed by 30 August 2015.
ii. Finalisation and endorsement of draft Agreements and Annexes by TMHS-PWG by February 2016.
iii. Legal scrubbing by LSAD by June 2016.
iv. Endorsement of Agreement by TMHS-PWG by June 2016.
v. Endorsement by ACCSQ by September/October 2016.
vi. Endorsement by SEOM by November 2016.
vii. National approval : November 2016 – January 2017.
viii. Signing by AEM (AMS) by February 2017

General Policy Updates

- **Medical device and pharmaceutical combination products**
  - All products under this category will be either classified as medical device under purview of MDB or pharmaceutical product under purview of NPCB according to their mechanism/mode of action of its principal function
  - Combination products will be evaluated by both MDB and NPCB but regulated by the agency according to its classification.
  - Transition period for registration of medical devices has been extended to July 2016

General Policy Updates

- **Application for third source in manufacturing for pharmaceutical products.**
  - Not allowed for pharmaceutical products (except biologics) except on a special case basis (eg emergency situations)
  - Suffix 'S' will be used at the end of the MAL number for third source products
- **Registered products that will not to be renewed**
  - Registered products that have been reclassified as food or medical devices.
- **Graphic differences on labels of products of different packaging sizes.**
  - For variation applications, applicants must ensure standardized graphics are used on labels of products with the same ingredients and strength of active ingredient even though packaging sizes may differ.

General Policy Updates

- **Registration for Products in Vials and Prefilled Syringes**
  - Separate registration applications must be submitted for vials and prefilled syringes
  - Prefilled syringes
    - Combination product: evaluation as a medical device & drug
- **Registration of psychotropics and dangerous drugs**
  - Require supporting letter from Pharmacy Enforcement Division before submitting for registration.
- **'Convenient packs' for OTC products**
  - Applications considered on case to case basis
  - Company to submit variation application MiV-PA32 : Change of Outer Carton Pack Sizes for a Drug Product and fulfill the requirements in DRGD 16.5 Application for a Convenient Pack.

General Policy Updates

- **Usage of Negative Statements on Product Labels**
  - Usage of positive statements only. E.g. Genetically Modified Organism (GMO) Free / Non-GMO → not allowed on product label.
- **Updates on the Drug Registration Guidance Document (DRGD)**
  - Will be updated twice a year → January & July
- **Biotech and NCE Product Registration**
  - Biotech & NCE product registration applications
    - Evaluation of Analytical Method Validation & Protocol of Analysis by the Center for Quality Control (PKK) is required

General Policy Updates

- Requirement for Stability Studies Data at Zone IVb for Registration Renewal.

Bil.	Perkara	Keputusan
1.	Minimum stability data required for variation approval	Stability studies data that are submitted with variation applications for storage condition and shelf life must fulfill the requirement in the ASEAN Variation Guideline (AVG) and Malaysia Variation Guideline (MVG), i.e. full real time stability study data for Zone IVb.
2.	Stability data conducted at 30ºC/ 70%RH	Stability studies carried out at 30ºC/ 70%RH is acceptable as this temperature and humidity is still within the range of **Zone IVb (30ºC ± 2 ºC / 75% ± 5%RH)**
3.	Shelf life claim (Same as item no. 1).	– An extrapolation of shelf life claim based on minimum stability studies data will not be accepted. – Full real time stability study data for Zon IVb as stated in the AVG and MVG need to be submitted for variation applications for storage condition and shelf life.
4.	Acceptance of "Store below 25ºC" for existing products found unstable at Zone IVb	No exceptions from the stability requirements at Zone IVb for registered products that are found to be unstable in Zone IVb if there are other registered products with the same active ingredient found to be stable in the same Zone. In this case, the product registration holder is to change the formulation so that the product is stable in Zone IVb.
5.	Acceptance of "bracketing" across different strengths for same active	"Bracketing" as stated in the ASEAN Stability Guideline (5th Draft) is acceptable for evaluation of stability studies data at Zone IVb.

