**SUMMARY OF DCA POLICY 2007**

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| **DCA 189 (25.01.2007)** | **1. THE USAGE OF ABBREVIATION FOR PRODUCT INDICATION.**<br><br>DCA has decided that the usage of abbreviation for product indication is not allowed as it can bring confusion/ cause its meaning to be altered. |
| **DCA 190 (22.02.2007)** | **1. PROPOSAL ON THE BANNING OF PREMIX INGREDIENTS IN NATURAL (TRADITIONAL) PRODUCT.**<br><br>DCA has decided that the usage of premix ingredients in the formulation of natural product are not to be allowed.<br><br>The date to implement this policy will be set after the dialogue with industrial side. |
| **DCA 191 (29.03.2007)** | **1. PROPOSAL ON THE IMPLEMENTATION OF VETERINARY PRODUCT REGISTRATION.**<br><br>DCA has agreed on the proposal to implement the registration of veterinary product and its procedures are as follow :<br><br>i) The registration of veterinary product will be implemented in stages starting with<br>Phase I - all categories of products except for cosmetics<br>Phase II- Cosmetics<br><br>ii) For quality control, analysis of product will be carried out after registration. However, analysis protocol and analytical method validation document have to be submitted during registration.<br><br>iii) Registration is done through online system and the online registration requirements are the same as the current requirements.<br><br>iv) For products that are already in the market, application has to be submitted within one year from the date of policy implementation.<br><br>v) Processing Fees.<br>Fees are the same as all other category of products used for human being.<br><br>vi) Proposal to amend Control of Drugs and Cosmetics Regulations 1984, Regulation 3, |

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| | Sub-regulation "(*2)(d)* ***seven*** *other members to be appointed by the Minister*" to be amended to "(2*)(d)* ***eight*** *other members to be appointed by the Minister* " and sub-regulation (3)*(e)*to be added as follow :<br><br>*"(3) (e) a veterinary surgeon in the public service."*<br><br>This member would be called to attend DCA meeting if there are presentation of proposal/policy pertaining to veterinary product and also presentation of registration/ rejection of veterinary products.<br><br>vii) Products containing pesticides are controlled by Pesticides Controls Division, Department of Agricultural, Malaysia under "Pesticides Act 1974".<br><br>**2. PROPOSAL TO INCLUDE SWITZERLAND AS A REFERENCE COUNTRY WHICH IS CERTIFIED BY DRUG CONTROL AUTHORITY.**<br><br>DCA has agreed to include Switzerland as a reference country for DCA.<br><br>**3. DRUG CONTROL AUTHORITY (DCA) 'TERM OF REFERENCE', MINISTRY OF HEALTH.**<br><br>DCA has agreed to establish "Term of Reference" (TOR) and its requirements so that all the DCA members and alternate members will sign the certificate of "Conflict of Interest" as a step to enhance "Good Governance in Regulatory Authorities" and further improve the integrity of DCA. |
| **DCA 192 (3.05.2007)** | **1. REGISTRATION OF TRADITIONAL PRODUCT.**<br><br>The usage of the word "BP" for the name of product is not allowed if its active ingredient has been shown to have therapeutic effect in lowering blood pressure.<br><br>**2. SAFETY ISSUE OF A REGISTERED PRODUCT- ZELMAC (TEGASEROD MALEATE)- MAL20021129A.**<br><br>The Registration holder, Novartis Corporation (Malaysia) Sdn. Bhd. has been instructed to stop importation, distribution and selling of Zelmac immediately and also to issue and distribute the letter of "Dear Healthcare Professional" to advise actions to be taken as follow :<br><br>i) Not to initiate treatment of new patients<br>ii) Review treatment options for patients already on Zelmac.<br><br>**3. THE USAGE OF CONFUSING WORDS SUCH AS APB/GMP FOR THE NAME OF PHARMACEUTICAL COMPANY WHICH IS REGISTERED WITH COMPANIES COMMISSION OF MALAYSIA.**<br><br>The Companies Commission of Malaysia has agreed with Drug Control Authority (DCA) |

