**SUMMARY OF POLICIES OF THE DRUG CONTROL AUTHORITY (DCA): 2008**

| DCA MEETING | POLICY |
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| **DCA 201: (31/1/08)** | **1. IMPLEMENTATION OF PATIENT PACK SIZE FOR PHARMACEUTICAL PRODUCTS IN MALAYSIA**<br><br>The DCA has agreed:<br><br>a) to implement a maximum pack size requirement for pharmaceutical products for **tablet, capsule, oral liquid preparation and external use preparation**.<br>b) The implementation is based on guidlines as in **Appendix 1, 2, and 3.**<br>c) Voluntary implementation will commence on **1st March 2008** and mandatory implementation will take effect on **1st September 2008.**<br>d) The manufacturing of local and import pharmaceutical products in bulk packing must be stopped once the mandatory implementation take effect.<br>e) Manufacturing of product in bulk packing is allowed for "Export Only Products".<br><br>**2. PROHIBITION ON THE USE OF COLOURING AGENT IN PRODUCTS CONTAINING PREDNISOLONE IN SOLID ORAL DOSAGE FORM.**<br><br>The DCA has agreed that the formulation of all solid oral prednisolone products MUST NOT contain any colouring agent due to an alarming number of adverse drug reaction reported. As such, all product registration holders affected are required to re-formulate their product to the new formulation with no colouring agent (s) and submit variation application within 3 MONTHS from the date of the circular (27th February 2008).<br><br>**3. NOTIFICATION PROCEDURE FOR COSMETICS - TEST FOR *HYDROQUINONE* AND *TRETINOIN***<br><br>The DCA has decided that applicant should carry out test for *hydroquinone* and *tretinoin* content in 'high risk' cosmetic products inclusive of skin whitening products. The certificate of analysis must be submitted to the National Pharmaceutical Control Bureau (NPCB) within one month from the date of notification. The notification of products will be cancelled if the applicant fail to fullfill this requirement.<br><br>**4. THE USE OF "FARMASEUTIKAL"/ "PHARMACEUTICAL"/ "PHARMA" FOR COMPANIES INVOLVED IN MANUFACTURING/ IMPORTATION/ DISTRIBUTION OF TRADITIONAL PRODUCTS.**<br><br>The DCA has agreed that companies who are involved in the manufacturing/ importation/ distribution of traditional products are not allowed to use words such as pharmacy/ 'pharmaceutical'/ 'pharma' due to the fact that the individuals (owners) are not a registered pharmacist. The affected companies are given a grace period of 6 months to comply with the directive. |

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| | **5. INCLUSION OF ACTIVE INGREDIENT 13-C UREA INTO THE POISON LIST.**<br><br>The DCA has decided that 13-C Urea to be included in the Poison List. |
| **DCA 202 (28/2/08)** | **ACTIVE INGREDIENT (PELARGONIUM SP) ADVERSE EVENTS REPORTS**<br><br>The DCA has decided to allow the use of Pelargonium sidoides extract in traditional product formulations only if the following warning statements on hypersensitivity adverse reactions is printed on the labels and package inserts for all products containing Pelargonium sidoides:<br><br>**"IN VERY RARE CASES, PELARGONIUM SIDOIDES MAY CAUSE HYPERSENSITIVITY REACTIONS"** |
| **DCA 204 (29/04/08)** | **PATIENT PACK SIZE FOR PHARMACEUTICAL PRODUCT**<br>The DCA has decided that appeals on the recently implemented regulation on patient pack size will be considered on a 'case to case' basis with justified reason (s). |
| **DCA 205 (29/05/08)** | **1. EXEMPTION OF BIOEQUIVALENCE STUDY REQUIREMENT FOR "EXPORT – ONLY " GENERIC PRODUCTS**<br><br>The DCA has agreed to grant exemption of bioequivalence studies requirement for locally manufactured generic products that are registered for export-only purposes.<br><br>However, product registration holders must present a letter from the relevant authorities of the importing country confirming that bioequivalence study is not a requirement and therefore not necessary. The letter must be submitted together with the application for registration of the said product.<br><br>**2. SIX MONTHS DEADLINE FOR SUBMITTING ADDITIONAL/ SUPPORTING DATA**<br><br>The Drug Control Authority (DCA) has decided to reject applications if insufficient/ incomplete data is provided to enable the evaluation of registration dossiers. Applicants are given 2 reminders within a six month time frame to revert to NPCB and provide the necessary information to complete their registration dossier. Failure to do so will result in the rejection of the application for registration. The above policy is implemented as follows:<br><br>➢ Applicants are given **90 days** from the date of request, to submit and the relevant documents or information.<br>➢ The **first reminder** will be issued if the applicant fails to respond within the stipulated period as above or if the information provided are found not satisfactory (does not assist in the evaluation process).<br>➢ The **second reminder** will be issued **60 days** after the issuance of the |