General Policy Updates

- **Stability Studies (Zone IVb) for currently Registered Products for renewal**
  - Extended to 31 Disember 2015
  - Products found not stable at 30°C (API stable)
    - To be reformulated and new stability study data to be submitted
- **Suffix 'C' for Products of 'Sister Companies' and Subsidiaries**
  - The product registration holder company that gives the manufacturing contract to a 'sister company' or a subsidiary can register the product **without** suffix 'C'

General Policy Updates

- **Change of Registered Product to For Export Only**
  - Administrative process without cancellation
  - Submit application with fee
- **Manufacturer, Importer and Wholesaler License**
  - Timeline: 4 working days upon receipt of complete application
- **Products with Conditional Registration**
  - Registration will be suspended if applicant fails to submit the required documents/samples within the time agreed upon

General Policy Updates

- **Requirement for brand name on generic products.**
  - DRGD Appendix 11 : Subappendix 11.2.1 STEP 1: PRODUCT VALIDATION :
    - [1] Product Name: *The generic name cannot be used alone as product name but in combination with another name other than generic name.*
    - Example: Mefenamic acid capsule (x),

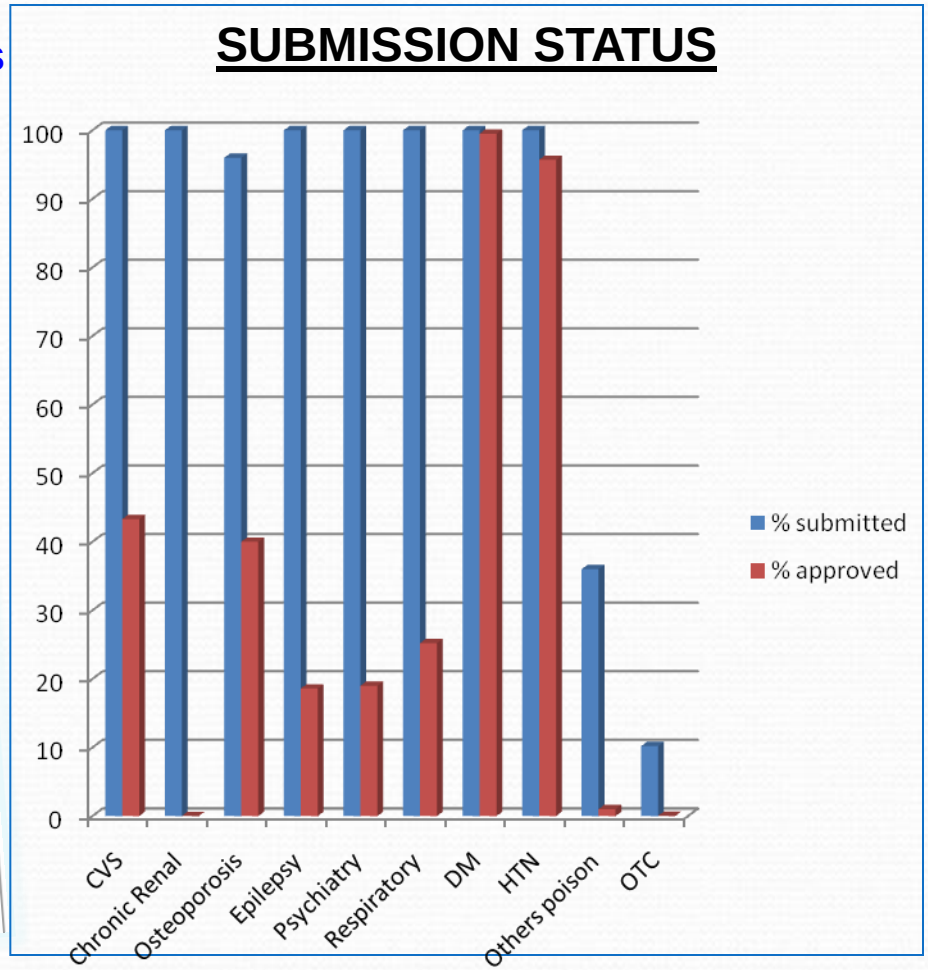
      ABC Mefenamic acid capsule (√)
- **RiMUP (Patient Information Leaflet)**
  - 1 Sept 2014 onwards, all approved RiMUP will have a serial number starting with a code R.

