

# Pharmacy Bulletin

## PRODUCT COMPLAINTS IN PPUKM

PPUKM has actively taken part in reporting product (drug complaints) to the Surveillance Section & Complaints Unit, National Pharmaceutical Control Bureau (NPCB). All complaints and feedbacks from patients and health-care providers are taken into account and will be forwarded to NPCB, along with the samples of the drug(s) for investigations. NPCB has recently updated complaint forms by separating those complaints by patients, and those by the healthcare professionals.

Complaints are classified into 4 categories ie **quality, efficacy, label and packaging**. Complainant(s) are required to provide information such as description of the issue and extent of complaint (eg quantity/ percentage of products involved). For complaints pertaining to efficacy, complainant(s) have to provide information on the storage condition of the products, number of patients having the problem, and whether or not this occur after brand switching.

Below are the complaints forwarded to NPCB in 2011:

Date of Submission	Drugs	Complaints	Remarks from Company/NPCB
12 <sup>th</sup> Jan 2011	Uniaspirin (Acetylsalicylic acid) 300mg [IDAMAN PHARMA]	Hard to break into half due to no scored line.	Short term solution: disperse in water and drink half of the mixture.
17 <sup>th</sup> Jan 2011	Ipramol Steri-Neb (ipratropium bromide 0.5mg, salbutamol 2.5mg) [IVAN PHARMACEUTICALS UK]	Patient developed rashes on neck and face.	No reply.
25 <sup>th</sup> Jan 2011	Zenpro (Omeprazole) 20mg [Xepa-Soul Pattinson]	Patient having reflux after brand switched.	No reply.
25 <sup>th</sup> Jan 2011, 29 <sup>th</sup> March 2011	Myonit Insta (Nitroglycerin sublingual) 0.5mg [Troikaa Pharmaceuticals Ltd.]	Patient claimed that the nitroglycerin tablet dissolve very fast and not effective in treating his chest discomfort.	Myonit Insta follows the US Pharmacopeia, which will rapidly dissolve the tablet (unlike the slowly dissolving tablet as compiled in British Pharmacopeia requirements). The active compound and potency does not changed. Company will change the packaging to 30 tablets/bottle to maintain freshness.
28 <sup>th</sup> Jan 2011	Calcium carbonate 500mg and Tranpam 0.5mg (Lorazepam) [MALAYSIAN PHARMACEUTICAL INDUSTRIES]	Look alike drugs with same batch number and expiry date, but labelled as Calcium carbonate and Tranpam.	Voluntary recall Stage III Level B of the product by the company.
18 <sup>th</sup> Feb 2011	Magnesium trisilicate mixture [Zontron Pharmaceuticals]	The solution appears light brown and cloudy instead of white and cloudy.	Company came to exchange.
9 <sup>th</sup> March 2011	Transdermal fentanyl patch (generic) [HEXAL AG, GERMANY]	2 patients having efficacy problem. The 25mcg/hr patch did not achieve the equivalent of 135mg of oral morphine.	The absorption is different between companies since it is based on the body temperature, skin type, fat composition, and the patch location. Different brands are not interchangeable.
21 <sup>st</sup> March 2011	Uniaspirin (acetylsalicylic acid) [MEDIBIOS LABORATORIES]	Patient experienced ulcers in the mouth cavity and tongue after taking different brands of medication.	Patient chew the tablet instead of dispersing it in water then drinks it. Thus, it increases the risks of mouth ulcer due to the acidic nature of aspirin. Have to advice patient on the correct usage. (BPFK replied on 28 <sup>th</sup> April 2011).

Date of Submission	Drugs	Complaints	Remarks from Company/BPFK
22 <sup>nd</sup> March 2011 (2cases)	Marcaine Spinal 0.5% Heavy (MOT)	Absence/inadequate block during spinal anesthesia.	No reply.
23 <sup>rd</sup> March 2011	Metcheck 850 (Metformin 850mg) [INDOCO REMEDIES LTD, INDIA]	Patient experienced severe stomach pain after taking the different brands.	The product follows specifications and regulations. The complaint can be categorized as adverse reactions. Patient has to be counselled to take metformin after food to reduce the side effects of the gastrointestinal system. If the problem still persists and affecting the compliance, patient should be supplied with the original or previous brand.
23 <sup>rd</sup> March 2011	Dicodine 30mg (Dihydrocodeine) [ROCHE PHARMA]	The quantity of tablet in a box : Short of 4 instead of 500 as labelled.	The company changed packaging to blister 5x10's.
20 <sup>th</sup> April 2011	Royce Enema [ROYCE PHARMA]	The nozzle of the enema is a bit rough and the plastic bulb is too hard to press. So the contents of the enema cannot be emptied.	No reply.
23 <sup>rd</sup> June 2011	Uniaspirin 300mg (Acetylsalicylic acid) [MEDIBIOS LABORATORIES]	Patient complained of nausea after taken different brands of aspirin.	No relevant reply.
1 <sup>st</sup> July 2011	Anikef Sterile 1.5g (Cefuroxime sodium 1.5g) and Anikef Sterile 750mg (Cefuroxime sodium 750mg)	Look alike medicines – fonts and colours of the packaging and vials are similar. May cause potential medication error.	Size of vials and boxes are different. Have to read the label carefully during dispensing and administration.No actions taken.
15 <sup>th</sup> July 2011	Uniaspirin (Acetylsalicylic acid) [MEDIBIOS LABORATORIES]	Patient complaint of mouth ulcers after taking the medicine for a month.	Patient chew the tablet instead of dispersing it in water then drinks it. Thus, it increases the risks of mouth ulcer due to the acidic nature of aspirin. Have to advice patient for the correct usage. (BPFK replied on 28 <sup>th</sup> April 2011).
18 <sup>th</sup> August 2011	Megapime (Cefepime) 1g	Froth/bubbles developed after water for injection added even before shaking. The froth/bubbles subside after shaking (1-2 mins).	BPFK previously received one complaint about frothiness in the reconstituted solution of Megapime for Batch No <b>9140329</b> . There are no deviations found in the manufacturing process of this batch. However, the company did a simulation test on the product (Batch No 9140329) and found that the reconstituted solution of Megapime will become frothy when the powder of Megapime is not wetted before reconstitution. This is due to the characteristic of L-Arginine in the formulation of Cefepime HCl, that is present as a solid buffering agent. Therefore, the company is currently revising their PI to include " <i>gently add the required diluent quantity (5ml for 500mg and 10ml for 1g) slowly in the vial and allow the vial to stand for 10 to 15 minutes and then gently swirl the vial</i> " in the section of reconstitution.
23 <sup>rd</sup> November 2011, 28 December 2011	Trostigmin (Pyridostigmine) 60mg	3 patients developed worsening of myasthenia gravis with muscle weakness and 2 patients required ventilation in ICU after taking the generic Mestinon.	BPFK requested for 100 tablets for urgent analysis. Still awaiting reply.

In conclusion, all product complaints from patients and healthcare professionals will be received by Drug Information who will then ensure adequate information before passing up to NPCB. You may obtain the form from : Drug Information Centre, Pharmacy Department. Kindly call ext 5401/5415 for further information. Alternatively, you can go to NPCB's website at <http://portal.bpfk.gov.my>. Under the Application Forms icon, kindly click BPFK418.4 [Borang Laporan Aduan Produk yang Berdaftar dengan PBKD] and BPFK 419 [Borang Laporan Aduan Ubat-ubatan /Reporting Form For Medicines Complaints by Consumers].