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| | first reminder if the status of the application remains unchanged.<br>➢ Subsequent to this, if the NPCB has still not received any response after an additional period of 30 days OR the response received found not satisfactory, the application will be tabled for rejection at the following DCA meeting.<br>➢ This policy also covers registration samples that are requested by the Centre For Quality Control, NPCB for testing purposes. Should the applicants fail to submit the samples within six months from the date of payment verification, the registration application will be tabled to the DCA meeting for rejection without any reminder being issued.<br><br>The above policy will take effect on 29th May 2008 and is applicable to all new applications as well as those currently undergoing evaluation process.<br><br>**3. CLASSIFICATION OF AROMATHERAPY PRODUCTS**<br><br>The DCA has decided that the following cosmetic products (which previously exempted from registration) will also be regulated under the cosmetics notification procedure as other aromatherapy product to ensure the safety of cosmetic product used in Malaysia as well as to be inline with the ASEAN Cosmetic Harmonisation :<br><br>• Concentrated essential oil or single ingredient essential oil/ mixture of essential oil where a few drops are used in a **bathtub filled with water**.<br>• Concentrated essential oil or single ingredient essential oil/ mixture of essential oil which is mixed with base oil and to be used for **massage.**<br><br>Based on the definition of cosmetic products, concentrated essential oil or single ingredient essential oil/ mixture of essential oil for cosmetics purposes are included in the scope of cosmetic products. These essential oils are usually used with base oil for **massage** or added into **bathing** water to produce the desired aromatherapy effects. Some essential oils cannot be used directly on the skin as it may cause irritation and damage to the skin.<br><br>Criteria to be used to differentiate between Aromatherapy Product regulated under the notification procedure OR as a raw material:<br><br>• Aromatherapy oils which are brought in as bulk product (whether a concentrated oil as single ingredient or mixture of essential oils, carrier oil mixed with essential oils or single ingredient) do not require notification. However, once the bulk product has gone through a manufacturing process and are produced as finished products, the **final products then require notification.**<br>• Aromatherapy materials in the finished product forms mentioned above, either with complete labeling or to be re-labeled require notification. |

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| | **4. WARNING STATEMENT ON "INCIDENTS OF MYOCARDIAL ISCHAEMIA IN PREGNANT WOMEN WHO RECEIVED BETA-AGONIST TREATMENT TO DELAY PRE-MATURE BIRTH"**<br><br>The DCA has decided that a warning statement on "incidents of myocardial ischemia in pregnant women who received beta-agonists treatment to delay pre-mature births' MUST BE printed on the package insert of all groups of beta-agonist products used for the said treatment.<br><br>The warning statements is as follows:<br><br>For products in **injection** dosage form :<br><br>• As material pulmonary oedema and myocardial ischemia have been reportde during or following premature labour in patients receiving beta2-agonists, careful attention should be given to fluid balance and cardio-respiratory function, including ECG monitoring. If signs of pulmonary oedema and myocardial ischemia develop, discontinuation of treatment should be considered.<br>• Due to the risk of pulmonary oedema and myocardial ischemia that has been observed during the use of beta2-agonists in the treatment of premature labour, before these products are given to any patient with known heart disease, an adequate assessment of the patient's cardiovascular status should be made by a physician experienced in cardiology.<br>• Cautious use of salbutamol/terbutaline injections is required in pregnant patients when it is given for relief of bronchospasm so as to avoid interference with uterine contractibility. During IV infusion of salbutamol/terbutaline, the maternal pulse should be monitered and not normally allowed to exceed a steady rate of 140 beats per minute.<br><br>For products in **oral tablet and capsule** dosage form :<br><br>• As maternal pulmonary oedema and myocardial ischemia have been reported during or following premature labour in patients receiving beta2-agonists, careful attention should be given to fluid balance and cardio-respiratory function, including ECG monitoring. If signs of pulmonary oedema and myocardial ischemia develop, discontinuation of treatment should be considered.<br>• Due to risk of pulmonary oedema and myocardial ischemia that has been observed during the use of beta2-agonists in the treatment of premature labour, before these products are given to any patient with known heart disease, an adequate assessment of the patient's cardiovascular status should by a physician experienced in cardiology.<br><br>However, this warning statement is exempted for products in the form of syrup, suspension and inhalation dosage forms as such dosage forms are not to be used for the said treatment. In addition, no adverse effect has been reported which involves beta2-agonists products in inhalation dosage form that are used for bronchospasm treatment. |

