Newsletter of the Drug Control Authority, Malaysia

BERITA UBAT-UBATAN

VOLUME 50 • No. 28 • ISSN 0128-0627 December 2010

HEADLINES

Cancellation of Registration of Products Containing Sibutramine due to Safety Concerns

The Drug Control Authority (DCA), on 25th January 2010 directed product registration holders of Sibutramine to circulate a "Dear Health Care Professional" letter to all prescribers in Malaysia and updated the product insert to further strengthen its safety information following the preliminary results of the Sibutramine Cardiovascular OUTcomes (SCOUT) study conducted by Abbott Laboratories for Reductil®.

The National Pharmaceutical Control Bureau (NPCB) through its National Adverse Drug Monitoring Programme had received a total of 38 adverse drug reports for Sibutramine. Five of the reports were related to cardiovascular events including palpitation (3 reports) and non-fatal myocardial infarction (2 reports).

On 11 October 2010, the DCA had suspended the registration of products containing Sibutramine due to safety concerns based on the final results of SCOUT study. The study confirmed that obese and overweight patients taking Sibutramine had higher cardiovascular risks such as heart attacks and strokes as compared to those who were on diet and exercise alone. The registration holders of products containing Sibutramine had also been directed to recall the products from the market. Subsequently, the DCA had cancelled the registration of products containing Sibutramine in its 235th Meeting on 23rd December 2010.

Facts

- **Generic name**: Sibutramine Hydrochloride
- **Trade name:** Reductil®, Slenfig®, Sibutramine Sandoz®, Fenslim® and Sibutrim®
- **Class:** Centrally acting appetite suppressant
- **Indication:** Adjunctive therapy to diet and exercise for the management of obesity in patients with risk factors such as diabetes, hypertension and dyslipidaemia
- **Mechanism of action:** Produces its therapeutic effects by norepinephrine, serotonin and dopamine reuptake inhibition, which enhance synaptic transmission of messages of satiety (appetite suppressants)
- **Contraindications:** History of coronary artery disease, congestive heart failure, tachycardia, peripheral arterial occlusive disease, arrhythmia or cerebrovascular disease (stroke or TIA) and inadequately controlled hypertension

Did You Know?

The World Health Organization (WHO) projection in 2005 indicated that there are at least 400 million adults that were obese (Body Mass Index ≥ 30). It was also projected that by 2015, the number will increase to more than 700 million.

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DCA EDITORIAL TEAM

SUMMARY OF PRESS RELEASES

1. *Studies from the United States Revealed That Anti-Hypertensive Drug, Micardis® May Increase the Risk of Suffering from Cancer*

An article published in Nanyang Siang Pau on 15th June 2010 reported that studies from the United States revealed that Micardis® may increase the risk of suffering from cancer. This was referring to the journal published in the Lancet Oncology by Sipahi *et al*. on 14th June 2010 involving the meta-analysis of randomised controlled trial based on five studies namely, LIFE, TROPHY, TRANSCEND, ONTARGET and PROFESS whereby 85.7% of the patients who participated were on Telmisartan. Results of the meta-analysis showed that patients taking ARBs had a higher risk of new cancer occurrence compared to the control group (7.2% vs 6.0%, risk ratio [RR] 1.08, p=0.016). Lung cancer occurrence was also found to be significantly higher as compared to the control group. (0.9% vs 0.7%, RR 1.25, 1.05-1.49; p=0.01). There was no statistically significant difference in cancer deaths observed (0.9% vs 0.7%).

Facts

- **Generic name:** Telmisartan
- **Trade name:** Micardis®
- **Class**: Angiotensin Receptor Blocker (ARB)
- **Indication:** Hypertension, heart failure, diabetic nephropathy and cardiovascular event risk reduction
- **Mechanism of action:** Exerts antihypertensive activity by preventing angiotensin II from binding to AT_1 receptors thus inhibiting the vasoconstriction and aldosterone-secreting effects of angiotensin II

There are currently seven types of ARB (with a total of 69 products of various strengths) registered by the Drug Control Authority (DCA). Out of these, only four ARBs: Telmisartan, Irbersartan, Losartan and Valsartan are listed in the Ministry of Health Malaysia Drug Formulary and supplied to the government hospitals and clinics.

Did You Know?

