Bula Vinaka from the Editor

Bula vinaka and welcome to the last issue of Pharmanews for 2014. We hope you enjoy this issue packed full of medicine safety and pharmaceutical updates.

If you have any questions, comments or suggestions for future articles or would like to contribute an article or be included in our electronic distribution, please contact:

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Wishing you all a very safe and Happy Christmas and New Year. We are looking forward to bringing you more issues in 2015!

Vinaka Vakalevu!
Proton pump inhibitors (PPIs) are widely prescribed, effective and generally safe for the management of acid-related gastrointestinal disorders. In older people, PPIs are widely used to treat gastroesophageal reflux, dyspepsia and peptic ulcer. These drugs are effective for reducing symptoms and have a favourable safety profile overall, however, there is an increasing awareness of rare but serious adverse drug reactions, particularly with high dose and long-term use.

The absolute risk of adverse outcomes from long-term use is very low and for most patients, the benefits of PPIs outweigh the potential risks. However, PPIs are increasingly used long term and often without proper indication.

Risks that may be elevated for some older people when PPIs are used regularly and long term include fractures, enteric infection and community-acquired pneumonia. Therefore, evaluate the indication for PPI treatment and consider the risk of harm from long-term use in older people, those malnourished and those with significant comorbidity.

The goal of treatment is to control symptoms at the lowest dose and for the shortest possible duration. Some patients require long-term treatment, so consider step-down or symptom-driven dosing and regularly review the need for treatment.

Currently Omeprazole is the only PPI available on the Fiji Essential Medicines List.

The Australian Therapeutic Goods Administration (TGA) has issued a safety warning regarding the risk of Serotonin Syndrome with the use of 5-HT3 anti-emetics.

Serotonin syndrome has been described following the use of 5-HT3 receptor antagonists when used concomitantly with other serotonergic drugs — selective serotonin reuptake inhibitors (SSRIs) and serotonin noradrenaline reuptake inhibitors (SNRIs.)

If concomitant treatment with a 5-HT3 receptor antagonist and other serotonergic drugs is clinically warranted, it is advised that the patient and caregivers are advised of this issue and that appropriate observation is undertaken.

Currently Ondansetron is the only 5-HT3 receptor antagonist on the Fiji Essential Medicines List.

The WHO has released their first global report on Antimicrobial Resistance Surveillance for 2014. Antimicrobial resistance (AMR) threatens the effective prevention and treatment of an ever-increasing range of infections. This report examines, for the first time, the current status of surveillance and information on AMR, in particular antibacterial resistance, (ABR) at country level worldwide.

Meropenem is currently only available at the three Divisional Hospitals—Colonial War Memorial Hospital, Lutoka and Labasa.

Below is an excerpt from the ‘Indications for Meropenem Use at Divisional Hospitals Policy,’ which outlines the clinical indications of Meropenem and its empirical use.

**INDICATIONS FOR MEROPENEM USE AT DIVISIONAL HOSPITALS POLICY**

Revised version of, Endorsed Amendment on the 4th National Medicines & Therapeutics Committee meeting, 20th June 2008

... Meropenem may be provided for the following clinical indications:

1. In any individual patient where there is clear clinical evidence of infection PLUS
   
   A blood culture plus other relevant body fluids confirmed positive for an organism shown to be resistant to all other available (or appropriate) antibiotics.

2. During a confirmed outbreak of an organism resistant to all other available (or appropriate) antibiotics in the Intensive Care Units only (NICU, PICU or adult ICU), as empirical therapy for patients with clinical evidence of infection, for a maximum of 72 hours pending results of microbiology specimens.

If infection with a multi-resistant organism is not microbiologically confirmed at this time, Meropenem must be ceased and appropriate alternative antimicrobial therapy instituted.

Once the outbreak is declared controlled by the Infection Control Unit, empirical antibiotic therapy must revert to a non-meropenem containing regimen.

In both situations the duration of treatment should be the decision of the treating Consultant.