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| | standpoint to not allow the usage of the words "**APB"** or **"GMP**" for the name of pharmaceutical company.<br><br>**4. <u>PROPOSAL ON THE BANNING OF PREMIX INGREDIENTS IN NATURAL (TRADITIONAL) PRODUCT</u>.**<br><br>The banning of the usage of raw materials in the form of premix for natural (traditional) product formulation will be implemented 6 months after the date of the circular distributed to the industry, i.e. until 31st December 2007.<br><br>Steps to be taken by manufacturers following the implementation of this policy includes:<br><br>i) Starting from 1st January 2008, manufacturers are not allowed to use raw materials in the form of premix for the formulation of natural (traditional) products.<br><br>ii) Manufacturers are given a period of (3) Three months to change information of the active ingredients via online variation application.<br><br>**5. <u>PROPOSAL ON THE IMPLEMENTATION OF VETERINARY PRODUCT REGISTRATION.</u>**<br><br>Registration of veterinary product will be implemented starting on 1st of August 2007. |
| **DCA 193 (24.05.2007)** | **1. <u>PROPOSAL ON THE BANNING OF PREMIX INGREDIENTS IN NATURAL (TRADITIONAL) PRODUCT,</u>**<br><br>DCA 190 has decided not to allow the use of premix ingredients in traditional product formulation based on the following grounds:<br><br>a) Existing manufacturers that are currently using "premix" in the formulation for their registered products, are given a period of **<u>six (6) months</u>** from 1st of June 2007 to find alternative source (single blended herbs) in replacement of the premix ingredients.<br><br>b) Existing manufacturers are also given a period of three (3) months to make necessary changes on active ingredients information via online variation application.<br><br>c) Effective 1st December 2007, all new products containing "premix" as the raw materials will not be registered.<br><br>d) Appeals to delay the period of execution will only be considered on a case to case basis.<br><br>**2. <u>CONSIDERATION TO REVOKE MANUFACTURING LICENSE FOR REGISTERED PRODUCT.</u>**<br><br>Format for the presentation of report has to be changed so as to emphasize on major/critical points and to identify criteria which may caused a manufacturing license to be revoked. |

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| | **3. <u>PROPOSAL TO INCLUDE WARNING STATEMENTS INTO PATIENT INFORMATION LEAFLET OF ORAL SEDATIVE-HYPNOTIC PRODUCTS PERTAINING TO:</u>**<br>**<u>(I) ANAPHYLAXIS (SEVERE ALLERGIC REACTION) AND ANGIOEDEMA (SEVERE FACIAL SWELLING) WHICH CAN OCCUR AS EARLY AS THE FIRST TIME THE PRODUCT IS TAKEN &</u>**<br>**<u>(II) COMPLEX SLEEP – RELATED BEHAVIORS WHICH MAY INCLUDE SLEEP DRIVING, MAKING PHONE CALLS, PREPARING AND EATING FOOD (WHILE ASLEEP).</u>**<br><br>DCA has agreed that warning statements should be included into patient information leaftlet of oral sedative-hypnotic products under the "Warning" and "Precautions" pertaining to risks associated with:<br><br>• **ANAPHYLAXIS (SEVERE ALLERGIC REACTION) AND ANGIOEDEMA (SEVERE FACIAL SWELLING) WHICH CAN OCCUR AS EARLY AS THE FIRST TIME THE PRODUCT IS TAKEN**<br><br>• **COMPLEX SLEEP – RELATED BEHAVIORS WHICH MAY INCLUDE SLEEP DRIVING, MAKING PHONE CALLS, PREPARING AND EATING FOOD WHILE ASLEEP.**<br><br>The list of sedative-hypnotic products registered with DCA which need to include such warning statements is as follow:<br><br>Zolpidem tartrate (5 products)<br>Flurazepam hydrochloride (1 product)<br>Triazolam (2 products)<br>Midazolam (5 products)<br><br>**4. <u>PROPOSAL TO UPDATE AND COORDINATE THE INFORMATION PERTAINING TO THE SIDE EFFECTS ON LABELS AND PATIENT-INFORMATION LEAFLET FOR PRODUCTS CONTAINING GLUCOSAMINE</u>**<br><br>DCA has agreed that patient information leaftet for products containing glucosamine has to be updated and coordinated with the information as below under "Side Effect" in the patient information leaflet:<br><br>• Cardiovascular:<br>Peripheral oedema, tachycardia were reported in a few patients following larger clinical trials investigating oral administration in osteoarthritis. Causal relationships has not been established.<br><br>• Central nervous system:<br>Drowsiness, headache, insomnia, have been observed rarely during therapy (less than 1%).<br><br>• Gastrointestinal:<br>Nausea, vomiting, diarrhoea, dyspepsia or epigastric pain, constipation, heartburn and anorexia have been described rarely during oral therapy with glucosamine.<br><br>• Skin:<br>Skin reactions such as erythema and pruritus have been reported with therapeutic administration of glucosamine. |