The presence of high blood pressure had long been recognised by the degree of "hardness" of the pulses (difficulty in obliterating the pulse by manually compressing the radial artery). Ancient historical records reported that acupuncture, venesection and bleeding by leeches were the sole means of treating the so-called 'hard pulse disease'. These sources included medical textbook from the Ashurbanipal Library at Nineveh (669-626 BC), the Yellow Emperor of China (2600 BC), the Roman Cornelius Celsus, Galen the great medical authority (131-201 AD), Erasistratus (304 BC – 250 BC) and even Hippocrates.

Feedback from Product Registration Holders

i. Telmisartan

Clinical experts appointed by Boehringer Ingelheim (Malaysia) Sdn. Bhd. (product registration holder of Telmisartan/Micardis®) had raised several limitations of the meta-analysis published by Lancet Oncology which are as follows:

- The studies involved were not intended to examine cancer outcomes
- The diagnosis for cancer is not standardised among the studies involved
- The analysis did not include individual patients' data
- The analysis did not consider the duration of cancer incidence
- The analysis did not consider factors such as gender, age, smoking or other risk factors

Boehringer Ingelheim had also performed a comprehensive review on all data obtained including those from ONTARGET, TRANSCEND, PROFESS, pre-clinical studies, clinical studies on Telmisartan, safety profiles reported and scientific publications. As a result, the company had concluded that there was no indication to associate the use of Telmisartan with increased incidence of cancer.

ii. Other ARBs

Product Registration Holders	Generic/Trade Names	Clinical Studies	Findings of studies
Sanofi Aventis (Malaysia) Sdn. Bhd.	Irbesartan/Aprovel®	ACTIVE-I, I-PRESERVE & IDNT	No indications of carcinogenicity
Novartis Corporation (Malaysia) Sdn. Bhd.	Valsartan/Diovan®	Val-HeFT, VALIANT, VALUE & NAVIGATOR	No increased risk of cancer incidence in general or in lung, breast and prostate cancer with use of Valsartan
Merck Sharp & Dohme (I.A) Corp.	Losartan/Cozaar®	LIFE, OPTIMAAL, RENAAL, ELITE I, ELITE II & HEAAL	No consistent pattern on the incidence of cancer or cancer motility among patients treated with Losartan

Regulatory Actions

Regulatory bodies such as the U.S. FDA, Health Canada and the UK MHRA are reviewing the findings of this meta-analysis and to date, no regulatory directive have been issued.

The NPCB had received 359 Adverse Drug Reaction (ADR) reports associated with the use of ARB. Nevertheless, most of them were associated with adverse effects such as rashes, itching, dizziness, headache, cough, body aches, hypotension, angioedema, hyponatremia and hypokalemia. The NPCB will continue to monitor, review any new information regarding the safety of these products and take further regulatory action when necessary.

References:

1. MIMSOnline Team. Telmisartan essential drug information. MIMS Malaysia. [cited 2010 Dec] Available from: http://mims.com.my/Page.aspx?menuid=mng&name=telmisartan&brief=true&h=telmisartan&CTRY=MY

2. Sipahi I, Debanne SM, Rowland DY, Simon DI, Fang JC. Angiotensin-receptor blockade and risk of cancer: meta-analysis of randomised controlled trials. Lancet Oncol. 2010 Jul;11(7):627-36. PubMed PMID: 20542468 [cited 2010 Dex] Available from: http://www.ncbi.nlm.nih.gov/pubmed/20542468

2. *Recall of Two 'Skin Food' Nail Polish Products Found to Contain Trace Amounts of Benzene by the Health Sciences Authority (HSA), Singapore (29th October 2010)*

In October 2010, the National Pharmaceutical Control Bureau (NPCB) had received a Post-Marketing Alert from the Health Sciences Authority (HSA), Singapore regarding the recall of two Korean made nail polish products namely 'Skin Food Jojoba Pure Nail PK 004' and 'Skin Food Milk Creamy Nail Base Coat'. These products were found to contain trace amounts of benzene at very low concentration levels of 22.3 parts per million (ppm) and 30.3 ppm respectively. Benzene is a cancer causing organic substance and is prohibited in all cosmetic product formulations in the ASEAN countries including Malaysia and European Union.

However, 'Skin Food Milk Creamy Nail Base Coat' (NOT07124125KE) had never been imported to Malaysia despite its notification approval in 2007. 'Skin Food Jojoba Pure Nail PK 004' (NOT06091091KE) on the other hand, had been discontinued from the Malaysia market since two years ago due to poor demand. As a result of recent safety status, both products have been denotified. The public is not advised to use these nail polish products due to safety reasons.