1 Procedural Requirements revised by Essential Medicines Authority 10th January 2009.

**Meropenem Utilisation at FPBS to Divisional Hospitals**

The EMA will be conducting a Drug Usage Evaluation (DUE) investigating the increased usage of Meropenem, especially over the past four years. The graph to the right shows, the distribution of Meropenem vials to Government health facilities has increased dramatically since 2007—from less than 100 vials in the year 2007 to nearly 2000 last year. The team will commence the DUE later this year.

Meropenem is a broad-spectrum antibacterial agent with wide activity against:
- Enteric Gram-negative rods
- Pseudomonas aeruginosa
- Excellent activity against anaerobes and many Gram-positive organisms.

Meropenem is INACTIVE against:
- Enterococcus faecium
- Multi-resistant Staphylococcus aureus
- Mycoplasma
- Chlamydia
- Stenotrophomonas
- Some Pseudomonas species

Meropenem is an important broad-spectrum drug and its use SHOULD be preserved.

Widespread use of Carbapenems has been linked with increasing prevalence of infections due to methicillin-resistant Staphylococcus aureus (MRSA), Vancomycin-resistant enterococci (VRE,) multi-resistant Gram-negative organisms and Clostridium difficile.

(Aust. ETG, March 2014)
The Guidelines International Network (G-I-N) Conference was held in Melbourne in August. G-I-N is a global network representing 40 countries. Participants shared experiences in supporting evidence-based health care and improved health outcomes.

Jeremaia Mataika won a scholarship to attend this conference to present his poster (abstract) and was able to gain more knowledge to strengthen support and treat guideline development, adaptation and implementation for Fiji. He also made valuable contacts with experts and organisations keen to provide ongoing support to FPBS.

The objective of the Medicinal Products Decree is to “protect the health and safety of the public by regulating medicinal products, devices, poisons and similar products in accordance with the National Medicinal Products Policy (NMPP)”.

IRA has been actively implementing the Medicinal Products Decree, with the official launch of the new National Medicinal Products Policy in April. Based on preliminary discussions earlier this year, regulations required to support the Decree were reviewed and drafted in order to support activities to effectively implement the Decree.

IRA has the important role of being the Secretariat of the Medicinal Products Board and the Pharmacy Profession Board. Therefore, IRA is responsible for organising and conducting consultations on the new Regulations for the Medicinal Products Decree.

Medicines Registration Regulations and the Medicinal Products Advertising Regulations consultations were held in Lautoka on 3 September for the Western Division and in Suva on 10 September for Suva based stakeholders. There was much active discussion on the draft regulations especially the Medicines Registration Regulation, with many issues raised and clarified.

To ensure safe, high quality and efficacious medicines are being imported and sold in Fiji, IRA under the direction of the Medicinal Products Board are creating a National Medicines Registration System. This process is in its preliminary stages and would require the support of all stakeholders to ensure that patients have access to assured quality medicines.

Currently the submission procedure for proposing medicine changes to the Fiji Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) is unclear and complicated, consequently resulting in the stagnation of updating guidelines and subsequent outdated medicine therapies being continued in the Government health facilities.

To allow new STG formation and subsequent evolution of the EML, the Ministry of Health established a Clinical Services Network (CSN) for each respective medical discipline. The CSNs were designed to include consultants and practicing clinicians to ensure collaboration and result in up-to-date therapeutic medicine recommendations being submitted to the National Medicines and Therapeutic Committee (NMTC), to ensure an efficient and effective patient care service to the public of Fiji.

The CSN arrangement hasn’t been effective entirely due to the lack of process in the system to sustain a workable procedure. In addition, the CSN requires results of clinical evidence based research to provide support to their submissions to convince the NMTC for any such changes.

To simplify the medicine amendments process, a new working standard procedure has been drafted, which includes a new application form for medicine amendments to existing treatment guidelines and essential medicines list. In addition, a new independent advisory review taskforce is being formed to critically evaluate all incoming applications.