Greater East Midlands Commissioning Support Unit in association with
Lincolnshire Clinical Commissioning Groups, Lincolnshire Community Health Services,
United Lincolnshire Hospitals Trust and Lincolnshire Partnership Foundation Trust

Lincolnshire Prescribing and Clinical Effectiveness Bulletin

Volume 8; Number 16 **September 2014**

What's new this month?

- **Ropinirole 2mg, 4mg and 8mg sustained release tablets *(Repinex XL)* for the treatment of Parkinson's disease are designated AMBER without shared care. Prescribers are urged to review all patients currently prescribed ropinirole prolonged release tablets generically or as *Requip XL* with a view to switching to branded *Repinex XL* (see page 3).**
- **In view of the lack of comparative data against alternatives and the relatively high cost of the product, *Lecicarbon A* suppositories are designated RED-RED (see page 4).**
- **Where a patient prescribed fluoxetine has genuine swallowing difficulties necessitating the use of a dispersible or liquid formulation, fluoxetine 20mg dispersible tablets (*Olena*) are preferred. They are also indicated for children over eight years with depression at an initial dose of 10mg or half a tablet. Within licensed indications the product is designated GREEN and approved for inclusion in the *Lincolnshire Joint Formulary*. Prescribers are advised to review all patients currently prescribed fluoxetine 20mg in 5ml oral solution with a view to transferring them to fluoxetine 20mg dispersible tablets (*Olena*) where possible (see page 5).**
- **Prescribers are advised to review all patients currently taking a combination of renin angiotensin system (RAS) blocking agents (i.e. a combination of two of the following: ACE inhibitors, angiotensin II receptor antagonists or aliskiren) at their next routine appointment. The MHRA do not recommend the combination use of these agents and specifically contra-indicate the use of a combination of RAS drugs in particular patient groups (see page 8).**
- **A recent review by the European Medicines Agency has concluded that there is no definite proven link between decreasing efficacy of emergency contraception and increasing body weight. As a result of this, emergency contraception (specifically levonorgestrel (*Levonelle 1500*/ *Upostelle*) and ulipristal (*EllaOne*)) can continue to be used to prevent unintended pregnancy in women of any weight or body mass index (see page 11).**

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SUMMARY OF PACEF DECISIONS: *AUGUST 2014 UPDATE*

Drug	Indication(s)	Traffic Light and Joint Formulary Status
Afatinib 20mg tablets (*Giotrif*) (Boehringer Ingelheim)	For the treatment of adults with epidermal growth factor receptor mutation positive locally advanced or metastatic non-small-cell lung cancer	RED Approved for inclusion in the *Lincolnshire Joint Formulary*
Bortezomib injection (*Velcade*) (Janssen)	For use in combination with dexamethasone or with dexamethasone and thalidomide for the induction treatment of adults with previously untreated multiple myeloma, who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.	RED Recommended by NICE. Approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.
Fluoxetine 20mg dispersible tablets (*Olena*) (Amdipharm Mercury)	For use in depression, bulimia nervosa and obsessive compulsive disorder in adults.	GREEN Approved for inclusion in the *Lincolnshire Joint Formulary*.
Ivabradine tablets 5mg and 7.5mg (*Procoralan*) (Servier)	For the treatment of patients with chronic stable angina in normal sinus rhythm who have a high heart rate and who (i) cannot tolerate beta blockers or calcium channel blockers or (ii) for whom beta blockers and calcium channel blockers are contra-indicated. For the treatment of chronic heart failure NYHA II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥75 bpm (beats per minute), in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contraindicated or not tolerated.	AMBER without shared care. Included in the *Lincolnshire Joint Formulary* for this indication. AMBER without shared care. Included in the *Lincolnshire Joint Formulary* for this indication.
Lecicarbon A suppositories (containing sodium dihydrogen carbonate (0.5g per suppository) and sodium dihydrogen phosphate (0.680g per suppository) (Aspire Pharma)	For all forms of frequent constipation (habitual or chronic), especially where the rectal emptying reflex is weak or constipation is due to low-fibre food or insufficient exercise (for example in bedridden patients) or for the stimulation of bowel movements after an operation or during labour or evacuation of the bowel prior to surgery or diagnostic procedures..	RED-RED Not approved for inclusion in the *Lincolnshire Joint Formulary*.

