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ISO 9000 CERTIFICATION NATIONAL PHARMACEUTICAL CONTROL BUREAU (NPCB)

Background

In an effort to improve the quality of the services provided by governmental agencies, the Public Services Department issued a circular in 1996 mandating all agencies within the public sector to aim to achieve MS ISO certification of their management systems. In line with this requirement and in its quest to achieve an efficient and effective regulatory system whilst ensuring customer satisfaction, the National Pharmaceutical Control Bureau (NPCB) began its efforts to obtain ISO 9002:1994 certification of its management system in 1998.

Benefits Derived

Under the ISO certification scheme, an organisation needs to demonstrate its ability to consistently provide a service that is in line with regulatory requirements that meets customer satisfaction through the effective application of an efficient quality management system. The organisation should also be able to assure conformity to set standards and that systems are in place for continual improvement.

In This Issue

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The benefits of the implementation of MS ISO 9000 in NPCB are as follows:

- Restructuring of the organisation within NPCB
- Streamlining of work processes
- Proper documentation of all critical activities such as in product evaluation, testing, licensing, surveillance and staff training.
- Structured management reviews and assessment of quality objectives, conformance to standards, outlier reports
- Continual improvement through findings of interal audits, root cause analysis of complaints, trend analysis of work outputs, implementation of preventive and corrective actions

Scope of Certification

The scope of the ISO certification for NPCB covers the regulation of pharmaceuticals, traditional medicines and cosmetic products via activities which include product evalution and registration, licensing and surveillance.

All centres/ sections/ units in NPCB are included in this certification process. They are:

a) Centre for Product Registration

b) Centre for Post Registration

c) Centre for Quality Control

d) Centre for Organisational Development

e) Centre for Good Manufacturing Practice

f) Administration Unit

Milestones in the Achievement of MS ISO 9000 by NPCB

Following the fulfillment of ISO documentation requirements, an Adequacy Audit was conducted on 16 January 2001 by SIRIM QAS. This was followed by a Compliance Audit which was carried out on 18-19 April 2001 during which five (5) non-conformances (NCR) and three (3) observations (now termed as Opportunities for Improvement or OFI) were identified. However, as there was overall compliance to the requirements of the ISO standards, NPCB was granted MS ISO 9002:1994 Certification on 17 July 2001.

The following year i.e 2002, a Surveillance Audit was done and as a result of which NPCB obtained 1 NCR and 3 OFI reports. Prior to the 2003 Surveillance Audit by SIRIM QAS, NPCB converted its quality management system from the ISO 9002:1994 to be in line with the new clauses as stipulated in the new MS ISO 9001:2000 standard. During the audit which was conducted on 11-13 August 2003, NPCB successfully upgraded its certification status to MS ISO 9001:2000 and obtained a total 4 NCR and 4 OFI reports.

During the Reassessment Audit in 2004, NPCB widened the certification scope to include the regulation of cosmetic products which was previously not included as cosmetics regulation had not yet started. NPCB was very happy with its achievements whereby there were no non-conformances reported but 12 OFI were identified.

NPCB further improved its performance in 2005 as during this Surveillance Audit, there were again no non-conformances reported but 5 OFI were identified.

In 2006, NPCB converted to an on-line electronic Document Control system which was developed in-house by NPCB's own staff. There was full commitment by the management and all the staff towards maintaining the standard achieved during the 2005 audit. Indeed, it was a memorable moment for the entire NPCB workforce when the audit finding showed only one (1) OFI and no non-conformances at all.

NPCB is committed towards ensuring the quality, efficacy and safety of products which it regulates and to achieve customer satisfaction through reducing bureaucracy without compromising on statutory and administrative requirements. NPCB has strived to continually improve the services that it provides its clients by having a competent and knowledgeable workforce who are professional and open minded as well as through dialogues with its stakeholders who have provided valuable feedback and constructive criticisms.

Future Plans

In its efforts for continual improvement, NPCB is now embarking on a journey towards achieving MS ISO/IEC 17025:2005 accreditation for the testing of traditional medicines.