Reference:

1. Health Sciences Authority (HSA). Product Quality Surveillance: Products Recalled in 2010. [cited 2010 Dec] Available from: http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/safety_information/product_recalls/2010.html

3. *Requirement of Bioequivalence (BE) Studies for all Generic Products - Press Release by the Minister of Health Malaysia in Conjunction with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Seminar on 10th November 2010 at the Le Meridien Hotel Kuala Lumpur*

The registration of pharmaceutical products and licensing of pharmaceutical manufacturers had been initiated by the Ministry of Health (MOH) Malaysia in 1985 with the enforcement of the Control of Drugs and Cosmetics Regulations 1984 to ensure products marketed in the country are safe, efficacious and of quality. The upgrading of manufacturing facilities by local pharmaceutical industries in accordance with Good Manufacturing Practice (GMP) requirements has undergone a huge transformation since then. With a licensing and GMP inspection system well in place, Malaysia has been accepted by the Pharmaceutical Inspection Co-operation Scheme (PIC/S) as its 26th member in January 2002.

An average yearly growth of 10-15% in pharmaceutical product market has been charted within the last decade. Stringent regulatory surveillance system that complies with international standards resulted in Malaysian pharmaceuticals being widely accepted and recognised for their quality. Currently, pharmaceutical product manufacturers export their products to about 70 countries worldwide.

Since 1999, the MOH through the Drug Control Authority (DCA) had enforced the need for bioequivalence (BE) studies for generic pharmaceuticals. These studies are performed at clinical research centres and aimed to prove that the effectiveness of a generic product is equivalent to the innovator drug. Currently, most BE studies are conducted in overseas due to the limited number (only six) of local BE centres that meet the required standard.

In line with international practice, MOH will soon enforce the requirements of BE studies to be conducted accordingly. Therefore, all BE research centres must strengthen their clinical and laboratory infrastructure to comply with these requirements. The need for more BE study centres in the country is crucial as there is a great demand for generic pharmaceutical products in line with the World Health Organization (WHO) recommendations to increase affordability and accessibility.

Currently, products containing the selected 112 active ingredients require BE studies. By 2012, MOH will enforce the requirement for BE studies for all generics to assure the quality of pharmaceutical products marketed in the county. Quality generics will boost the local pharmaceutical industry as well as increasing export opportunities. The requirement of BE studies for all generic products will also spur the local BE centres to upgrade their facilities and systems to be in line with international standards.

NEW DIRECTIVES

Three directives under the Control of Drugs and Cosmetics Regulations 1984 (amendment 2006) has been issued on 13th and 14th December by the Senior Director of Pharmaceutical Services, Dato' Eisah A. Rahman following the decisions made by the DCA members during its 233rd and 234th meeting on 28th October 2010 and 22nd November 2010 respectively.

1. Directive 08/2010: Justification for the Change in Pack Size of Dermatological Products for Certain Skin Diseases

The directive stated that the change in pack size of dermatological products for certain skin diseases had been approved. This was following an appeal from the Dermatological Society of Malaysia to allow bigger pack size of dermatological products used for the treatment of extensive eczema, exfoliative dermatitis and erythrodermic psoriasis whereby 90% to 100% of the body/skin require treatments. However, the bigger pack size of D07AA Corticorsteroids, weak (Group I) and D07AB Corticorsteroids, moderately potent (Group II) are restricted to be used only at hospitals or specialised skin clinic. This directive is effective from 14th December 2010.

The approved recommended pack sizes are as below:

ATC Code	Recommended Pack Sizes	Newly Approved Recommended Pack Sizes	Notes
D02A Emollients and protectives	Non poisons (liquid preparation) – 250ml **Others – 60gm**** Except D02AC Soft Paraffin and fat products and D02AX Other emollients and protectives (Aqueous cream) – max 500gm	** **Max: 500gm for emollients**	• Pack sizes of 500gm is allowable
D03 Preparation for management of wounds and ulcers	**Max 120ml****	** **Max: 500ml – 1L**	• Chlorhexidine gluconate aqueous 1L • Povidone 10% 500ml • Povidone-iodine 1L • Dermacyn 500ml • Hydrogen peroxide 1L • Prontosan 500ml • Octenisan 500ml • Acetic acid 500ml • Cetrimide 500ml
D05A Antipsoriatics for topical use	Liquid – Max 500ml (with a dispenser) **Others – Max 60gm**** Bar – Max 100gm	****Others – Max 500gm**	• Tar preparations • Coal tar ointment/ solution • Liquor Picis Carbonis (LPC) 500gm • Dithranol ointment 500gm

