Medicines Update

Dextropropoxyphene and Paracetamol (co-proxamol) advisory

Following a review of co-proxamol by the Committee on the Safety of Medicines UK (CSM), the efficacy of co-proxamol was poorly established and the risk of toxicity in overdose, both accidental and deliberate was found to be unacceptable. As a result, this compound preparation is being phased out by the end of this year in the UK. In Malta, the Medicines Authority has issued a circular (No P02/2005) which emphasised that co-proxamol is a Prescription Only Medicine (POM).

This circular, which can be accessed at http://www.health.gov.mt/mru/pub/co-proxamol.pdf also specifies that co-proxamol should not be used: for chronic pain; in patients aged below 18years of age and in alcohol-dependent, suicidal or addiction-prone patients. Refer to circular for additional cautions and specific warnings which should be taken into consideration when prescribing and dispensing co-proxamol.

Thioridazine withdrawal

Thioridazine (Melleril®) has been withdrawn worldwide after a risk-benefit analysis concluded that:

- QT prolongation and sudden death are more common in treatment with thioridazine versus other antipsychotics
- There is no clear advantage concerning other adverse drug reactions that would outweigh the risk of QT-prolongation
- The risk-benefit balance of thioridazine is negative.

This withdrawal also affects all thioridazine-containing medicinal products. Thus, no thioridazine-containing medicines will be available on the market.

Medicines Authority Circular P01/2005 http://www.health.gov.mt/mru/pub/ma_thioridazine.pdf

Interferon beta 1-b Advisory

Healthcare Professionals are reminded of the prescribing information concerning interferon beta-1b and hepatic toxicity. Hepatotoxicity has been a reported adverse reaction to ALL beta-interferons. There have been rare reports of serious hepatic injury including autoimmune hepatitis and severe liver damage leading to hepatic failure and transplant. AST (SGOT), ALT (SGPT) and -G T levels should be obtained prior to initiation of interferon beta-1b therapy and regularly during therapy. The occurrence of elevations in serum transaminases should lead to close monitoring and investigation with withdrawal of the drug if the levels become significantly increased or if there are associated symptoms suggesting the development of hepatitis.

Avonex® SPC
http://emc.medicines.org.uk/emc/assets/c/html/displayDocPrinterFriendly.asp?documentid=15349

Betaferon® SPC
http://emc.medicines.org.uk/emc/assets/c/html displayDocPrinterFriendly.asp?documentid=1809

Betaseron USA - Dear Healthcare professional letter
http://www.fda.gov/medwatch/SAFETY/2005/Betaseron_DHCP.pdf

Selective Serotonin Reuptake Inhibitor Antidepressants advisory

Last December, the Committee on Safety of Medicines UK (CSM) issued two advisories, one regarding the use of SSRIs in adults and another regarding use in children and adolescents. SSRIs are effective medicines in the treatment of depression and anxiety conditions, and the CSM has concluded that the balance of risks and benefits of all SSRIs in adults remains positive in their licensed indications. Clear advice is to be given in all SSRI product information in 3 areas: withdrawal reactions, dose changes and suicidal behaviour. This information can be accessed through: http://medicines.mhra.gov.uk/ourwork/monitorsafequalmed/safetymessages/SSRI_Letter_061204.pdf http://medicines.mhra.gov.uk/ourwork/monitorsafequalmed/safetymessages/SSRIfinal.pdf

On the basis of this review of the available clinical trial data, CSM has advised that the balance of risks and benefits for the treatment of major depressive disorder (MDD) in under 18s is judged to be unfavourable for sertraline, citalopram and escitalopram and unassessable for fluvoxamine. In fact, sertraline, citalopram and escitalopram, as well as paroxetine and venlafaxine (as per previous advisories) are now contraindicated in paediatric MDD in the under 18s. Only fluoxetine has been shown in clinical trials to have a favourable balance of risks and benefits for the treatment of MDD in under 18s. The full document, which contains more information as regards stopping treatment with SSRIs and general advice, can be accessed at: http://medicines.mhra.gov.uk/ourwork/monitorsafequalmed/safetymessages/cemssri%5F101203.pdf Medicines Authority circular No P11/2005 http://medicinesauthority.gov.mt/news&events.htm