NEWS UPDATE ON ASEAN TRADITIONAL MEDICINES AND HEALTH SUPPLEMENT HARMONISATION

The Fifth Meeting Of The ASEAN Consultative Committee for Standards and Quality (ACCSQ) Traditional Medicines and Health Supplements Product Working Group (TMHS PWG)

The 5th ACCSQ Traditional Medicines & Health Supplements Product Working Group (TMHS PWG) Meeting 27 to 28 July 2006, Singapore

The 5th Meeting of the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) was held on 27-28 July 2006 in Singapore. The meeting was preceded by a Regional Seminar on the 'Regulation of Traditional Medicines and Health Supplements-The Challenges' on 26 July 2006 in the same venue.The Meeting was chaired by Mrs. Mawarwati Djamaluddin, Diplm Pharm, Permanent Secretary of the National Agency of Drug and Food Control of the Republic of Indonesia, and was attended by delegates from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand and Viet Nam, as well as representative of the ASEAN Secretariat and WHO.

Among the Agenda adopted by the meeting include the following :

1. ***Follow Up Action from the 27th ACCSQ Meeting (held on 20-22 March 2006 in Penang, Malaysia)***

The following three(3) issues relevant to the TMHS PWG were highlighted:

i. The adoption of the ASEAN Policy Guideline on Standards and Conformance by the ASEAN Economic Ministers at their 37th Meeting. This was with the aim of providing the guiding principles for the implementation of joint efforts of ASEAN Member Countries in the area of standards and conformance both in regulated and non-regulated sectors as one of the measures for accelerating economic integration towards the AEC. The guideline focuses on harmonisation of standards and the implementation of the relevant conformity assessment schemes as well as their adoption and use in technical regulations. The mechanism for the implementation of the Guideline is being developed .

ii. The ACCSQ decided that the TMHS PWG would pursue the issue on borderline products by identifying issues to be addressed as well as conducting consultation with the Prepared Foodstuff PWG when necessary to address such issues.

iii. The inputs from the TMHS PWG on the Draft Roadmap for the Healthcare Sector-Phase II to be submitted to the ACCSQ by 7th August 2006.

2. Consideration of the Outcome of the Regional Seminar on the "Regulation of Traditional Medicines and Health Supplements – The Challenges" held on 26 July 2006

The Meeting agreed to take note of all feedback and comments at the seminar and in particular the following points:

i. A risk-based approach is useful in the development of an appropriate regulatory framework.
ii. Development of negative list of herbs and toxic substances would be useful for all relevant stakeholders.
iii. Involvement of the industry and scientists to provide the expertise needed for risk assessment.
iv. The ASEAN harmonisation of regulations in traditional medicines and health supplements could use as reference the experience of the harmonisation initiatives undertaken by the Australia New Zealand Therapeutic Product Authority(ANZTPA)
v. The TMHS PWG could learn from the experience in the various developed countries in order to avoid similar problems previously faced by them.

3. Implementation of the TMHS PWG Work Programmes.

3.1 Harmonisation on Specific Areas of Technical Requirements.

The meeting was informed that the Profile of Terminologies, Definitions and Technical Requirements on TMHS among ASEAN Member Countries had been completed and is to be circulated among Member Countries for comments.The Profile would be posted on the ASEAN website if no comments were received by 15 August 2006.

The meeting also agreed to embark on the harmonisation of additional areas as follows:

- Safety/ Quality Requirements:
  - Negative list of ingredients
  - Certification requirements
  - Limits of Microbial Contamination

- Limits of Toxic Substances
- Limits of Pesticide Residue
- Maximum levels of vitamins and minerals

- Claim requirements which include the list of prohibited claims and list of permissible claims.
- Post-marketing surveillance

3.2 Development of ASEAN Common Technical Requirements for TMHS

(a) GMP

The meeting agreed on the following :

i. A Technical Workshop on GMP for TMHS be held as soon as possible in order to identify an appropriate approach for ASEAN in developing the GMP requirement for TM and HS. Malaysia will assist in coordinating with Member Countries in conducting the workshop.

ii. Malaysia will develop a checklist which makes reference to the WHO GMP and PIC/s guidelines and circulate to Member Countries. Member Countries will then use the checklist in conducting the survey at national level including potential GMP compliance by industry as well as challenge they may face if GMP is enforced.

iii. The next TMHS PWG Meeting will discuss follow-up action based on the findings from the survey.

iv. Member Countries to identify and submit their training needs to Malaysia for consideration.

(b) Testing method

The meeting agreed:

i. Priority should be given to strengthen testing laboratories infrastructure in member countries to perform safety requirements.

ii. A one-day workshop on testing methods to be held together with the GMP Workshop

3.3 Requirement on Product Placement

The meeting agreed that a workshop to be held to discuss this issue in detail prior to the presentation at the next Meeting.

