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Incivo listed on PBS

THE Federal Government has included Incivo (telaprevir) on the Pharmaceutical Benefits Scheme for the treatment of chronic hepatitis C genotype-1 infection in combination with peginterferon alfa and ribavirin from 01 April 2013.

The listing means that up to 120,000 Australians with Genotype 1 hepatitis C will be soon eligible to receive subsidised access to the new antiviral medication.

The drug is a protease inhibitor, and belongs to a new class of medicine known as direct-acting antivirals that represent the first new treatment for hepatitis C in over a decade.

The therapy works to prevent the virus replicating in people infected with genotype-1 hepatitis C virus, considered the hardest strain to treat.

"Hepatitis C can be cured, but until now only 2% of people with the infection received treatment each year," said Professor Geoff McCaughan, Head of the Liver Immunobiology Program, Centenary Research Institute. "The listing creates an environment where the opportunity to effectively treat and cure a patient with chronic hepatitis C genotype-1 has never been better," he added.

PBS spending in decline

FOR the first time in 20 years government expenditure on the Pharmaceutical Benefits Scheme (PBS) is in decline, according to previously unpublished PBS data.

Revealed at the Pharmacy Guild's Australian Pharmacy Professional conference by the Guild's National

Director of Health Economics, Stephen Armstrong, the data was provided by the Department of Health and was analysed by the Guild.

According to the Guild, as the data shows prescriptions are recorded against the month in which they are dispensed, it reflects true PBS growth rather than patterns of PBS claims processing, which are of no relevance to monitoring the scheme.

"For the 12 months to 30 November 2012, the latest available data based on date of supply, PBS and Repatriation PBS expenditure decreased by 0.5%," the Guild said in a statement.

"This is the first time in 20 years that PBS expenditure has declined year on year.

"The data published on the Medicare Australia website currently shows growth of 13.5% year on year.

"The entire industry knows that this completely misrepresents the true condition of the PBS.

"The data is meaningless and of no use to commentators, the industry or policy makers, and should not be published," the Guild added.

Shopping for insurance

INCREASES in health insurance premiums are leading more Australians to shop online for a better product and greater transparency, according to social bid-based platform Moneytribe.

Set to come into effect 01 April 2013, the health insurance premium rise means the average private health insurance premium will increase by 5.6%.

This is higher than the 2012 increase of 5.06%.

"Most Aussies are familiar with the benefits of shopping around - the yearly increase in private health insurance premiums encourages consumers to take a closer look at what they are paying and getting and how that compares to people like them," said Moneytribe co-founder Dr David Urpani.

CF drug approved in US

NOVARTIS has announced today that the US Food and Drug Administration has approved TOBI Podhaler (tobramycin inhalation powder) 28mg per capsule for the management of cystic fibrosis (CF) patients with pseudomonas aeruginosa (Pa) bacteria in the lungs.

Pa is the leading cause of loss of lung function in CF patients.

TOBI Podhaler is a new, non-nebulized formulation and delivery system of tobramycin, the same active ingredient as in TOBI (tobramycin inhalation solution, USP) 300mg/5 mL, which has been on the market for approximately 15 years.

TOBI Podhaler is the first and only FDA-approved dry powder inhaled antibacterial for Pa in the US.

The drug delivers tobramycin into the patient's lungs via a pocket-sized dry powder inhaler and offers better portability than TOBI, which is administered to the patient using a nebuliser.

It is not known if TOBI Podhaler is safe and effective in patients under six years of age, in those with lung function outside of a certain range, or in those whose lungs contain bacteria called Burkholderia cepacia.

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Reducing brain loss

IN a new analysis of over 3,600 patients from three large Phase III studies (TRANSFORMS, FREEDOMS, and FREEDOMS II) Gilenya (fingolimod) showed a significant reduction in the rate of brain volume loss vs. a comparator – consistent with previously reported results.

Gilenya is the first oral disease modifying therapy (DMT) approved to treat relapsing forms of MS and the first in a class of compounds called sphingosine 1-phosphate receptor (S1PR) modulators.

Gilenya is thought to act on inflammatory processes implicated in the MS disease process although the exact mechanism in MS is unknown.

