Year 2004

DCA News Update (DCA 165 23/12/2004)

New information regarding cardiovascular safety of Celebrex (Celecoxib), Bextra (Valdecoxib) and Naproxen

CELEBREX
Based on emerging information, including preliminary reports from one of several long term National Institutes of Health (NIH) prevention studies, the risk of cardiovascular events (composite endpoint including MI, CVA and death) may be increased in patients receiving Celebrex. Subsequently, the DCA will be analyzing all available information from these studies to determine whether additional regulatory action is needed.

NAPROXEN
Patients who are currently taking naproxen products should be advised to carefully follow the instructions on the label and not to exceed the recommended doses for naproxen (220 milligrams twice daily). Naproxen should not be taken for longer than ten days unless a physician directs otherwise.

BEXTRA
Based on action taken by US FDA, The DCA has instructed Pfizer (M) Sdn. Bhd to include a boxed warning in the package insert about the risk of life- treatening skin reactions Steven-Johnson Syndrome and Toxic Epidermal Necrolysis & Cardiovascular Risks.

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DCA News Update (DCA 161 27/07/2004)

Use of Thiomersal in Vaccines An Update

The Drug Control Authority (DCA) at its 124th meeting decided not to allow thiomersal as a preservative in vaccines. A new proposal has emerged requesting a review of that decision based on latest findings of the safety of thiomersal.

DCA has taken into account that the latest epidemiological research showed no relation of thiomersal-containing-vaccine causing specific neurodevelopmental disorders.

Therefore, the DCA at it 161st meeting held on the 5 August 2004 has decided the following:

i) Thiomersal can be considered in being used as a preservative in vaccines.

ii) Vaccines registration application, which has thiomersal content, will be evaluated case by case while taking into account product efficacy and general health needs.

iii) Products with thiomersal content have to be accompanied with a label and warning stating risk of sensitization in relation to thiomersal and other preservatives.

iv) In accordance with the global aim of reducing exposure to mercury, vaccine preparations without thiomersal or minimum thiomersal content is encouraged.

Cadmium (Cd) in the Toxic Metal Tests for Traditional Products

The Drug Control Authority (DCA) at its 161st meeting held on the 5 August 2004 has agreed on the following:

(i) Cadmium test is included in the test for testing of traditional products whereby the limit for the test is 0.3mg/kg. This rule will come into effect from 1 January 2005.

(ii) To accept the limit stated in Appendix 1 as the latest specification for Quality Control of Traditional Medicine Products.

Appendix 1

Quality Control Test Specifications for Traditional Medicine Products

1. **Limit Test for Heavy Metals**

Maximum limit for heavy metals

1.1 Lead : = 10.0 mg/kg or mg/litre (= 10.0ppm)

1.2 Arsenic : = 5.0 mg/kg or mg/litre (= 5.0ppm)

1.3 Mercury : = 0.5 mg/kg or mg/litre (= 0.5ppm)

2. **Disintegration Test (for tablets, capsules and pills)**

Disintegration time

2.1 Uncoated tablets : = 30 minutes

2.2 Film-coated tablets : = 30 minutes

2.3 Sugar-coated tablets : = 60 minutes

2.4 Enteric-coated tablets : = 120 minutes in an acid solution
= 60 minutes in buffer solution

2.5 Capsules : = 30 minutes

2.6 Pills : = 120 minutes

3. **Test for Uniformity of Weight (tablets and capsules only)**

= 2 capsules / tablets exceed the limit by ± 10% from the average weight.
No tablet / capsule exceed the limit by ± 20% from the average weight.

4. **Test for Microbial Contamination**

4.1 Preparations for topical use and for use in the respiratory tract except where required to be sterile and transdermal patches

4.1.1 Total viable aerobic count : = 5 x 102 cfu/gram (aerobic bacteria and fungi) cfu/ml

4.1.2 Enterobacteria and certain : = 5 x 101 cfu/gram or other Gm-negative bacteria cfu/ml

4.1.3 Pseudomonas aeruginosa : Absent in 1 gram or 1 millilitre

4.1.4 Staphylococcus aureus : Absent in 1 gram or 1 millilitre

4.2 Transdermal Patches

4.2.1 Total viable aerobic count : = 5 x 102 cfu/patch (aerobic bacteria and fungi)

4.2.2 Enterobacteria and certain : Absent in 1 patch other Gm-negative bacteria

4.2.3 Pseudomonas aeruginosa : Absent in 1 patch

4.2.4 Staphylococcus aureus : Absent in 1 patch

4.3 Preparations for oral administration containing raw materials of natural origin (animal, vegetable or mineral) for which antimicrobial pre-treatment is not feasible, and for which the competent authority accepts a microbial contamination of the raw material exceeding 5 x 103 viable microorganisms per gram or per millilitre (excluding herbal remedies described in 4.4)

