Biro Pengawalan Farmaseutikal Kebangsaan
National Pharmaceutical Control Bureau
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

Ruj. Kami : (49) dlm. BPFK/PPP/01/03
Tarikh : 14 APR 2010

SEMUA PEMEGANG PENDAFTARAN

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan/ Puan,

PERATURAN-PERATURAN KAWALAN DADAH DAN KOSMETIK 1984
(PINDAAN 2006)
ARAHAN BILANGAN 2 TAHUN 2010
DESKRIPSI KAJIAN SIBUTRAMINE CARDIOVASCULAR OUTCOME (SCOUT) YANG PERLU DIMUATKAN PADA SISIP BUNGKUSAN PRODUK SIBUTRAMINE

Adalah saya merujuk kepada Arahan Bilangan 2 tahun 2010 oleh Pengarah Kanan Perkhidmatan Farmasi.

2. Dimaklumkan bahawa Pengarah Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia dalam Arahan Bilangan 2 Tahun 2010 telah mengarahkan supaya deskripsi maklumat kajian tersebut **wajib** dimuatkan ke dalam sisip bungkusan produk Sibutramine seperti pada surat arahan Bil. (49) BPFK/PPP/01/03 (Lampiran 1).

3. Pihak pemegang pendaftaran adalah diarahkan untuk mematuhi keperluan tersebut.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

(SELVARAJA SEERANGAM)
Pengarah Regulatori Farmasi,
Biro Pengawalan Farmaseutikal Kebangsaan,
b.p. Pengarah Kanan Perkhidmatan Farmasi,
Kementerian Kesihatan Malaysia

s.k. Timbalan Pengarah Pusat Pendaftaran Produk,
Ketua Pusat Pasca Pendaftran Produk

Jalan Universiti, P. O. Box 319, 46730 Petaling Jaya, Selangor, Malaysia
Tel.: +603 7883 5400 Fax: +603 7956 2924/7958 1312
http://www.bpfk.gov.my

BPFK/PPP/01/03(49)

ARAHAN DI BAWAH PERATURAN 29 PERATURAN – PERATURAN KAWALAN DADAH DAN KOSMETIK 1984

BILANGAN _2_ TAHUN 2010

DESKRIPSI KAJIAN SIBUTRAMINE CARDIOVASCULAR OUTCOME (SCOUT) YANG PERLU DIMUATKAN PADA SISIP BUNGKUSAN PRODUK SIBUTRAMINE

TUJUAN

1.1 Arahan ini bertujuan memaklumkan deskripsi kajian Sibutramine Cardiovascular Outcome (SCOUT) yang perlu dimuatkan pada sisip bungkusan produk Sibutramine.

1.2 Peraturan 29 Peraturan – Peraturan Kawalan Dadah dan Kosmetik 1984 (Pindaan 2006) memberi kuasa kepada Pengarah Perkhidmatan Farmasi untuk mengeluarkan arahan tersebut.

LATAR BELAKANG

2.1 Pihak Berkuasa Kawalan Dadah (PBKD) di dalam mesyuaratnya kali ke **224** pada 28 Januari 2010 telah memutuskan bahawa deskripsi maklumat kajian Sibutramine Cardiovascular Outcome (SCOUT) **wajib** dimuatkan pada sisip bungkusan produk Sibutramine. Ini adalah berdasarkan keputusan kajian Sibutramine Cardiovascular OUTcomes (SCOUT) bagi produk Reductil® yang dijalankan untuk menilai keselamatan penggunaan jangka panjang dalam pesakit obes dan didapati mempunyai risiko kardiovaskular dimana mengikut kegunaan asal adalah dikontraindikasi.

PELAKSANAAN

3. Oleh itu arahan – arahan yang berikut dikeluarkan iaitu:-

3.1 Deskripsi maklumat kajian tersebut yang perlu dimuatkan ke dalam sisip bungkusan produk Sibutramine adalah seperti berikut:

❖ ***The Sibutramine Cardiovascular OUTcomes (SCOUT) Study***

- ***The SCOUT Study was a randomized, double-blind, placebo-controlled study, with a single-blind, sibutramine lead in period. The study was conducted as a post approval commitment to the European regulatory authorities.***

- ***The study enrolled 10,744 and randomized 9,805 overweight or obese patients at high risk of cardiovascular events (the majority who were not indicated to received treatment with sibutramine) In the study, these cardiovascular high risk subjects were treated with sibutramine for up to 6 years and were not discontinued from treatment for inadequate weight loss response which is not consistent with the instruction for use.***