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| | **5. <u>PROPOSAL TO CANCEL REGISTRATION OF PRODUCTS CONTAINING TEGASEROD.</u>**<br><br>DCA has agreed to the proposals below and to limit the supply of tegaserod without compromising treatment for patients who are really in need of tegaserod :<br><br>• Products containing tegaserod will no longer be registered in Malaysia as its risks outweigh its benefits.<br><br>• Cancellation of registration of Zelmac 6mg Tablet, (MAL20021129A) shall take effect immediately.<br><br>• Novartis Corporation (Malaysia) Sdn Bhd, registration holder of Zelmac 6mg Tablet (MAL20021129A), is given a grace period of 6 months to ensure that all products are removed from the market.<br><br>• Novartis is allowed to import this product upon request by precribers on named patient basis when no such alternative drugs are available for use. |
| **DCA 194 (21.06.2007)** | **1. <u>DECISION TO BAN THE USAGE OF PREMIX INGREDIENTS IN NATURAL (TRADITIONAL) PRODUCT.</u>**<br><br>DCA has agreed to allow local manufacturer that has the facilities to produce premix ingredients to supply these ingredients commercially to other local manufacturer.<br><br>**<u>2.'INCENTIVE SCHEME' FOR DCA ADVISORY PANEL OF EXPERTS</u>**<br><br>DCA has agreed that the "expert review" process is not the critical time limiting factor in product registration and NPCB has been asked to review the current system and refine these procedures.<br><br>**<u>3.SAFETY ISSUE ON THE USAGE OF ROSIGLITAZONE (AVANDIA) PERTAINING TO THE RISK OF HEART ATTACK AND DEATH DUE TO CARDIOVASCULAR COMPLICATIONS.</u>**<br><br>DCA will monitor with care on the safety aspect of *rosiglitazone* and the action taken by other regulatory agencies on this matter. DCA will also make sure that the risk of heart attack is clearly stated in the warnings column in all Avandia packages. |
| **DCA 195 (7.08.2007)** | **1. <u>PROPOSAL TO ADD WARNING ON PRODUCT PACKAGE AND LATEST WARNING INTO PATIENT INFORMATION LEAFLET OF ALL GADOLINIUM BASED "CONTRAST MEDIUM" AGENT USED IN "MAGNETIC RESONANCE IMAGING".</u>**<br><br>DCA has agreed on the adding of warning statement and latest warning statements into patient information leaflet of all Gadolinium based "Contrast Medium" agent used in "Magnetic Resonance Imaging". |

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| | a) Warning on product package<br><br>- Exposure to gadolinium – based contrast agents (GBCAs) increases the risk for Nephrogenic Systemic Fibrosis (NSF) in patients with:<br>• acute or chronic severe renal insufficiency (glomerular filtration rate < 30mL/min/1.73m²), or<br>• acute renal insufficiency of any severity due to the hepato-renal syndrome or in the perioperative liver transplantation period.<br><br>- NSF is a debilitating and sometimes fatal disease affecting the skin, muscle, and internal organs.<br><br>- Avoid use of GBCAs unless the diagnostic information is essential and not available with non-contrast enhanced magnetic resonance imaging (MRI).<br><br>- Screen all patients for renal dysfunction by obtaining a history and/or laboratory tests.<br><br>- When administering a GBCA, do not exceed the dose recommended in product labelling. Allow sufficient time for elimination of the GBCA prior to any readministration.<br><br>b) New warnings<br>Among the factors that may increase the risk for NSF are repeated or higher than recommended doses of a GBCA.<br><br>• For patients receiving haemodialysis, healthcare professionals may consider prompt haemodialysis following GBCA administration in order to enhance the contrast agent's elimination. However, it is unknown if haemodialysis prevents NSF.<br><br>• Determine the renal function of patients by obtaining a medical history of conducting laboratory tests that measure renal function prior to using GBCA.<br><br>• The risk, if any, for developing NSF among patients with mild to moderate renal insufficiency or normal renal function is unknown.<br><br>• Post-marketing reports have identified the development of NSF following single and multiple administrations of GBCAs.<br><br>The list of registered "contrast medium" agents used in Magnetic Resonance Imaging that require affixation of such warnings is as follow:<br><br>Gadoxetic acid (1 product)<br>Gadoversetamide (3 products)<br>Gadoteric acid (2 products)<br>Gadolinium oxide (11 products)<br>Gadodiamide (8 products) |