4.3.1 Total viable aerobic count : Bacteria : = 5 x 104 cfu/gram or cfu/ml

Fungi : = 5 x 102 cfu/gram or cfu/ml

4.3.2 Enterobacteria and certain : = 5 x 102 cfu/gram or cfu/ml other Gm-negative bacteria

4.3.3 Salmonella : Absent in 10 gram or 10 ml

4.3.4 Escherichia coli : Absent in 1 gram or 1 ml

4.3.5 Staphylococcus aureus : Absent in 1 gram or 1 ml

4.4 Herbal medicinal products consisting solely of one and more herbal drugs (whole, reduced or powdered)

4.4.1 Herbal medicinal products to which boiling water is added before use

4.4.1.1 Total viable aerobic count : Bacteria : = 5 x 107 cfu/gram
or cfu/ml
Fungi : = 5 x 105 cfu/gram or cfu/ml

4.4.1.2 Escherichia coli : = 5 x 102 cfu/gram or cfu/ml

4.4.2 Herbal medicinal products to which boiling water is not added before use

4.4.2.1 Total viable aerobic count : Bacteria : = 5 x 105 cfu/gram or cfu/ml

Fungi : = 5 x 104 cfu/gram or cfu/ml

4.4.2.2 Enterobacteria and certain : = 5 x 103 cfu/gram or cfu/ml other Gm-negative bacteria

4.4.2.3 Escherichia coli : Absent in 1 gram or 1 ml

4.4.2.4 Salmonella : Absent in 10 gram or 10 ml

References:-
Test 1 : Akta Racun 1952
Tests 2, 3 & 4 : BP 2002*

*The specifications for tests 2,3 and 4 will depend on the changes in the pharmacopoeia. The latest edition of the British Pharmacopoeia is followed if there are changes.

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DCA News Update (DCA 160 22/06/2004)

Additional Warning Related to Hyperglycaemia for all Atypical Antipsychotic Agents.

The Drug Control Authority (DCA) at its 160th meeting held on the 1 July, 2004 made the decision that the following warning on hyperglycemia adverse event must be included in package insert of all atypical antipsychotic agents listed below:

- clozapine
- olanzepine
- risperidone
- quetiapine
- ziprasidone
- aripiprazole.

WARNINGS:

Hyperglycemia and Diabetes Mellitus.
Hyperglycemia in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalties is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given this confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g. obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during teatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydypsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however some patients require

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DCA News Update (DCA 159 27/05/2003)

Cancellation Of Registered Products - Yi Shou Fang and Long Dan Cao

At its 159th meeting held on the 27 May 2004, the Drug Control Authority (DCA) had agreed and decided to cancel the registration of two products, registered under Versinix Pharm Sdn. Bhd. The products are as follows:
Name of Product
Registration No.
Registration Holder/Manufacturer
Reason For Cancellation

1) Yi Shou Fang
MAL 20032105TC
Versinix Pharm Sdn. Bhd.
(Vitarite Pharm Sdn. Bhd.)
Adulteration issues (Sample of product had been tested and found positive for Dexamathasone and Chlorpheniramine).

2) Long Dan Cao
MAL 20032106TC
Versinix Pharm Sdn. Bhd.
(Vitarite Pharm Sdn. Bhd.)
The registration number was used to manufacture and market unregistered product under the name Supertox.

Extension on the Marketing Duration of Cosmetic Products in the Market

At its 159th meeting on the 27 May 2004, DCA took into consideration the suggestion to extend the marketing duration of cosmetic products which had been submitted for registration before 31 January 2004. The dateline has been extended from 30 June 2004 to 31 December 2004.
As of 1 January 2005, all cosmetic products in the market are required to comply with the labeling requirements as stated in the Guidelines For Cosmetic Registration.

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DCA News Update (DCA 158 27/04/2003)

Cancellation of Product Containing Terfenadine

The Drug Control Authority (DCA) at its 158th meeting held on the 27 April 2004 decided to cancel the registration of all products containing Terfenadine. All registration holders are given a grace period of six months starting from the date of DCA 158th meeting to ensure that all products containing Terfenadine are no longer in the market.
The affected products will also be deleted from the manufacturers or the importers license of the companies concerned.