According to the findings, the TRANSFORMS study found that over one year, Gilenya reduced the rate of brain volume loss by 32% ($p < 0.001$) compared to Avonex (interferon beta-1a IM), a commonly prescribed injectable treatment.

Over two years, Gilenya reduced the rate of brain volume loss compared to placebo by 35% ($p < 0.001$) in the FREEDOMS study, and by 33% ($p < 0.001$) in the FREEDOMS II study, respectively.

The data also showed that brain volume, at baseline, consistently correlated with the level of disease severity and disability.

Lower brain volume was linked with more severe disease and disability, while higher brain volume correlated with less severe levels.

In addition, traditional markers of disease activity (such as MRI lesion counts) at baseline were predictive of the rate of brain volume loss over two years.

Telehealth not cost effective?

TELEHEALTH may not be a cost effective solution to improving treatment outcomes for patients with long term conditions, according to a study published in the *British Medical Journal*.

The British study recruited 3,230 people with a long term condition (heart failure, chronic obstructive pulmonary disease, or diabetes), into the Whole Systems Demonstrator telehealth trial which ran in three areas in England between 2008 and 2009.

The patients were then divided into two groups, with 845 randomised to telehealth and 728 to usual care.

The telecare patients received telehealth equipment and

monitoring services for 12 months, as well as standard health and social care services, whilst the controls received usual health and social care.

According to the results, telehealth patients had similar gains to patients receiving usual care only, whilst the total costs associated with the telehealth intervention were higher.

“Telehealth does not seem to be a cost effective addition to standard support and treatment,” the researchers said.

Diabetic concerns

ONE in four diabetic patients believe that their families resent them for their condition, according to a new HealthEngage study.

The US study was conducted by HealthEngage in December 2012, and included 3,765 adults.

According to the study four out of every ten people with diabetes say their families don't fully support their efforts to manage their diabetes, one in four resent them for having diabetes, and three in 10 think their families blame them for getting diabetes.

In addition 57% of respondents say that their families don't make sacrifices in their lives to make it easier for them to manage their diabetes; whilst 50% of respondents believe that their families are afraid of their diagnosis.

Hip replacement issues

IN addition to improving life quality and diminishing pain, total hip replacement (THR) is associated with reduced mortality, heart failure, depression and diabetes rates in patients with osteoarthritis, according to a new study presented at the 2013 Annual Meeting of the American Academy of Orthopaedic Surgeons.

The study looked at more than 43,000 patients with osteoarthritis of the hip from 1998 to 2009, dividing them into two groups, those receiving THR and those not receiving THR.

The researchers then followed all of the patients for at least one year, and nearly 24,000 for seven years, looking at annual US Medicare payments, mortality, and new diagnoses of congestive heart failure, ischemic heart disease, arteriosclerosis (hardening and narrowing of the arteries), diabetes and depression.

According to the results, the THR patients had a consistently lower mortality risk – less than 52% of that in the non-THR group; whilst heart failure was similar between groups in the first year, but there was a consistent reduced risk (risk was between .85 and .92 of the risk for the non-THR group) at 3-to-7 years following surgery.

In addition, THR patients had a reduced risk of diabetes at one and three years and they also had a reduced rate of depression starting at three years post THR surgery.



DISPENSARY CORNER

HIGH-rise eco systems.

French architectural firm Vincent Callebaut Architects has released plans for a series of ‘farmscrapers’.

The futuristic-styled skyscrapers combine farming ecosystems with apartment living and office units.

Measuring 396-metres in height, and featuring 111 floors, the farmscrapers include suspended gardens on each of the structures' exteriors, as well as wind turbines and solar panels to green the whole process.

“It is a prototype to build a green, dense, smart city connected by technology and eco-designed from biotechnologies,” a statement from the firm said.

According to reports, the six farmscrapers are destined for Shenzhen, and are aimed at combating environmental issues with overcrowding.



Souvenaid in Australia

SOUVENAID, a medical food said to improve the memory of people during the early stages of Alzheimer's disease, will be available from community pharmacies around Australia from 01 May 2013.