Consumer Medicine Information Leaflets

Risalah Maklumat Ubat untuk Pengguna (RiMUP)

Available on www.bpfk.gov.my for download by Consumers or Healthcare professionals

- **Requirement effective 1 April 2011**
- **Compulsory for self-administered products**
- **Available in Bahasa Malaysia and English**



General Policy Updates

Regulatory action taken on companies involved with adulteration:

- **First offence:**
  - Cancellation of product registration as well as product recall from the market for the product involved.
  - Minimum 6 month revocation of manufacturer's license
  - All registration activities frozen for 6 months
- **Repeat offence:**
  - Cancellation of registration as well as product recall from the market for the product involved.
  - Cancellation of all registered products from the offending manufacturer/holder.
  - Revocation of manufacturing, importing and wholesale license (if applicable)

General Policy Updates

- **Punitive Action on Product Registration Holders (PRH) that cannot be contacted or fail to give feedback to NPCB**
  - PRH legally responsible for all issues related to their product and must update NPCB on any changes in their contact information – Name, Address, Tel. & Fax Number, e-mail address etc
  - Products Registration Suspended: If uncontactable after 6 weeks from first attempt
  - Products Registration Cancelled: If uncontactable after 6 months from first attempt

General Policy Updates

- **The DCA in its 284th. meeting (January 2015)**
  - Implementation of Bioequivalence (BE) Requirements for Generic Products in Tablets/Capsules:
    - Oral Effervescent
    - Sublingual
    - Buccal
    - Dispersible
    - Orodispersible
    - Chewable
- **Implementation dates:**
  - New application : 1st July 2016
  - Registered products : Expiring from 1st. July 2017
  - Circular Bil. (27)dlm.BPFK/PPP/07/25 dated 27th.February 2015

General Policy Updates

A biowaiver may be granted based on:

- Biopharmaceutics Classification System (BCS)- List A
  - Subjected to the completeness and fulfillment of the requirements
- Unavailability/inaccessibility of comparator/innovator - List B
  - Comparator/innovator product is no longer available in Malaysia, and
  - Fulfills ALL the criteria approved by DCA such as:
    - Innovator registered before 1999 (Implementation of BE)
    - No comparator available according to ASEAN Selection Criteria
    - ASEAN Selection Criteria cannot be used
- Other considerations (List C)
  - Products with local effect and no significant systemic absorption

Vaccines: Lot Release and Cold Chain Inspection

- **Implementation for all vaccines : 1 Jan 2015**
- **Common problems encountered :-**
  - Electronic temperature device is not included in each shipping cartons
    - Expired data logger being used during transportation
    - Some of data logger was not activated
    - Incomplete data logger temperature recording
  - Inability of product registration holder to submit documents on transportation and packing validation to support temperature excursion
  - Poor compliance on timeline for documents submission
  - Deviation in amount stated in VLR application form
  - Information of vaccines not updated in NPCB's Database

API - Reminder

- **Control of API in registered pharmaceutical products containing scheduled poisons (all dosage forms)**
  - Products with registrations that expire 1st January 2020 onwards.
    - Submit documents with the required API information **at least 1 year** before the registration expires.
  - Implementation date of control of API for new applications:
    - Parenteral dosage form → 1 July 2014
    - Oral dosage form → 1 July 2016
    - Dosage form other than parenteral and oral → 1 July 2018
  - Bil (11) dlm BPFK/PPP/01/03 Jld 3