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| | Gadobutrol (1 product)<br>Gadobenic acid (1 product)<br><br>**2. PROPOSAL ON THE ADDITION OF PRODUCTS INTO THE LIST OF ORAL PRODUCTS THAT INDICATED FOR INSOMNIA WHICH NEED TO INCLUDE WARNING INTO PATIENT INFORMATION LEAFLET PERTAINING TO "COMPLEX SLEEP - RELATED BEHAVIORS WHICH MAY INCLUDE SLEEP DRIVING, MAKING PHONE CALLS, PREPARING AND EATING FOOD (WHILE ASLEEP)"**<br><br>DCA has agreed that the same warning statements to be included under "Warning" and "Precautions" in patient information leaflet of 7 additional products used for insomnia, pertaining to the risks are as below :<br><br>• ANAPHYLAXIS (SEVERE ALLERGIC REACTION) AND ANGIOEDEMA (SEVERE FACIAL SWELLING) WHICH CAN OCCUR AS EARLY AS THE FIRST TIME THE PRODUCT IS TAKEN<br><br>• COMPLEX SLEEP – RELATED BEHAVIORS WHICH MAY INCLUDE SLEEP DRIVING, MAKING PHONE CALLS, PREPARING AND EATING FOOD WHILE ASLEEP<br><br>The list of additional registered products which need to include such warnings are as follow (except for another 4 products which have been approved in the 193rd DCA meeting) :<br><br>Nitrazepam (2 products)<br>Zopiclone (4 products)<br>Lorazepam (9 products)<br>Diazepam (18 products)<br>Bromazepam (4 products)<br>Alprazolam (13 products)<br>Clobazam (1 product)<br><br>**3.PROPOSAL TO NOT APPROVE THE REGISTRATION OF PRODUCT CONTAINING PERGOLIDE IN MALAYSIA.**<br><br>Drug Control Authority (DCA) in its 195th meeting has decided :<br><br>• Products containing **PERGOLIDE** are not allowed to be registered due to safety issues. There was an adverse reaction report which stated that the use of **PERGOLIDE** can increase the risk of **regurgitation of the mitral, tricuspid and aortic valves of the heart** which can cause adverse effect of **serious heart valve damage**.<br>• New application of product registration for products containing **PERGOLIDE** will not be registered.<br><br>**4.PROPOSAL TO SUSPEND THE SALES OF PRODUCTS CONTAINING NIMESULIDE DUE TO SAFETY ISSUES.**<br><br>Drug Control Authority (DCA) at its 195th meeting decided to suspend the sales of all products containing nimesulide because:<br><br>a) The safety of these products are doubted.<br>• There are adverse effect reports of serious liver failure known as *fulminant hepatic failure* (FHF) with the use of nimesulide. |