2. Directive No. 09/2010: General Guidelines for the Registration of Homeopathic Products

The DCA has implemented the use of the General Guidelines for the Registration of Homeopathic Products effective from 14th December 2010. This guideline was developed by the National Pharmaceutical Control Bureau (NPCB) in collaboration with the Malaysian Homeopathic Medical Council and the Traditional & Complementary Medicine Division, Ministry of Health Malaysia and will serve as an additional guideline to the existing requirements for the registration of homeopathic products stated in the Drug Registration Guidance Document (DRGD).

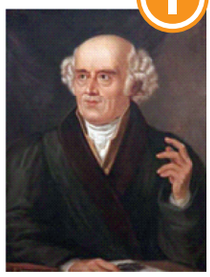
Overview of the General Guidelines for the Registration of Homeopathic Products

- **Introduction**
  - Definition of terms used in homeopathic medicine and related acts and regulations for the registration of such products are mentioned in this guideline
- **Exemptions**
  - Products that are exempted from registration under the Control of Drugs Cosmetic Regulation 1984 are:
    i) Products with single homeopathic dilution,
    ii) Extemporaneous preparation for an individual patient by a registered/licensed homeopathic practitioner,
    iii) All mother tinctures not listed in Appendix 1 and 2
- **Preparations not considered by the DCA for registration**
  - Sterile preparations (eye drops and injectables), suppositories, vaginal tablets, transdermal patch, sublingual preparations, preparations in combination with non-homeopathic active ingredients such as vitamins, minerals and herbs and preparations containing substances listed in the Poison List
  - DCA will only register homeopathic products used for oral or external administration
- **Ingredients**
  - Natural or synthetic ingredients that are referenced in the recognised pharmacopoeia (a copy of monograph must be provided for each medicinal product and the claim must be supported by the same level of evidence as for traditional products)
  - Combination of homeopathic and non-homeopathic are not considered as homeopathic products
  - List of ingredients allowed (Appendix 1) and prohibited (Appendix 2 and 4)
  - Up to a maximum of 4 mother tinctures (not listed in Appendix 1 and 2) are allowed in a homeopathic product
- **Quality**
  - A certificate of analysis (CoA) must be provided as proof on the dilution used
- **Good Manufacturing Practice (GMP)**
  - Requirements for GMP of the premise as outlined in the Guidelines on Good Manufacturing Practice (GMP) for Traditional Medicines applies
- **Labelling**
  - The words homeopathic product/homeopathic medicine/homeopathic preparation/homeopathic remedy as well as the scientific name/common name of the active ingredient, the potency & type of scale used and lastly, the percentage of alcohol contained in the product must appear on the innermost label
  - The other requirements are the same as for traditional products (DRGD)

- **Indications for use**
  - Same as those allowed for traditional products in the DRGD whereby recommended use or indications for specific claims must be supported by evidence for the multi ingredient homeopathic products
  - No indication will be allowed for single homeopathic product and mother tinctures
- **Appendices**
  - List of exempted single homeopathic dilutions (Appendix 1),
  - Negative List (Appendix 2),
  - List of acceptable references (Appendix 3) and
  - List of endangered animal species/protected wildlife (Appendix 4).

The full guideline is available on our website at http://www.bpfk.gov.my

Did You Know?



In the late 18th century, Dr. Samuel Hahnemann carried out an experiment because he did not believe the claim that cinchona bark's effectiveness in treating malaria was due to its astringency as there were other astringent substances that are not effective against malaria. In the experiment, he ingested cinchona bark and shortly after that he developed symptoms similar to malaria. Further experiments and researches on various substances have led to the formulation of the "Law of Similars", a healing principle in which he believed that substance in minute amounts that produce similar symptoms of the disease in healthy individuals can be used to treat the disease. This principle which is also known as "like cures like" forms the basis for approach to medicine in which he named Homeopathy.