GMP Policy Updates

- **Requirement for full time registered pharmacist to head the production section of all pharmaceutical, radiopharmaceutical and veterinary product manufacturing premises registered with the DCA.**
  - Pharmaceutical and radiopharmaceutical product (Poison & OTC)
    - Extended 2 years (Effective: 1 January 2017)
  - Veterinary product (Schedule Poisons)
    - Extended 5 Years (Effective 1 January 2020)

Veterinary Policy Updates

- **Transfer of Jurisdiction to DVS after enforcement of the Animal Feed Act 2009**
  - Veterinary herbal and supplement products – 1 July 2014
  - Medicated Feed – 1 January 2015
  - Medicated Premixes without therapeutic claims – 1 July 2015
- **DCA to maintain regulatory of all Vet. Products with therapeutical claims including premixes used for therapy**

Veterinary Policy Updates

- **Animal Feed Containing Scheduled Poison**
  - Under jurisdiction of Department of Veterinary Services (DVS).
- **Licensing Requirements.**
  - Enforced since 1st July 2015
  - Only registered products can be:
    - Imported
    - Manufactured

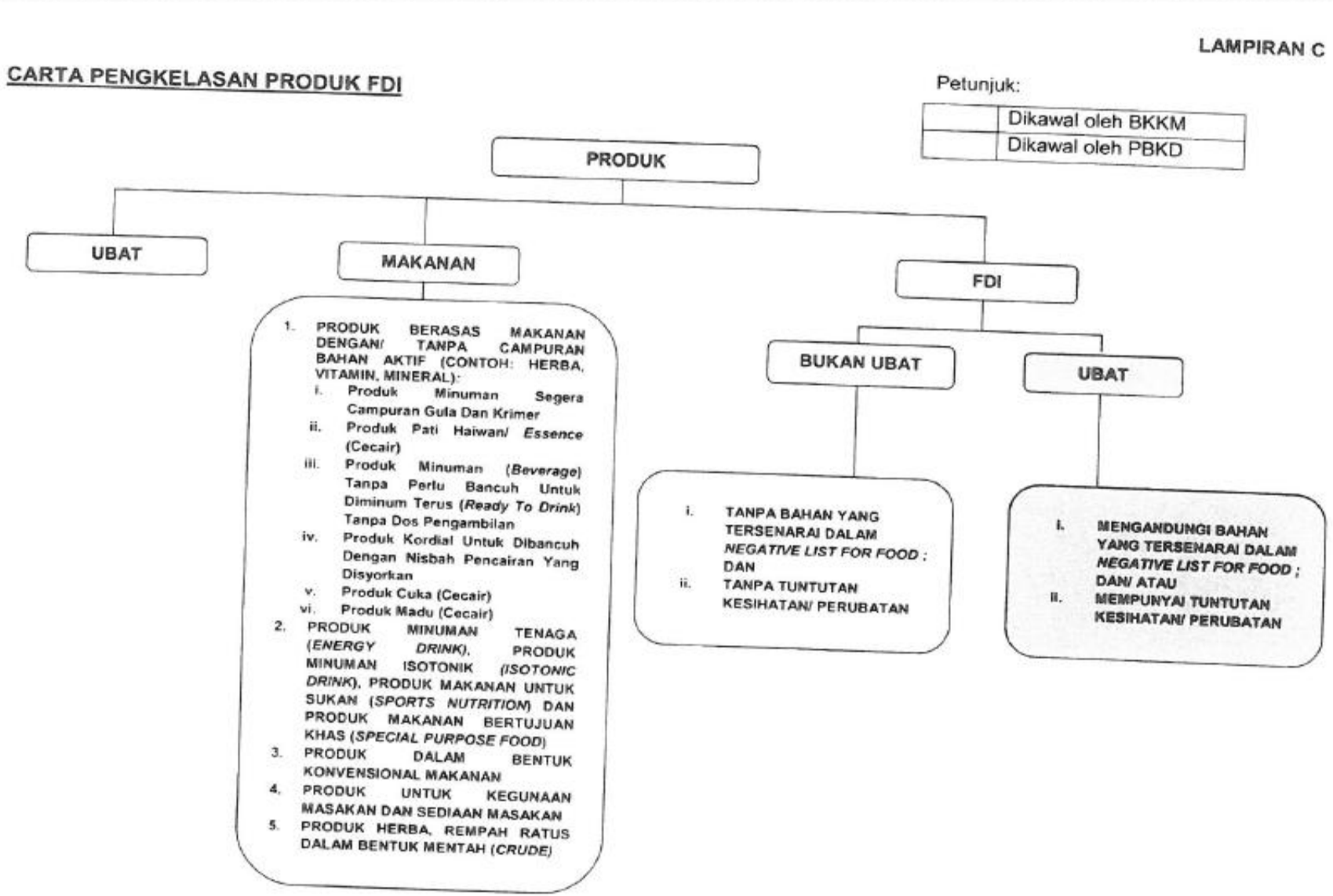
FDI Policy Updates

- **Grace period to register FDI classified as registrable products**
  - Products for Sale in Malaysia
    - 31 December 2014
  - For Export Only (FEO) Products
    - 30 June 2015
  - As of 1 July 2015, all FDI products that are classified as a registrable product must be registered with DCA

FDI Policy Updates

- **Reclassification of FDI products.**
  - Products with function and presentation likeness of conventional food ⟹ Food