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| | DCA has agreed to suspend all products containing nimesulide until further information on the study carried out by European Medicines Agency (EMEA) and feedback from local medical expert regarding the usage of nimesulide are obtained.<br><br>**5.PERMISSION TO PRESCRIBE RETINOID PRODUCTS.**<br><br>Considering that the use of retinoid products without supervision of an expert, can cause serious side effect of teratogenicity, DCA has imposed a few registration criterias on the registration of retinoid products, as a safety and prevention measure. The supply/ selling of these products will only be allowed for dermatologist or for government hospitals/institutions where there are dermatologists or medical officers who have experience in dermatology and approved by DCA.<br><br>DCA has agreed to allow NPCB to review the qualification criteria in prescribing retinoid considering that there are appeals from a few medical practitioners who do not meet the qualification that has been set to prescribe retinoid but have wide experiences in prescribing these products.<br><br>**6.VETERINARY PRODUCTS REGISTRATION GUIDELINES**<br><br>DCA has agreed to accept and approve the guidelines for veterinary products registration. |
| **DCA 196 (30.08.2007)** | **1. PROPOSAL TO INCLUDE ADDITIONAL STATEMENTS INTO PATIENT INFORMATION LEAFLET OF PRODUCT CONTAINING CEFTRIAXONE PERTAINING TO THE POTENTIAL RISK ASSOCIATED WITH CONCOMITANT USE OF CEFTRIAXONE WITH CALCIUM CONTAINING SOLUTIONS.**<br><br>DCA has agreed that warning pertaining to the potential risk with the use of Ceftriaxone with calcium or product containing calcium to be included into patient information leaflet for all Ceftriaxone products.<br><br>i) Warning statements to be included into patient information leaflet under the heading "Warning" are as follow:<br><br>**"Ceftriaxone must not be mixed or administered simultaneously with calcium – containing solutions or products, even via different infusion lines.**<br>**Calcium containing solutions or products must not be administered within 48 hours of last administration of ceftriaxone.**<br>**Cases of fatal reactions with calcium – ceftriaxone precipitates in lung and kidneys in both term and premature neonates have been described. In some cases the infusion lines and times of administration and calcium – containing solutions differed".**<br><br>(ii) Warnings to be included under the heading "Dosage and Administration : Direction for use" are as follow :<br><br>**"Do not use diluents containing calcium, such as Ringer's Solution or Hartmann's Solution, to reconstitute ceftriaxone. Particulate formation can result."**<br><br>(iii) Registration holder, Roche (M) Sdn. Bhd. was asked to issue a letter to professional medical practitioners (Dear Health Care Professional Letter) to notify about |

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| | the changes of these prescriptions information. |
| **DCA 197 (27.09.2007)** | **1.PERMISSION TO MANUFACTURE UNREGISTERED RADIOPHARMACEUTICAL PRODUCTS TO BE SUPPLIED FOR HOSPITAL.**<br><br>DCA has agreed to give exemption to Hospital Pulau Pinang to get supply of unregistered radiopharmaceutical products which are manufactured by Hospital Putrajaya according to the exemption provided under regulation 15(6), Control of Drugs and Cosmetics Regulations 1984, Amendment 2006.<br><br>**2. PRODUCT CLASSIFICATION OF 'STEM CELL (LIVE)'.**<br><br>Currently, products under the category of "Stem cell (Live)' are not control by DCA.<br><br>**3.PROPOSAL TO LIMIT THE INDICATION OF PRODUCTS CONTAINING PIROXICAM FOR SYSTEMIC USE TO: "FOR THE SYMPTOMATIC RELIEF OF PAIN AND INFLAMMATION IN PATIENTS WITH OSTEOARTHRITIS, RHEUMATOID ARTHRITIS AND ANKYLOSING SPONDYLITIS" AND TO ADD ADDITIONAL WARNING STATEMENTS AND LATEST CONTRAINDICATION IN PATIENT INFORMATION LEAFLET.**<br><br>**Decision :**<br><br>DCA has agreed to limit the indication and to add additional warnings and latest contraindication in patient information leaflet for registered products and all product registration applications (oral, injection, suppository preparation) containing piroxicam.<br><br>Piroxicam for systemic use will not be allowed as "treatment of short-term painful and inflammatory conditions".<br>Indication for registered products containing piroxicam for systemic use will be limited to:<br><br>**FOR THE SYMPTOMATIC RELIEF OF PAIN AND INFLAMMATION IN PATIENTS WITH OSTEOARTHRITIS, RHEUMATOID ARTHRITIS AND ANKYLOSING SPONDYLITIS.**<br><br>**HOWEVER IT SHOULD NOT BE THE FIRST CHOICE OF NON-STEROIDAL ANTI-INFLAMMATORY DRUG (NSAID) TREATMENT IN THESE CONDITIONS.**<br><br>Under "Warning and Precautions" and "Contraindications" in patient information leaflet, the following statements have to be included :<br><br>**Warning and Precautions:**<br><br>- **TREATMENT SHOULD ALWAYS BE INITIATED BY A PHYSICIAN EXPERIENCED IN THE TREATMENT OF RHEUMATIC DISEASES.**<br>- **USE THE LOWEST DOSE (NO MORE THAN 20MG PER DAY) AND FOR THE SHORTEST DURATION POSSIBLE. TREATMENT SHOULD BE REVIEWED AFTER 14 DAYS.**<br>- **ALWAYS CONSIDER PRESCRIBING A GASTROPROTECTIVE AGENT.** |