Quinine and Thrombocytopenia

As a consequence of the risk of thrombocytopenia, quinine is no longer approved in Australia for the treatment of nocturnal cramps. This decision followed many reports which the ADRAC (Adverse Drug Reactions Advisory Committee- Australia) received about quinine causing thrombocytopenia. American FDA has long withdrawn this indication for quinine because of the lack of efficacy.

The Malta Medicines Authority has reviewed the licensing status of quinine and its use in nocturnal leg cramps and has issued a statement (link below) reminding all Healthcare professionals about the risks and about the importance of reporting any side effects.

Medicines Authority
http://www.health.gov.mt/mru/pub/ma_statement_quinine.pdf

Australian Prescriber Bulletin
http://www.tga.gov.au/adr/aadrb/aadr0410.htm#5

Problems with Alendronic acid 70mg tablets (Fosamax)

Even though this tablet does not contain a coating for sustaining the release of alendronate, this preparation is not manufactured to be split. Splitting the tablet may result in both dust and multiple irregularly shaped pieces of the partial tablets, that when taken by patients, could increase the potential of local irritation (oropharyngeal ulceration and oesophageal irritation).

As referred to the Summary of Product Characteristics (SPC):

"Patients should not chew the tablet or allow the tablet to dissolve in their mouths because of a potential for oropharyngeal ulceration."

Link to SPC: http://emc.medicines.org.uk/emc/assets/c/html/displayDocPrinterFriendly.asp?documentid=4115

Non-cardiac QTc-prolonging drugs and the risk of sudden cardiac death

The European Heart Journal Advance Access online published the results from a population-based case-control study suggesting that the use of non-cardiac QTc-prolonging drugs is associated with an increased risk of sudden cardiac death, the risk being highest in women and in recent starters. The exposure of interest was the use of non-cardiac QTc-prolonging drugs, comprising chloroquine, chlorpromazine, cisapride, clarithromycin, domperidone, droperidol, erythromycin, halofrantine, haloperidol, levomethadyl, mesoridazine, pentamidine, pimozide, sparfloxacin and thioridazine. Many other drugs may cause this side effect.
http://www.druginfozone.org/Record%20Viewing/viewRecord.aspx?id=549111

The Medicines and Poisons Information Service, In Patients Dispensary, St Luke's Hospital, operates on a national basis to offer information and advice to health care professionals in primary and secondary care. It also offers the same service to patients. The Medicines Information Pharmacists have received specialised training to enable the provision of a professional dynamic service, which constantly meets the increasing demands of healthcare professionals and patients.

The Medicines and Poisons Information team includes:
Mark L Zammit BPharm (Hons), MSc (AgrVetPharm), PgDip Med Tox (Cardiff)
Corinne Bowman BPharm (Hons.), MSc (AgrVetPharm.)
Eileen Vella BPharm(Hons)

Tel: 2595 2057
Email: medinfo@gov.mt

The **Malta College of Pharmacy Practice** has formed an alliance with the **Medicines and Poisons Information Service** at St Luke's Hospital and the **Medicines Authority** to facilitate the provision of medicines information to both pharmacists and medical doctors. We are thus in the process of building a database of email address of those health care professionals who would like to receive updates. We would therefore like to invite all pharmacists and medical doctors who wish to receive updates to send an email with their name and email address to: info@mcppnet.org or to log on to the website www.mcppnet.org and register to receive these updates. The names and email address will only be used by the Malta College of Pharmacy Practice for the purpose stated above and will not be accessible to third parties.

Any registered individuals who wish to unregister from this database, are asked to email info@mcppnet.org with their request.