3. Directive No. 10/2010: Restriction on Rosiglitazone Use & Strengthening of Warnings Associated With the Risk of Cardiovascular Adverse Events on the Package Inserts of All Rosiglitazone Products Including Combination Products

The DCA has decided to restrict rosiglitazone use and strengthen warnings related to the risk of cardiovascular adverse events in the form of boxed warning on package inserts of all rosiglitazone products including combination products.

The compulsory **black boxed warning** to be printed on the package inserts of all rosiglitazone-containing products is as below:

- *Rosiglitazone is contraindicated in patients with established NYHA Class I to IV heart failure and in patients with known ischaemic heart disease, particularly in those taking nitrates.*
- *Thiazolidinediones, including rosiglitazone, cause or exacerbate congestive heart failure in some patients. Patients on rosiglitazone should be monitored carefully for signs and symptoms of heart failure (including excessive, rapid weight gain, dyspnea, and/or edema). If these signs and symptoms develop, the heart failure should be managed according to current standards of care. Furthermore, discontinuation or dose reduction of rosiglitazone must be considered.*

Product holders were instructed to update the package inserts for the following sections as below:

Indications

The updated information on indications as follows has to be informed to all prescribers via "Dear Healthcare Professional Letter":

- Rosiglitazone is to be prescribed to new patients only if they are unable to achieve adequate blood glucose control with all other oral anti diabetic medications and it is the only suitable alternative in the healthcare professional's assessment as mono therapy or in combination with other oral anti diabetic.

- Patients who are already on the drug will be monitored closely by the attending physician especially for cardiovascular events.
- The risk of fracture should be considered in the care of patients, especially female patients treated with Rosiglitazone. In patients whose diabetes were well controlled when Rosiglitazone was used in combination with another anti diabetic drug, Rosiglitazone can be continued on condition that they are monitored closely and informed of the cardiovascular risk and osteoporosis and fracture risk.
- For patients established on Rosiglitazone receiving add-on insulin therapy, insulin must be titrated cautiously following appropriate clinical evaluation to assess the patient's risk of developing adverse reactions relating to fluid retention and other cardiovascular events. This combination therapy should only be limited to stable cases.
- Doctors will have to attest to and document their patients' eligibility and patients have to be well informed of this safety issue.

Contraindications

- Contraindicated in patients with NYHA Class I to IV heart failure or history of cardiac failure, patients with known ischaemic heart disease and patients with Acute Coronary Syndrome (unstable angina), non-ST elevation myocardial infarction (NSTEMI) and ST segment elevation myocardial infarction.

Warning and Precautions

- Rosiglitazone has been shown to be associated with an increased risk of myocardial ischaemia (angina, infarction) in pooled short term clinical studies compared to combined active/placebo control (2.00% versus 1.53%). Death from myocardial ischaemic events occurred in 0.15% on rosiglitazone-containing regimens and 0.12% on comparator regimen.

OTHER NEWS

Foot Patch Circular - Foot Patch Products with medical/therapeutic claims to be classified as drugs

On 30th September 2010, the Director of Pharmacy Regulatory, Mr. Selvaraja Seeragam has issued a circular regarding the classification of foot patch. It was stated that the Medical Device Drug Interphase Committee, Ministry of Health Malaysia has decided that foot pads/patch products (pasted on human body) containing herbs with medical/therapeutic claims should be classified as drug and controlled by the Drug Control Authority (DCA).

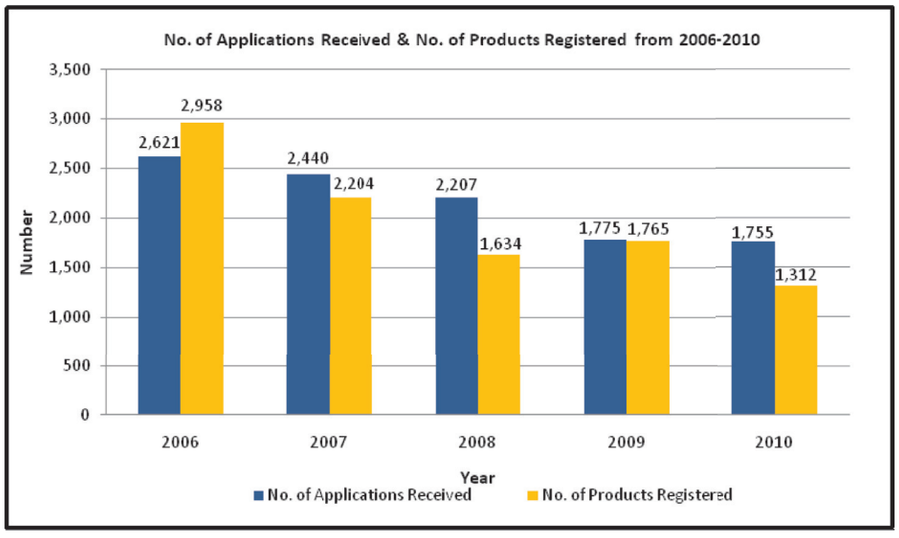
Product holders are given a period of 6 months from the date of circular (30th September 2010) to register the above-mentioned products with the DCA. In addition to that, products in the market should be cleared within 6 months from date of circular after which the products without a registration number will be classified as an unregistered product.