    - Food based products eg. Essense of Chicken, Coffee 3 in 1
    - Beverages eg. Energy & sports drink, special purpose food
    - Conventional food presentation eg. Cakes, gummies, candy
    - Products used in cooking eg Olive oil, cooking oil
    - Raw and Crude herbs & spices
  - Products with function and presentation likeness of a pharmaceutical product ⟹ Drug
    - Ingredients in Negative List for Food
    - Therapeutic Claims

FDI Policy Updates



LAMPIRAN C

CARTA PENGKELASAN PRODUK FDI

Petunjuk:

	Dikawal oleh BKKM
	Dikawal oleh PBKD

PRODUK

UBAT

MAKANAN

1. PRODUK BERASAS MAKANAN DENGAN/ TANPA CAMPURAN BAHAN AKTIF (CONTOH: HERBA, VITAMIN, MINERAL):
   - i. Produk Minuman Segera Campuran Gula Dan Krimer
   - ii. Produk Pati Haiwan/ *Essence* (Cecair)
   - iii. Produk Minuman (*Beverage*) Tanpa Perlu Bancuh Untuk Diminum Terus (*Ready To Drink*) Tanpa Dos Pengambilan
   - iv. Produk Kordial Untuk Dibancuh Dengan Nisbah Pencairan Yang Disyorkan
   - v. Produk Cuka (Cecair)
   - vi. Produk Madu (Cecair)
2. PRODUK MINUMAN TENAGA (*ENERGY DRINK*), PRODUK MINUMAN ISOTONIK (*ISOTONIC DRINK*), PRODUK MAKANAN UNTUK SUKAN (*SPORTS NUTRITION*) DAN PRODUK MAKANAN BERTUJUAN KHAS (*SPECIAL PURPOSE FOOD*)
3. PRODUK DALAM BENTUK KONVENSIONAL MAKANAN
4. PRODUK UNTUK KEGUNAAN MASAKAN DAN SEDIAAN MASAKAN
5. PRODUK HERBA, REMPAH RATUS DALAM BENTUK MENTAH (*CRUDE*)

FDI

BUKAN UBAT

- i. TANPA BAHAN YANG TERSENARAI DALAM *NEGATIVE LIST FOR FOOD* ; DAN
- ii. TANPA TUNTUTAN KESIHATAN/ PERUBATAN

UBAT

- i. MENGANDUNGI BAHAN YANG TERSENARAI DALAM *NEGATIVE LIST FOR FOOD* ; DAN/ ATAU
- ii. MEMPUNYAI TUNTUTAN KESIHATAN/ PERUBATAN

