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In this week’s Pharmacy Daily:

**GSK execs travel ban**

SENIOR GlaxoSmithKline executives in China have been prohibited from leaving the country as authorities continue investigating bribery allegations.

Some GSK staff have been detained over the claims which have seen the company accused of transferring hundreds of millions of dollars to a network of travel agencies and consultancies.

The payments were billed as “conference services” but were then allegedly directed to bribes for officials and doctors, aiming to boost sales and prices of GSK drugs.

The company said it’s fully cooperating with the probe, and is “deeply concerned and disappointed by these serious allegations of fraudulent behaviour and ethical misconduct by certain individuals at the company and third party agencies”.

**RB’s Nurofen headache**

THE TGA’s Complaints Resolution Panel has asked the Secretary of the Department of Health and Ageing to make official orders that Reckitt Benckiser comply with a determination relating to advertising of Nurofen, after the company gave “an indication to the panel that it would not comply with all of the Panel’s requests.”

The panel has requested withdrawal of the advertisements, representations and the publication of a retraction (PD 11 Jul).

However a letter from CRP Executive Officer, Judith Brimer, confirms that at a meeting earlier this month the Panel noted that RB’s response to the determination “failed to indicate an intention to comply with all of the requests”.

**Generics gathering**

DRUG regulators from the Heads of Agencies Consortium from Australia, Canada, Singapore and Switzerland met in Canberra in May this year to further develop the processes for generic drug regulation, with details of the meeting now on the TGA website.

Progress was made on the issue of adopting universal quality assessment templates aligned with those developed by the EU.

The main focus of discussion in Canberra was transitioning from “proof of concept” pilots to the integration of regulatory collaboration into routine business practices and submission application processes.

Another topic high on the agenda was the importance of pro-active engagement with industry and other stakeholders, including pharmacists, in order to facilitate the timely availability of safe, effective and quality generic drugs.

International staff exchanges were also identified as important means of enhancing communication, understanding and respect.

The ACT meeting was followed by the larger International Generic Drug Regulators Pilot (IGDRP), and the next meeting of the Consortium Generics Working group will be in Bern, Switzerland in October 2013.

**Diabetes vaccine**

IT may be possible to reverse type 1 diabetes by training a patient’s own immune system to stop attacking their body, an early trial suggests.

A study in 80 patients, published in the journal Science Translational Medicine, showed a vaccine could retrain their immune system not to destroy insulin, the hormone that controls blood sugar levels.

Experts described the results as a “significant step”.

Prof Lawrence Steinman from the Stanford University Medical Centre said, “We’ve very excited by these results, which suggest that the immunologist’s dream of shutting down just a single subset of dysfunctional immune cells without wrecking the whole immune system may be attainable.”

Australia is commemorating Diabetes Week 15-19 July.

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US compounding

THE US National Community Pharmacists’ Association has expressed concerns about proposals circulating in response to the recent series controversies where several compounding pharmacies have been shut down. Some lawmakers have suggested granting the US Food and Drug Administration unrestricted authority over a ‘do not compound’ list, which the NCPA says could impact patient access to compounded medication such as hormone treatments, thyroid preparations & promethazine gels. Another proposal would see pharmacies required to notify the FDA when compounding medications are in short supply.

NPSA warns on direct model

THE National Pharmaceutical Services Association (NPSA) has warned that reliable access to critical medicines will be threatened if others in the industry move to an exclusive direct distribution model. A report published earlier this week by consulting firm PricewaterhouseCoopers (PD Tue) revealed that 31% of suppliers are considering a “Pfizer Direct”-style model which bypasses full line wholesalers by going direct to pharmacy.

NPSA president Patrick Davies from Symbion said that further moves in this direction will erode the viability of the Community Service Obligation which funds wholesalers to deliver PBS medicines to pharmacies nationally. He urged legislative action to protect the PBS, the National Medicines Policy and the “principle of equality of access that underpins Australia’s healthcare system.”

“Pharmacies need more than one source of supply and they need to be able to access all PBS medicines from their full line CSO wholesaler - otherwise patient care is compromised,” Davies said.

The PwC report, which is the outcome of an industry survey, said that 69% of respondents don’t see the value in the direct model and don’t have distribution expertise. However “some are open to explore this model to see if they can receive more value from it in relation to existing or specific products,” the report adds. However Davies warned that specialist pharmaceutical wholesaling in Australia depends on economies of scale that will be lost if large pharma companies pull out of the supply chain.

“Our healthcare system is the envy of much of the world and we must act to defend it by ensuring the exclusive supply of PBS medicines is prevented, as part of negotiations around the Sixth Community Pharmacy Agreement,” he urged.

NPSA members currently include Sigma, Symbion, National Pharmacies and Central Healthcare Services, but not API.

Pradaxa set for Sep

BOEHRINGER Ingelheim says it’s now “extremely confident” that its novel anticoagulant Pradaxa (dabigatran) will be PBS listed on 01 Sep for patients with non-valvular atrial fibrillation and at least one additional risk factor for stroke. The company said it’s now completed all the paperwork and processes to enable the PBS listing, and thanked doctors who cared for around 25,000 AF patients during the past two years as part of the product familiarisation program.

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