DCA NEWS

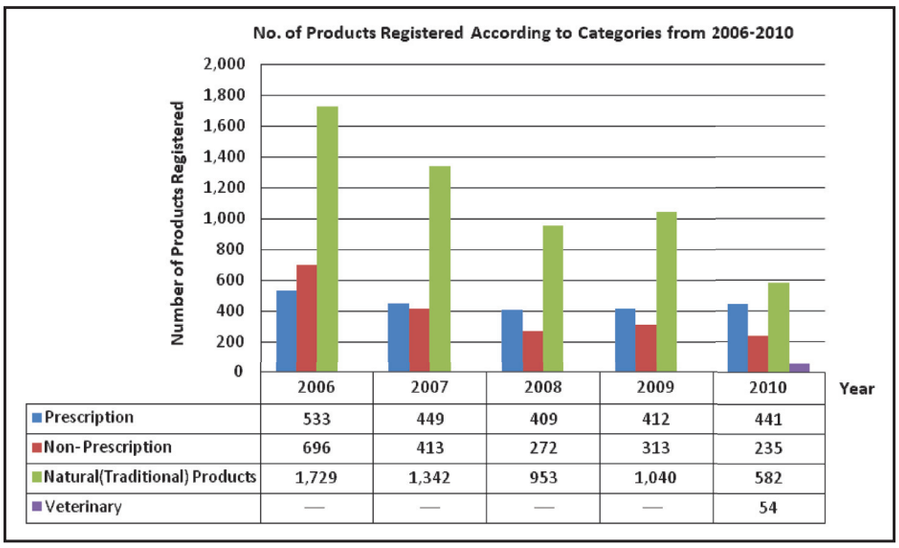
Below is the summary of DCA's policies/decisions from October-December 2010:

DCA Meeting	DCA Policies/Decisions
232nd Meeting 05/10/2010	The registration for the two products below were cancelled due to the adulteration with scheduled poison: 1. Product Name: Vegrow Capsule Registration Number: MAL08111900TC Substance Detected: Thiodimethylsildenafil 2. Product Name: NCHK PilZhiKe Registration Number: MAL06030949T Substances Detected: Dextrometrophan
234th Meeting 22/11/2010	Restriction on Rosiglitazone use and strengthening of warnings associated with the risk of cardiovascular adverse events on the package inserts of all Rosiglitazone products including combination products *This is mentioned in Directive 10/2010 on Page 7-8
235th Meeting 23/12/2010	1. The registration of the product below is suspended following complaints on the quality: Product Name: Osmivir Powder for Oral Suspension 12mg/ml Registration Number: MAL07082972A 2. The DCA has approved a list of immediate release generic products that require Bioequivalence (BE) studies. The list that was proposed by the Bioequivalence Study Committee consists of twenty nine (29) active ingredients as follows: 1. Letrozole 2. Anagrelide 3. Chlorpromazine 4. Haloperidol 5. Perphenazine 6. Trifluoperazine 7. Aripripazole 8. Olanzapine 9. Quetiapine 10. Ziprasidone 11. Citalopram 12. Escitalopram 13. Paroxetine 14. Duloxetine 15. Venlafaxine 16. Mirtazapine 17. Imipramine 18. Maprotiline 19. Nortriptyline 20. Pregabalin 21. Diazepam 22. Nitrazepam 23. Zolpidem 24. Chlordiazepoxide 25. Alprazolam 26. Lorazepam 27. Bromazepam 28. Clobazam 29. Zopiclone The requirement to submit BE study reports for the listed products will be enforced: • New applications – starting on 1st July 2011 • Registered products – before 1st July 2011