TMHS Products Policy Updates

- **Submission of Traditional Samples for Testing**
  - Within 14 working day or application will be rejected
- **No appeal for sample retesting of pre-registration applications: Effective 1st January 2015**
- **OTC Products with Traditional Medicines Names**
  - Prohibited to use names that will give a 'traditional' image to the OTC products that contain synthetic active ingredients
    - Example: Pagoda Fever Mixture (Not allowed)
    - Recommend: Pagoda Paracetamol Fever Mixture
  - Implementation Date
    - New Applications: 1 June 2015
    - Products containing Paracetamol/Aspirin: NPCB will contact
    - Others: To be Determined

TMHS Products Policy Updates

- **Dosage form stated in TMHS product name**
  - DRGD, Appendix 11, 11.2.1: Product Validation (1) Product Name:
  - Product name and dosage form shall be entered. (e.g. X Brand Tongkat Ali Tablet)
    - Dosage form in product name only in QUEST system
    - Not necessary to be in label
  - New & existing registration applications → effective immediately
  - Registered products → effective 1 Jan 2016

TMHS Products Policy Updates

- **Stability studies (Zone IVb requirements)**
  - Stability studies other than Zone IVb
  - Shelf life: 2 years (Status Quo)
- **Shelf-life approved as in real time stability data (> 2 years)**
  - 2 batchs at Zone Ivb
  - Accelerated : 6 months
  - Done in Malaysia (exemptions allowed on a case to case basis with valid justification)
  - Evidence that Active Ingredient is stable
- **NPCB will prepare a list of companies / private laboratories that are able to provide commercial stability studies services**

TMHS Products Policy Updates

- **Conditional approval of Change of Site (COS) for traditional medicine**
  - Approval: 7 working days
  - Condition: 6 months from the date of the conditional approval to update product information via variation process
- **Outsourcing of Pre-registration Testing**
  - Currently in planning stage
  - Testing in Listed Approval Laboratories
- **Enforcing Requirements for Batch Testing**
  - Tests as stated in DRDG
  - Implementation: To be determined

TMHS Products Policy Updates

- **Extension of GMP inspection Overseas**
  - TMHS manufacturing premises
  - Same procedure and charges as for pharmaceutical premises
- **Enforced requirements for centralised air-conditioning & treated water system for Traditional medicine manufacturers**

Cosmetic Updates

Guidelines for Control of Cosmetic Products in Malaysia

- To replace the current **Guidelines for Control of Cosmetic Products in Malaysia version MEI 2009 (revo2)**.
- New information added to the guidelines include:
  - Definition and responsibility of the Cosmetic Notification Holder (CNH)
  - Information on Post Market Surveillance Programme for Cosmetics
  - Annex I, part 2 – Non-permissible product name for cosmetic product
  - Annex I, part 4 – Heavy metal and microbiological test limit for cosmetic product
- The new guidelines will be made available on the NPCB's website by September 2015.

QUEST 3 + Updates

- Development started: March 2015
- Q3+ estimated to be ready in second quarter of 2016
- Status updates and related news in the NPCB website
- Payment online facilities (credit card/bank transfer)
  - MyGovXchange gateway for online payments including FPX (Financial process exchange) and credit card.
  - Corporate/business account only, No personal account.
  - Rates/processing fees → To be determined.
  - No manual payment.