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| | **5. REGISTRATION OF HEALTH SUPPLEMENT PRODUCTS AS SINGLE ACTIVE INGREDIENT**<br><br>The DCA has decided to expedite the approval process for the registration of health supplement products as single active ingredient. The procedure involves the issuance of registration number once the products approved in the NPCB internal "Drug Evaluation Committee" meeting. The DCA will then be notified at it's meeting in the same month. |
| **DCA 207 (04/08/08)** | **1. THE 7TH BIOEQUIVALENCE REQUIREMENT LIST**<br>The DCA has agreed on the 7th list for bioequivalence studies. This list can be obtained from NPCB's webpage under the subtitle 'Bioequivalence – Generic Product for Bioequivalence studies – 7th Generic Immediate Release Product List'.<br><br>**2. WARNING ON LABELS OF COSMETIC PRODUCTS CONTAINING ROYAL JELLY**<br><br>The DCA has decided to consider the exemption of warning statements regarding allergic reactions on the labels of cosmetic products containing royal jelly.<br><br>This exemption was given as the safety of consumers has been taken into consideration through the labelling requirement, whereby every ingredient in a particular cosmetic formulation (including royal jelly) must be stated on the product label using the globally used INCI (International Nomenclature for Cosmetic Ingredients) name. The aim of this requirement is to provide sufficient information to the consumer so as they can avoid the usage of cosmetic products which may cause allergic reactions.<br><br>**3. STANDARDZATION OF THE PHYSICAL PROPERTIES OF METHADONE SYRUP**<br><br>The Drug Control Authority has agreed to standardize the colour and flavour of methadone syrup to avoid any doubts arising among patients regarding the efficacy of the product.<br><br>Hence, the DCA has decided that methadone syrup products registered for use in Malaysia must have the following specifications:<br><br>• **Colouring Agent: Ponceau 4R red colouring agent at concentrations between 0.06% to 0.08%** w/v which will be able to produce the colour of pink after dilution to 100ml . This is a suitable formulation and in accordance with the specificied take home dose dispensing policy**.**<br><br>• **Flavouring: The use of any flavourings are not allowed.** However, the DCA has no objections in the use of sweeteners.<br><br>In addition, the manufacturer is required to carry stability studies before and after dilution to specify the concentration of the colouring agent so that the efficay of |

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| | the products containing methadone are not affected by changes in the formulation. The methods accepted by the DCA for stability studies after dissolution are:<br><br>• Dilution to 50ml for doses below 25mg<br><br>• Dilution to 100ml for doses more than 25mg<br><br>• Minimum study duration of one (1) week at room temperature<br><br>Data of the results obtained from the stability study must be submitted by the manufacturer to the DCA. Adjustments on the concentration can only be made after this process. |
| **DCA 208 (28/08/08)** | **<u>BIOEQUIVALENCE STUDY REQUIREMENT</u>**<br><br>DCA has decided to suspend the registration for registered products that contain active substances in the BE list but has yet to have the BE Report after the effective date (as stipulated in the 1st – 6th BE List) where the due date is on 31st December 2007. |
| **DCA 209 (25/09/08)** | **<u>REGISTERED PRODUCTS WITH BE REPORT ISSUES</u>**<br>The DCA has agreed :<br><br>➢ For registered products where the company has confirmed that they will not be conducting the BE study but has applied for registration to be sustained for the purpose of For Export Only (FEO), will not be considered and the registration will be terminated.<br>➢ For registered product under the Government's tender where the company confirm that they will not be conducting the BE study, the registration for these products will be terminated and Pharmacy Services Divison, MOH has to be inform of the list of products with BE study report to replace the tendered products that have been terminated.<br>➢ For registered products containing active substances which are listed in the BE list but has yet to have the BE study report after the effective date (as listed in 1st-6th BE list) will be suspended until a satisfactory BE report has been submitted. |
| **DCA 210 (27/11/08)** | **<u>PROPOSAL TO CLARIFY THE WARNING LABEL FOR ADVERSE EFFECTS RELATED TO TENDINITIS AND TENDON RUPTURE FOR ALL SYSTEMIC FLUOROQUINOLOES ANTIMICROBIAL PRODUCTS</u>**<br><br>The DCA has decided that the ADR to be printed **(written in bold)** on the package insert under "Special Warning and Precautions for Use" of all systemic fluoroquinolones antimicrobial products - oral preparation and injection. Topical preparations such as oftalmic and otic preparations are exempted from this labelling requirement. |

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| | ***Special warnings and precautions for use'*:**<br><br>**Musculo-skeletal system:**<br><br>**"The risk of developing fluoroquinolone-associated tendonitis and tendon rupture is further increased in people older than 60, in those taking corticosteroid drugs, and in kidney, heart, and lung transplant recipients.** Patients experiencing pain, swelling, inflammation of a tendon or tendon rupture should be advised to stop taking their fluoroquinolone medication (to specify the active ingredient) and to contact their health care professional promptly about changing their antimicrobial therapy. Patients should also avoid exercise and using the affected area at the first sign of tendon pain, swelling, or inflammation". |
| **DCA 211 (18/12/08)** | **PROPOSAL ON PUNITIVE ACTIONS AGAINST COMPANIES INVOLVED IN ADULTERATION OF PRODUCTS**<br><br>The DCA has agreed with the proposal that punitive action should be taken against companies involved in products adulteration. However, before it is being enforced, a press release must be issued to ensure public awareness. |