The product contains a patented combination of nutrients, and is specifically designed to support the nutritional needs of people with early Alzheimer's disease.

This combination of nutrients found in Souvenaid supports synapse formation and memory function and is at levels difficult for people with early Alzheimer's disease to achieve through their normal dietary intake alone.

For more info see www.souvenaid.com.au.

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Weekly Comment

Welcome to *PD's* weekly comment feature. This week's contributor is **Paul Rowe**, Chief Executive of Razor Group of Companies.



Build a Better Pharmacy Team

In my 28 years of business finance experience one thing I have learned is that a business is a team effort and pharmacy is no exception.

This is one of the important points I include when I develop and lecture pharmacy courses for Universities and professional bodies around Australia.

I remind myself to network and attend conferences such as the recent APP conference – even when I feel I am too busy!

Although I consider myself an expert in my field, there is always more to be learned.

The "business of business" is multi-faceted.

The importance of networking extends into everyday good practice.

Running a pharmacy involves multi-tasking on a massive scale and sometimes there are tasks for which others may be better suited.

Even a small pharmacy requires some bookkeeping skills, I.T knowledge, HR regulations and more!

Learning how to delegate tasks and build an effective team maybe the single most important aspect of success.

This team may include third parties such as lawyers, business mentors and financial consultants, but don't forget that your staff are also your team and need a clear set of goals and expectations in order to perform at their best.

That requires leadership skills – but that's another article!

In the meantime, take a moment to look at any gaps in your pharmacy business knowledge and find someone to fill them!

ADHD drug management

IMPROVEMENTS in quality of life for children diagnosed with ADHD should drive clinical decision-making related to the condition, according to a panel of experts convened for the recent Clinical Insights panel discussion in Sydney.

"In some ways there has been an over-emphasis on 'correcting' symptoms or 'fixing' the condition when what is really required is a collaborative approach from all the key people in a young person's life towards helping them adapt and progress. It requires acceptance of

the condition, compassion and genuine care for the affected children to focus on those important future outcomes," said Queensland paediatrician Associate Professor Michael McDowell.

"The debate on whether medication is 'good' or 'bad' is particularly unhelpful.

"The more important question is how best to use medications, when they are necessary, to assist children towards achieving personal best development and well-being," he added.

Meanwhile, speaking on the subject of medication, Dr Caroline Stevenson, Clinical Psychologist from Macquarie University, said that education around the role of stimulants was important in confirming better outcomes in the future.

"A lot of my discussions with families are around the benefits of medication and discussing with families the potential benefits of trying medication as part of the overall management program, which for example, may include coaching or counseling," Stevenson said.

Botulism approval

THE US Food and Drug Administration has approved Botulinum Antitoxin Heptavalent (A, B, C, D, E, F, G)-(Equine) to treat patients showing signs of botulism following documented or suspected exposure to botulinum neurotoxin.

The product is derived from horse plasma and contains a mixture of antibody fragments that neutralize all of the seven botulinum nerve toxin serotypes known to cause botulism.

"This product approval meets an urgent unmet medical need for the treatment of sporadic cases of life-threatening botulism and provides a medical countermeasure should botulinum nerve toxins be used in a terrorism event," said Karen Midthun, M.D., director of the FDA's Center for Biologics Evaluation and Research.



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Aubagio thumbs up

THE European Medicine Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending the granting of a marketing authorisation for Sanofi-Aventis Aubagio 14 mg film-coated tablet intended for the treatment of multiple sclerosis.

The Committee also concluded that the active substance contained in Aubagio, teriflunomide, could not be considered to be a new active substance.

Teriflunomide is a selective immunosuppressant (L04AA31) with anti-inflammatory properties.

The exact mechanism by which teriflunomide exerts its therapeutic effect in MS is not fully understood, but it is known to reduce the proliferation of lymphocytes by blocking the mitochondrial enzyme dihydroorotate dehydrogenase (DHO-DH).

The benefit with Aubagio is its ability to reduce the relapse rate in patients with relapsing remitting MS.

Side effects include upper respiratory tract infections, urinary tract infections, diarrhoea, nausea, paraesthesia, alopecia and increase in the liver enzyme alanine aminotransferase.

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