3.4 Labelling Requirements.

Proposal by Thailand on the harmonised labelling was agreed on and ASEAN Member Countries were encouraged to start exercising the labelling requirements on trial basis. Feedback on the implementation to be reported at the 6th TMHS PWG Meeting.

3.5 Post-Marketing Alert System

Viet Nam was appointed coordinator to monitor the implementation of the Alert System.

4. *Mapping of Existing and Potential Capacity of Member Countries*

The meeting agreed on the need to properly document all available information compiled in different surveys for future reference by stakeholders.

5. *Update on Cooperation Activities with Other Partners*

The Meeting was informed that the Natural Health Product Directorate of Canada and TGA of Australia are willing to assist Member Countries in harmonisation of technical requirements on TMHS, subject to the identification of Member Countries' need.

The meeting agreed that the 6th TMHS PWG Meeting be tentatively held on 18-20 December 2006 in Viet Nam, the 7th and 8th meetings in Brunei Darussalam and in Philippines respectively.

DCA NEWS

THE 6TH LIST OF BIOEQUIVALENCE STUDIES FOR IMMEDIATE-RELEASE GENERIC PRODUCTS

In an effort to improve quality, efficacy and safety of generic products as compared to innovator products, the Bioequivalence (BE) Studies Committee has decided to add twenty six (26) more immediate-release products to the existing list. The need to submit BE Studies Reports will be enforced periodically within two (2) years (2006-2007).

No.	TEST PRODUCTS (Pharmaceutical Name)	Effective Date for Submission of BE Studies Report	Closing Date for Submission of BE Studies Report of Registered Product	
		New Application	Imported Product	Local Products
1.	Amlodipine	1 December 2006	1 June 2007	31 December 2007
2.	Azithromycin			
3.	Buprenorphine			
4.	Carvedilol			
5.	Cefuroxime Axetil			
6.	Cetrizine			
7.	Doxycycline			
8.	Gliclazide			
9.	Glimepiride			
10.	Hydroxyzine			
11.	Ibuprofen			

No.	TEST PRODUCTS (Pharmaceutical Name)	Effective Date for Submission of BE Studies Report	Closing Date for Submission of BE Studies Report of Registered Product	
		New Application	Imported Product	Local Products
12.	Itraconazole	1 December 2006	1 June 2007	31 December 2007
13.	Ketoconazole			
14.	Ketoprofen			
15.	Lamotrigine			
16.	Loratadine			
17.	Losartan			
18.	Lovastatin			
19.	Meloxicam			
20.	Metronidazole			
21.	Naproxen			
22.	Risperidone			
23.	Roxithromycin			
24.	Simvastatin			
25.	Tamoxifen			
26.	Ticlopidine			

WARNING STATEMENT ON THE LABEL AND PACKAGE INSERT OF ORAL HEALTH SUPPLEMENTS CONTAINING ARGININE CONCERNED WITH "ARGININE IS NOT RECOMMENDED FOR PATIENT FOLLOWING A HEART ATTACK"

The DCA at its 185th meeting held on 29th September 2006 agreed that the warning, **'Arginine is not recommended for patient following a heart attack'** is compulsory to be put on the labels and package inserts of **oral health supplement products** containing Arginine under **"Warning".**

However non-oral products containing Arginine are exempted from the ruling as the usage is for therapeutic purpose and the administration is under the supervision of a medical doctor.

WARNING STATEMENT ON LABEL AND PACKAGE INSERT OF TRADITIONAL PRODUCTS CONTAINING BLACK COHOSH *(CIMICIFUGAE RACEMOSAE)* CONCERNED WITH "SERIOUS HEPATIC REACTION"

The DCA at its 183rd meeting held on 27th July 2006 agreed that the warning, **'serious hepatic reaction'** is compulsory to be put on the labels and package inserts of traditional/natural products containing **Black Cohosh** ***(Cimicifugae Racemosae)***.
The **"Warning"** should also contain the following statement:

- **Stop taking this product if signs and symptoms suggestive of liver injury develop such as tiredness, loss of appetite, yellowing of the skin and eyes or severe upper stomach pain with nausea and vomiting or dark urine and consult your doctor immediately.**
- **Patients using herbal medicinal products should tell their doctor about it.**

MEDITAG™ - UPGRADING OF SECURITY FEATURES

The implementation of the security labelling using Meditag ™ has been enforced by the DCA and effective from 2005.

