Re:action 41

Re:Action Bulletin – selected drug safety news from the MHRA, EMA, and FDA, along with other interesting literature reports concerning drug safety issues.

MHRA News
The MHRA have published January 2013 Drug Safety Update, which includes:

1. **Fingolimod (Gilenya▼): bradycardia and heart block – repeat enhanced cardiovascular monitoring when restarting fingolimod after treatment interruption**

2. **Lenalidomide (Revlimid): risk of serious hepatic adverse drug reactions – routine monitoring of liver function now recommended**

3. **Tredaptive (combined niacin-laropiprant): no longer for prescribing as preliminary HPS2-THRIVE trial failed to show benefit outweighs risks**

4. **Roflumilast (Daxas▼): risk of suicidal behaviour – avoid use in patients with previous or existing psychiatric symptoms and discontinue treatment if new or worsening psychiatric symptoms occur**

5. **Learning about Yellow Card reporting and pharmacovigilance**
6. **New MHRA Twitter channel on medicines' safety**

Additionally the list of drug safety letters sent to healthcare professionals in January has been released, including **fingolimod** (Gilenya), **Sodium Stibogluconate** (Pentostam), **dabigatran** (Pradaxa), **Tiseel and Artiss sprayable fibrin sealants**, **Bivalirudin** (Angiox), **combined laropiprant-nicotinic acid** (Tredaptive), **anagrelide** (Xagrid), and **Insulin degludec** (Tresiba).

MHRA press releases
The MHRA have issued a press release about the sale of unlicensed medicines from Eastern Europe being sold in the UK.
74 cases involving Polish and other medicines from Eastern European countries being sold in "corner shops" were investigated by the MHRA last year – these included medicines which fall into the category of pharmacy-only and prescription only medicines.

The MHRA have also started a new campaign to encourage the reporting of adverse drug reactions, with a particular focus on pharmacists. There continues to be a fall in General Practitioner reporting. If you would like our centre to come and give a talk at your surgery, please get in touch.

EMA News
The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has started a formal safety review of **Diane 35**(cyproterone acetate 2 mg, ethinylestradiol 35µg), associated names and its generics. This was requested by the French medicines regulatory agency (ANSM), who announced they would be suspending the marketing authorisations for **Diane 35** and its generics for acne treatment in France over the next three months. This was caused by concerns about reports of venous and arterial thromboembolism (VTE and ATE, the formation of blood clots in the veins or arteries) collated in the French national pharmacovigilance over a period of more than 20

years. Stakeholders, including patients and healthcare professionals may respond to the EMA consultation here.
The European Medicines Agency has also issued a press release concerning it's decision to recommend that **Tredaptive, Pelzont and Trevaclyn (nicotinic acid / laropiprant)** should no longer be prescribed. Advice is provided at the previous link, as well as at the MHRA's previously mentioned Drug Safety Update.

Of note…

NSAIDS – all are not equal
The cardiovascular safety of non-steroidal anti-inflammatory drugs has been a subject of concern for a number of years. McGettigan and Henry have examined the use NSAIDs across 15 countries (low, middle and high income) in a recent paper in PLOS Medicine, and found that NSAIDs with the highest cardiovascular risks were commonly used within all. They argue that the evidence base for cardiovascular safety has not been translated into either evidence-based guidance or usage patterns of these drugs that reflect the cardiovascular safety profile of the drugs. For example, diclofenac and etoricoxib, two NSAIDs with the highest cardiovascular risk, are widely used. They draw attention to the recent EMA review of NSAID cardiovascular safety.

The MHRA website provides addition information about NSAIDs and cardiovascular safety and notes *"Whilst, there is some evidence of an increased risk with naproxen and ibuprofen, this is still considered to be lower than the risk with diclofenac or selective Cox-2 inhibitors."*
We remind readers that ADRs to NSAIDs can be reported via the Yellow Card Scheme.