- ***Subject treated with Sibutramine experienced 16% increased risk of a primary outcome event nonfatal myocardial infarction, nonfatal stroke, resuscitated cardiac arrest, or cardiovascular (CV) death (561/4906, 11.4%) compared to placebo treated subjects (490/4898, 10.0%) (hazard ratio 1.161 [95% CI 1.029, 1.31]; p=0.016) There was however no difference in the incidence of CV death or all cause mortality between the treatment groups.***

3.2 Pemegang pendaftaran juga diarahkan untuk mengeluarkan surat "**Dear Healthcare Professional**" kepada semua pengamal perubatan yang berkaitan dengan penggunaan ubat ini berikutan dengan tindakan PBKD (*Sila rujuk Lampiran 1*).

3.3 Arahan ini berkuatkuasa **mulai dari tarikh pekeliling ini** dan merangkumi semua permohonan pendaftaran produk baru dan produk yang sedang dalam proses penilaian.

3.4 Walaubagaimanapun, bagi produk yang telah berdaftar, pemegang pendaftaran adalah dibenarkan untuk menggunakan sisip bungkusan lama sehingga stok habis atau sekiranya terdapat pindaan pada sisip bungkusan (pindaan dilakukan melalui Seksyen Variasi, Pusat Pasca Pendaftaran Produk, Biro Pengawalan Farmaseutikal Kebangsaan(BPFK)), pemegang pendaftaran diarah mematuhi keperluan amaran tersebut di atas pada sisip bungkusan ini.

TARIKH KUAT KUASA

4. Tarikh kuat kuasa arahan ini ialah mulai 14 APR 2010

"BERKHIDMAT UNTUK NEGARA"

(**EISAH A. RAHMAN**)
Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia.

s.k:
Pengarah Regulatori Farmasi
Pengarah Amalan Perkembangan Farmasi
Pengarah Penguatkuasa Farmasi

Date: January 2010

Dear Healthcare Professional,

Communication on Sibutramine based on the results of the SCOUT Trial

Summary:
Following the availability of results from the Sibutramine Cardiovascular OUTcomes (SCOUT) study, company's name would like to reinforce the appropriate use of Product Brand® (sibutramine).

Product Brand® is indicated in Malaysia as adjunctive therapy within a weight management programme for:

- Patients with nutritional obesity and a body mass index (BMI) of 30kg/m^2 or higher
- Patients with nutritional excess weight and BMI of 27kg/m^2 or higher. If other obesity-related risk factors such as type 2 diabetes or dyslipidaemia are present

Further information on the SCOUT study:
SCOUT was a randomised, double-blind, placebo-controlled study, with a single-blind, sibutramine lead-in period. The study was conducted as a post approval commitment of the innovator product company to the European regulatory authorities.

The study enrolled 10,744 and randomised 9,805 overweight or obese patients, aged 55 years or older, at high risk of cardiovascular events (the majority who were contraindicated to receive treatment with sibutramine) and was designed to evaluate the cardiovascular safety of long-term treatment with sibutramine. In the study, these cardiovascular high risk patients were treated with sibutramine for up to 6 years and were not discontinued from treatment for inadequate weight loss response, which is inconsistent with the Dosage and Administration instructions for sibutramine.

Patients treated with sibutramine experienced a 16% increased risk of a primary outcome event of non-fatal myocardial infarction, non-fatal stroke, resuscitated cardiac arrest, or cardiovascular death (561/4906, 11.4%) compared with placebo treated patients (490/4808, 10.0%) (hazard ratio 1.161 [95% CI 1.029, 1.311]; p = 0.016). There was however, no difference in the incidence of CV death or all-cause mortality between the treatment groups.

Further information on recommendations for healthcare professionals:
Based on the results of the SCOUT study, it is recommended that all patients should be evaluated to determine whether they have a history of cardiovascular disease prior to the initiation of treatment with sibutramine.

Any adverse drug reactions should be reported on-line to the National Adverse Drug Monitoring Centre, National Pharmaceutical Control Bureau at their website www.bpfk.gov.my

Please find enclosed the revised Data Sheet for Product Brand® (sibutramine), which include the description of SCOUT study and further strengthen the safety information.

Communication information:
Should you have any questions or require further information regarding the use of sibutramine, please contact company name and contact number

Yours sincerely,

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Enclosed: Product Brand® Datasheet – January 2010