QUEST 3 + Updates

- Digital signature concept will be applied.
  - Once submission is made, the data is definite and cannot be modified.
  - Applicants have the responsibility to check thoroughly and confirm before submission.
  - Example: LHDN e-filing submission.
- Proposed Implementation Process
  - Suspend all transactions for 1 month
    - Data migration from Q2 and Q3 needs to be done.
    - Data Clean up
    - Q2 and Q3 to go offline
    - Possibility of product updating required

Future Plans

Organisation Changes

- Proposal to transform NPCB to a Independent Body
  - Different models : Statutory Board, etc
  - Feasibility Studies
    - Financial
    - Regulatory Impact
      - Client Charter
      - Stakeholder Engagement
    - Organisation, Legal, Legislative etc
  - Timeline
    - 3 years

Policies Under Consideration

- Security Labelling
  - Usage of Barcoding – different systems, worldwide practice
  - Engagement with stakeholders
  - Implementation in phases
  - Timeline : To be determined
- GMP
  - Review directive on recognition of GMP certificate for overseas facilities issued by participating authorities in PIC/S.
  - Currently unilateral recognition
- Multiple Manufacturing Sites for Pharmaceuticals
  - Multiple sites for different activities
  - Regulatory requirements – validation, stability etc
- All Parenteral Products to be classified as scheduled poisons

Malaysian Pharmacovigilance Guidelines

- To replace Malaysian Drug Safety Reporting and Monitoring Guidelines 2002

- Consist of seven main parts :-
  - Part 1 – Guidelines for Healthcare Professionals
  - Part 2 – Guidelines for Product Registration Holder
  - Part 3 – Periodic Benefit Risk Evaluation Report (PBRER)
  - Part 4 – Risk Management Plan
  - Part 5 – Pharmacovigilance Master Files
  - Part 6 – Pharmacovigilance Audit and Inspection
  - Part 7 – Miscellaneous : Signal detection activities
    Risk Communication

1st Phase Implementation effective Jan 2016

2nd Phase, 2017

1st Phase Implementation effective Jan 2016

- Briefing to representative of association has been carried out in July 2015
  - Pharma, MOPI, MAPS, MADSA, PURBATAMA, PERTIM, DSAM, MPHM Persekutuan Persatuan[2] Tabib & Perdagangan Ubat Tionghua.

- Pre Conference Seminar – Preparing for Pharmacovigilance Inspection
  3 August 2015, NPCB

Upgrading of Pharmacovigilance Information System

- Web-based system
- Comply to ICH E2B standard
- Integrate with MOH Pharmacy Information System & Clinic Pharmacy System (PHIs/CPS)
- Analyse statistically to detect Safety Signal
- Reporting through QR code with smart phone
- Monitoring submission of PSUR/PBRER
- Real-time reports and statistics

TMHS Products

- Rebranding of Complementary Medicines Section to Complementary and Integrative Medicine Section
  - Traditional Products unit
  - Health Supplement Unit
  - Natural Products Unit
- Variation – Considering notification process for minor changes
- Traditional medicine - Indication based on philosophy of use
- New category of products
  - Natural products with high and medium claims
    - Animal / Herbal / Mineral origin
- Studying Classification of FDI products
  - Pharmaceutical Dosage forms
  - Individual Ingredients eg Collagen

Designation of Orphan Drugs

- NPCB – tasked with the designation of appropriate products as orphan drug
- Definition: Medicine, vaccine or in vivo diagnostic agent that is intended to treat, prevent or diagnose a rare disease OR not commercially viable to supply to treat, prevent or diagnose another disease or condition.
- SOPs, Flexibilities, Implementation date to be determined

Cell & Gene Therapy Products (CGTPs)

- 2nd draft of Guidance Document and Guidelines for Registration of CGTPs and Good Tissue Practice Guideline being prepared.
- Timelines:
  - Revised draft circulated for comments: September 2015
  - Deadline for comments: November 2015
  - Preparation & Finalisation of 3rd Draft : Nov – Dec 2015
  - Draft Guidelines presented to the Minister and DCA for approval
  - **Implementation Date: To be determined**

Proposed Implementation of Blood Products Lot Release in Malaysia

Initial Stage	***January – December 2015***	***Administrative and paperwork :*** ***• Framework & Guidelines*** ***• Submission of product Lot Summary Protocol by Product Registration Holder (PRH) for preparation of checklist***
Pilot Study	***January – June 2016***	***To conduct Lot Release Pilot Study on selected imported Blood Products by Lot Summary Protocol Evaluation and Cold Chain Inspection***
Full Implementation	***July 2016 onwards***	***To conduct Lot Release on all imported Blood Products by Lot Summary Protocol Evaluation and Cold Chain Inspection***