The Meditag ™ contains security features and serial numbers to authenticate DCA registered products in the market, thus allowing different levels of authentification for consumers to recognise as well as enforcement teams to verify, track and trace registered products in the market.

After more than one year of their use and in accordance to the contractual terms the suppliers for Meditag ™ label has introduced some upgraded features not only to enhance the security but also to further facilitate the enforcement officers in their enforcement work.

The old version is still usable, while the new ones are estimated to be available for distribution in September 2006.

PUBLIC ANNOUNCEMENT

Update on the much publicised news of SK-II products which were tested in China and found to contain prohibited substances.

On the 15th of September 2006, information was received regarding nine (9) cosmetic products under the brand name SK-II which were tested in China and found to contain Chromium and Neodymium which are listed as prohibited substances in cosmetics.

The products which were tested are as follows:

1. SK-II's Whitening Source Foundation
2. SK-II's Advanced Protect Essence
3. SK-II's Sign's Treatment
4. SK-II's Cleansing Oil
5. SK-II's Facial Treatment Essence
6. SK-II's Whitening Liquid Foundation OB-2
7. SK-II's Whitening Liquid Foundation OD-3
8. SK-II's Facial Treatment Mask
9. SK-II's Skin Essence Foundation OB-2

In Malaysia, Chromium and Neodymium are also listed as ingredients which are not allowed to be used. The Drug Control Authority (DCA) evaluates all cosmetic products prior to registration and there are no known products which have been registered including the above SK-II products which contain any banned or prohibited substances.

However, Chromium and Neodymium have been detected in trace amounts in these products but is probably due to their natural occurrence in some of the ingredients used in their formulation. Taking into account that Chromium and Neodymium are naturally occuring elements, the current guidelines used in the regulation of cosmetic products do make provision for the presence of such substances found in cosmetics.

Chromium may cause skin reactions and Neodymium may irritate the eyes, cause pulmonary embolism or damage the liver. However, at trace levels, they are highly unlikely to give rise to such reactions.

To date, there have been no reports of any adverse effects arising from the use of these SK-II products and based on the current situation, the use of these products is still allowed in Malaysia.

UPCOMING EVENTS

The following events have been planned by the National Pharmaceutical Control Bureau (NPCB) as part of the continuous training programme for either the staff or the industry:

1. TRAINING COURSE ON QUALITY CONTROL OF TRADITIONAL PRODUCT (MICROBIAL CONTAMINATION TESTING)
   18-22 September 2006

2. ISO 17025 LABORATORY INTERNAL AUDITING TRAINING
   2-3 November 2006

3. SEMINAR OF PHARMACY ASSISTANTS
   9-10 November 2006

4. SEMINAR ON HEALTH SUPPLEMENTS 2006
   22 November 2006

5. NATIONAL GMP SEMINAR 2006
   19-21 December 2006

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Centre for Product Registration	Deputy Director	Selvaraja S. Seerangam	270
Application for Registration of:			
(i) Generic Medicines Section	-Prescription Unit	Rohani Ismail	255
	-Non-Prescription Unit	Abdullah Hisham Ahmat Yaya	233
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(ii) Complementary Medicines & Cosmetic Section	-Natural Products Unit	Saleha Md. Ewan	238
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(iii) Investigational & New Drug Section	-New Drug Unit	Noorizam Ibrahim	239
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(iv) Regulatory Coordination Unit	-Regulatory Coordination Unit	Rosilawati Ahmad	245
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(i) Reference Standard Unit	Reference Standard Unit	Ahmad Zakhi Ramli	510
(ii) Laboratory Services Unit	Laboratory Services Unit	Tan Ann Ling	515
(iii) Pharmaceutical Chemistry Testing Section	-Chromatography Unit	Dr. Hasenah Ali	521
	-Dosage Performance Unit	Faridah Abdul Malek	613
	-Spectroscopy/General Chemistry Unit	Ani Abdullah	604
	-Chemistry Research Unit	Dr. Hasenah Ali	521
(ii) Pharmaceutical Biology Testing Section	-Microbiology Unit	Siti Madziah Mohamed	608
	-Pharmacology/Toxicology Unit	Ani Abdullah	346
(iii) Natural Product Testing Section	-Herbal Monograph Unit	Mazli Muhamad	250
	-Adulteration Screening Unit		
	-Toxic Compound Detection Unit		