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DCA News Update (DCA 157 23/03/2003)

HALAL LOGO FOR REGISTERED PHARMACEUTICAL PRODUCTS, TRADITIONAL PRODUCTS AND COSMETIC PRODUCTS.

The Drug Control Authority (DCA) at its 157th meeting held on 23rd March 2004 decided on the following regarding HALAL logo for registered pharmaceutical, traditional and cosmetic products:

- To continue with the existing policy of not allowing the HALAL logo to be stated on the label of pharmaceutical products,

- To continue with the existing policy of allowing the HALAL logo to be stated on the label of local and for export only cosmetic products,

- To consider the use of HALAL logo certified and issued by JAKIM only on the label of local and for export only cosmetic products as well as dietary supplements,

- To consider the use of HALAL logo for traditional products, cosmetics and dietary supplements based on request by the registration holders but non-mandatory.

CONTROL ON PACKING SIZE OF ALL LIQUID COUGH PREPARATIONS FOR LOCAL AND FOR EXPORT ONLY .

The Drug Control Authority (DCA) at its 157th meeting held on 23rd March 2004 decided that no exemption on packing size of for export only products. Packing size of 120ml +/- 10ml is applicable for local and for export only of all liquid cough preparations.

REQUEST ON PACKING SIZE OF PARENTERAL PREPARATIONS, PERITONEAL DIALYSIS SOLUTIONS AND HAEMOFILTRATION SOLUTIONS.

The Drug Control Authority (DCA) at its 157th meeting held on 23rd March 2004 decided to consider the different packing sizes and packaging of parenteral preparations, peritoneal dialysis solutions and haemofiltration solutions (which are introduced into patients bodies) as one single product for a particular product. However, comprehensive stability studies on the different types of packaging are required to determine suitable shelf lives and storage conditions for the products.

MALAYSIA INDONESIA ISSUES ON PRODUCT REGISTRATION

For bilateral cooperation and teamwork by ASEAN, the Drug Control Authority (DCA) at its 157th meeting held on 23rd March 2004 has agreed to allow both Malaysia and Indonesia to market their pharmaceutical products in their respective countries.
Nevertheless, they must comply with the rules and regulations set by these countries as well as the standard and requirements stipulated by ASEAN.

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DCA News Update (DCA 156 24/02/2004)

PRODUCTS CONTAINING CISAPRIDE AS AN ACTIVE INGREDIENT.

The Drug Control Authority (DCA) at its 156th meeting held on 24th February 2004 decided to cancel the registration of five (5) products and to reject the application for registration of one (1) product containing the active ingredient CISAPRIDE as shown below due to SAFETY issue.

No.
Product Name
Ref. No.
(Registration No.)
Product Holder
Product Manufacturer
Remarks

1.
PREPULSID SUSPENSION 1MG/ML
1989050019A
(MAL19900360A)
JOHNSON & JOHNSON S/B
JANSSEN PHARM N.V.
CANCELLED

2.
PREPULSID TABLETS 10MG
1991080032A
(MAL19921106A)
JOHNSON & JOHNSON S/B
JANSSEN PHARM N.V
CANCELLED

3.
CISAPAN TABLET 5MG
2001086535A
DUOPHARMA(M) S/B
DUOPHARMA(M) S/B
REJECTED

4.
CISPRIDE TABLET 10MG
2000102988A
(MAL200335510A)
YSP INDUSTRIES (M) S/B
YSP INDUSTRIES (M) S/B
CANCELLED

5.
CISPRIDE TABLET 5MG
2000102987A
(MAL20033511A)
YSP INDUSTRIES (M) S/B
YSP INDUSTRIES (M) S/B
CANCELLED

6.
CIZA TABLET 10MG
2000102931A
(MAL20021145A)
KOMEDIC S/B
INTAS PHARM LTD
CANCELLED

However, all holders who have registered and marketed the products containing CISAPRIDE will be given an exemption to import such products based on prescribers request on a named patient basis.

Holders of all registered products containing CISAPRIDE are given a grace period of six (6) months from the date of DCA 156th meeting to recall their products from the market.

RECALL OF PRODUCTS CONTAINING Comfrey & Senecio spp HERBS.

The Drug Control Authority (DCA) at its 156th meeting held on 24th February 2004 made the decision to recall all products containing Comfrey and Senecio spp from the market as these ingredients contain pyrrolizidine alkaloid and have been linked to hepatic failure.

The DCA has therefore decided not to register any product containing Comfrey and Senecio spp. Subsequently, all registration holders of products containing these ingredients are given a grace period of six (6) months from the date of DCA 156th meeting to recall their products from the market.

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