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| | **Contraindications:**<br><br>- **PIROXICAM SHOULD NOT BE PRESCRIBED TO PATIENTS WHO ARE MORE LIKELY TO DEVELOP SIDE EFFECTS, SUCH AS THOSE WITH A HISTORY OF GASTRO-INTESTINAL DISORDERS ASSOCIATED WITH BLEEDING, OR THOSE WHO HAVE HAD SKIN REACTIONS TO OTHER MEDICINES.**<br>- **PIROXICAM SHOULD NOT BE PRESCRIBED IN ASSOCIATION WITH ANY OTHER NSAID OR AN ANTICOAGULANT.**<br><br>**4. THE USAGE OF THE SAME PRODUCT NAME (EDOLY KAPSUL) FOR NEW PRODUCT REGISTRATION APPLICATION THAT HAS BEEN CANCELLED BY DCA DUE TO SAFETY ISSUE (ADULTERATION).**<br><br>DCA has agreed that for **certain cases**, the usage of similar name will be considered if the company has valid reasons and justification. For example :<br><br>i) For the case of a product named "Edoly Kapsul", its registration holder has evidence to show that its product has been counterfeited. Considering that the company has been working hard to build its product reputation in the market, DCA has agreed to allow the usage of the same product name (Edoly Kapsul) for the new application of product registration that has been cancelled due to safety issue (adulteration). |
| **DCA 198 (25.10.2007)** | **1.PROPOSAL TO CANCELTHE REGISTRATION OF N-HANZ PRODUCT DUE TO ADULTERATION ISSUE.**<br><br>DCA has agreed to cancel N-Hanz product (MAL05051139TC) because this product has been found to be adulterated with scheduled poison, homosildenafil (sildenafil analog). |
| **DCA 199 (04.12.2007)** | **1.PROPOSAL TO REMOVE THE WORDING "DILULUSKAN OLEH KKM" ON THE PRODUCT LABELS EXISTING AND NEW PRODUCTS.**<br><br>DCA acknowledged this issue and has agreed with the above proposal. Companies are given a grace period of 6 months to comply with this order.<br><br>**2.PROPOSAL TO CANCEL THE REGISTRATION OF PRODUCTS CONTAINING NIMESULIDE.**<br><br>DCA has agreed to cancel the registration of products containing nimesulide due to safety issue whereby its risks outweighs its benefits.<br><br>**3. PROPOSAL TO PROHIBIT THE ADDITION OF RED 2G COLOURING AGENT IN ALL ORAL PREPARATIONS AND PRODUCTS USED ON MUCOSA MEMBRANE.**<br><br>DCA acknowledged this issue and has agreed that:<br><br>a) The use of Red 2G colouring agent is prohibited in all oral preparations and products used on mucosa membrane.<br><br>b) For the existing registered products, the registration holders must have their products reformulated to replace the colouring agent in the products. |

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| | **4. METHOD TO IMPLEMENT THE CONTROL ON COSMETIC PRODUCTS THROUGH NOTIFICATION PROCEDURES.**<br><br>DCA has agreed with this proposal paper.<br><br>**5. CONSIDERATION AND APPROVAL TO CARRY OUT INSPECTION ON OVERSEA MANUFACTURING PREMISES.**<br><br>DCA has agreed to allow auditing officers from NPCB to carry out inspection on manufacturing premises as in the list in the proposal paper.<br><br>**6. CHING DU WAN 300MG: PROPOSAL TO CANCEL REGISTRATION OF PRODUCT DUE TO ADULTERATION ISSUE.**<br><br>DCA has agreed that :<br><br>• The registration of this product will be cancelled as the screening test for scheduled poison is positive for **chloramphenicol, chlorpheniramine and caffeine**.<br><br>• Manufacturing license for Maxi Herbs Sdn Bhd at the address of No. 68, Jalan Tanming 6, Kawasan Perindustrian Tanming Jaya, 43300 Seri Kembangan, Selangor shall be revoked.<br><br>• The cancellation of this product will be announced in the newspaper. |