Proposal Charges for Services

BIL	PERKHIDMATAN / AKTIVITI	YURAN YANG DICADANGKAN	
1.	Pemprosesan Pengkelasan Produk	RM 300	
2.	Pemprosesan Permohonan Variasi Produk dan Tambahan Indikasi	Penilaian penuh (A, X, H)	Penilaian ringkas (N, T, H)
	Minor Variation prior approval (MiV-PA)	RM150 setiap jenis permohonan	RM50 setiap jenis permohonan*
	Major Variation (MaV)	RM300 setiap jenis permohonan	RM100 setiap jenis permohonan
	Tambahan indikasi	RM1000	Tidak berkenaan
3.	Pemprosesan Permohonan Pertukaran Tapak Pengilang Jenis I	Farmaseutikal (A, X, N, H) RM1000 setiap produk	Tradisional (T) RM100 setiap produk
4.	**Pemprosesan dan Pemeriksaan Pusat Kajian Bioekuivalens (BE) Tempatan**		
	Yuran Pemprosesan Permohonan**	RM1,000	
	Penilaian Dokumentasi***	RM1,000	
	Pemeriksaan Penuh (Klinikal, Bioanalitikal dan Method Validation)	RM1,000/pemeriksa/hari bekerja	
	Pemeriksaan Tambahan Tapak Klinikal / Bioanalitikal	RM1,000/pemeriksa/hari bekerja	
	Pemeriksaan Verifikasi	RM1,000/pemeriksa/hari bekerja	
	Pemeriksaan Triggered#	RM1,000/pemeriksa/hari bekerja	
5.	**Pemeriksaan Amalan Makmal Baik (Good Labroratory Practice, GLP) ke atas Fasiliti Kajian Bukan Klinikal di Malaysia**		
	Permohonan	RM 2000	
	Penilaian dokumentasi	RM 2000	
	Pra-pemeriksaan	RM 2000/hari/inspektor	
	Pemeriksaan	RM 2000/hari/inspektor	
	Verifikasi	RM 2000/hari/inspektor	
	Surveilan	RM 2000/hari/inspektor	
	Yuran pakar teknikal	RM 2000/hari/inspektor	
	Sijil Tahunan	RM 2000	

Proposal Charges for Services

6.	**Aktiviti Penilaian Pelan Susun Atur Premis**	**Permohonan Pelan Baru**	**Permohonan Pindaan Pelan**
	Semua jenis pelan susun atur premis pengilang produk.	RM1,000	RM500
7.	Pemprosesan Permohonan Sijil Indikasi dan Sijil Deklarasi	RM50 / setiap sijil yang dikeluarkan	
8.	**Pemprosesan Aktiviti Vaccine Lot Release**		
	Jenis Vaksin	Pemeriksaan Rangkaian Sejuk dan Penilaian Lot Summary Protocol	Pemeriksaan Rangkaian Sejuk bagi Lot Summary Protocol yang pernah dinilai
	Semenanjung Malaysia		
	Monovalent	RM300 / lot vaksin	RM200 / lot vaksin
	Polyvalent	RM500 / lot vaksin	
	Combination	RM1000 / lot vaksin	
	Sabah dan Sarawak		
	Monovalent	RM600 / lot vaksin	RM500 / lot vaksin
	Polyvalent	RM800 / lot vaksin	
	Combination	RM1300 / lot vaksin	

Implementation date: to be announced

THANK YOU

Address : Lot 36, Jalan Universiti,
46200 Petaling Jaya, Selangor,
Malaysia.
Telephone : +603-78835400
Fax : +603-79562924
Website : www.bpfk.gov.my
www.pharmacy.gov.my