Statistics of DCA Activities from 2006-2010:



Statistics of DCA Activities from 2006-2010:



Number of Existing Registered Products According to Categories as of 31st Dec 2010

Category of Products	No. of Products Registered
Prescription	7,102
Non-prescription	4,743
Natural (Traditional)	11,896
Veterinary	54
Total	23,795

Product Status from 2006-2010

Year / Product Status	2006	2007	2008	2009	2010
Registered	2,958	2,204	1,634	1,765	1,312
Rejected	181	340	615	342	500
Cancelled/Withdrawn	12	66	183	60	63
Suspended	0	0	118	3	14

Number of Cosmetics Notified and Notifications Cancelled from 2008-2010

Year / Number	2008	2009	2010
Cosmetics notified and screened	30,351	37,466	53,262
Notifications cancelled	307	244	892

The notification procedure for cosmetic products was implemented in January 2008, replacing the cosmetic product registration procedure.

Did You Know?

There is another organisation in India which shares the same acronym (NPCB) as the National Pharmaceutical Control Bureau. This organisation, known as the National Programme for Control of Blindness is a division of the Ministry of Health and Family Welfare, Government of India.

EVENTS

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) Annual Meetings and Seminar 2010

The PIC/S Annual Meetings (Sub-Committee on Training Meeting, Executive Bureau Meeting and Committee Meeting), PIC/S Seminar and PIC/S-ASEAN Forum were held from 7th to 12thNovember 2010 at the Le Meridien Hotel, Kuala Lumpur. These events were organised by the National Pharmaceutical Control Bureau (NPCB).

The seminar which was held from 10th-12th November 2010 was officiated by the Minister of Health Malaysia, Dato' Sri Liow Tiong Lai. The theme for the seminar was "GMP Inspection of Manufacturers of Traditional/Herbal Medicinal Products". A total of 93 inspectors and regulators from 36 countries comprising of members from the PIC/S, PIC/S Partners and also ASEAN countries participated in this seminar.

There were 11 speakers from PIC/S Participating Authorities (Malaysia, Singapore and United Kingdom), the World Health Organization (WHO), Chinese SFDA, academia and industry associations. The four workshops which were carried out on the second day of the seminar were held at both the hotel and the Forest Research Institute of Malaysia (FRIM).

Objectives of this PIC/S Seminar 2010 were:

- To learn about Traditional/Herbal Medicinal Products from experienced Asian countries.
- Bridging the gap of interpretation of PIC/S Annex 7: Manufacture of Herbal Medicinal Products; to achieve consistence and similar interpretation of GMP for traditional/herbal medicinal products amongst PIC/S Participating Authorities.
- To harmonise the inspection approaches for the PIC/S Participating Authorities to achieve the desired compliances of the GMP for traditional/ herbal medicines industry.
- To identify necessary improvements of PIC/S Annex 7 and to establish Aide-Memoire on inspection of the traditional/herbal medicinal products with the aim of facilitation of the effective planning and conduct of GMP inspection on traditional/herbal medicinal products.

CONTACTS & MAP

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CENTRES	EXTENSION NO.
Centre for Product Registration	5487
• New Drug Section	5522
• Generic Medicine Section	5490
• Biotechnology Section	8423
• Complementary Medicine Section	8415
• Active Pharmaceutical Ingredient Section	8424
• Veterinary Medicine Section	5500
• Regulatory Coordination Section	5502
Centre for Post-Registration	5538
• Surveillance and Product Complaints Section	5543
• Pharmacoviligance Section	8470
• Variation Section	8474
• Cosmetic Section	5532
Centre for Organisational Development	5553
• Information Communication Technology Section	8578
• Quality System Section	8484
Centre for Compliance and Licensing	5564
• GMP Section	5566
• Quality, Certification, Licensing and GDP Section	5569
• Clinical Research and Compliance Section	5581
Centre for Quality Control	5429
• Bio-Pharmaceutical Testing Section	5477
• Research and Development Section	8446
• Pharmaceutical Chemistry Testing Section	5462, 5456, 5450
• Laboratory Services Unit	5431
• Natural Product Testing Section	5471
• Reference Standard Unit	5468
Centre for Administration	8458

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