Pemetrexed injection (*Alimta*) (Lilly)	For the maintenance treatment of locally advanced or metastatic non-squamous non-small-cell lung cancer (NSCLC) in people whose disease has not progressed immediately following induction therapy with pemetrexed and cisplatin.	RED Not approved by NICE but approved through the *National Cancer Drugs Fund List* (July 2014) Approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.
Rituximab infusion (*MabThera*) (Roche)	For use in combination with glucocorticoids for the induction of remission in adult patients with severely active granulomatosis with polyangiitis (Wegener's) and microscopic polyangiitis.	RED Recommended by NICE. Approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.
Ropinirole 2mg, 4mg, 8mg prolonged release tablets *(Repinex XL)* (Aspire Pharma)	For use as monotherapy or as an adjunct to levodopa in the treatment of Parkinson's disease.	AMBER without shared care. Prescribers are urged to review all patients currently prescribed ropinirole prolonged release tablets generically or as *Requip XL* with a view to switching to branded *Repinex XL*. Approved for inclusion in the *Lincolnshire Joint Formulary.*
Ustekinumab injection 90mg/ml (*Stelara*) (Janssen)	For the treatment of psoriatic arthritis in adults, alone or in combination with methotrexate when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.	RED-RED Not recommended by NICE. Not approved for inclusion in the *Lincolnshire Joint Formulary.*
Ustekinumab injection 90mg/ml (*Stelara*) (Janssen)	For the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate or PUVA (psoralen and ultraviolet A)	RED Recommended by NICE. Approved for inclusion in the *Lincolnshire Joint Formulary* for this indication.

This bulletin has been created specifically to convey details of decisions taken at the Prescribing and Clinical Effectiveness Forum (PACEF) to all stakeholders across the Lincolnshire Healthcare Community in both primary and secondary care. Back issues of the *PACE Bulletin* and other PACEF publications are available through the NHS in Lincolnshire website (www.lincolnshire.nhs.uk); follow the commissioning link to PACEF. Electronic copies of both the *PACE Bulletin* and our sister publication *PACE Shorts* (a short summary of the *PACE Bulletin*) are circulated to a wide readership via email. If you are not currently on our distribution list and wish to receive regular copies of PACEF publications please contact Sandra France on sandra.france@gemcsu.nhs.uk.

Google searching can be a quick and effective way of finding back numbers of the *PACE Bulletin* relevant to a specific topic of interest. Searchers are advised to use the official version of the *Bulletin* available from the NHS in Lincolnshire website rather than depend on a potentially unreliable draft or variant found through Google or an alternative search engine.

The *Lincolnshire Joint Formulary* is available on line and is fully searchable; it can be accessed at www.lincolnshirejointformulary.nhs.uk

RAPID DRUG ASSESSMENT: *ROPINIROLE 2MG, 4MG AND 8MG PROLONGED RELEASE TABLETS (REPINEX XL)*

A lower cost prolonged release ropinirole tablet available in a range of strengths offers potential savings to practices and CCGs.

Repinex XL is a prolonged release tablet formulation of ropinirole indicated as monotherapy or as an adjunct to levodopa in the treatment of Parkinson's disease. The marketing authorisation and dose titration regimen are the same as for the original sustained release ropinirole formulation, *Requip XL.* Three clinical trials have been undertaken comparing the 2mg and 8mg strengths of *Repinex XL* with *Requip XL* and have demonstrated bioequivalence.

A cost comparison between the two formulations reveals that *Repinex XL* is approximately half the price of *Requip XL*:

	Dose	**Cost (£) (28 days)**
Ropinirole prolonged release tablets 2mg (*Repinex XL*) (Aspire Pharma)	2mg once daily	£6.20
Ropinirole prolonged release tablets 4mg (*Repinex XL*) (Aspire Pharma)	4mg once daily	£12.50
Ropinirole prolonged release tablets 8mg (*Repinex XL*) (Aspire Pharma)	8mg once daily	£21.00
Ropinirole prolonged release tablets 2mg (*Requip XL*) (GlaxoSmithKline)	2mg once daily	£12.54
Ropinirole prolonged release tablets 4mg (*Requip XL*) (GlaxoSmithKline)	4mg once daily	£25.09
Ropinirole prolonged release tablets 8mg (*Requip XL*) (GlaxoSmithKline)	8mg once daily	£42.11

As ropinirole prolonged release tablets are in category C of the *Drug Tariff*, the standard reimbursement price for generically written prescriptions will be for the higher price of the originator brand.

The potential annual savings for all four of the Lincolnshire CCGs if ropinirole prolonged release tablets were prescribed entirely as the *Repinex XL* brand are as follows:

	Potential annual saving
Lincolnshire East CCG	£23,502
Lincolnshire West CCG	£14,766
South Lincolnshire CCG	£15,423
South West Lincolnshire CCG	£14,057

PACEF Recommendation:
Ropinirole prolonged release tablets 2mg, 4mg and 8mg (*Repinex XL*) are designated AMBER without shared care. Prescribers are urged to review all patients currently prescribed ropinirole prolonged release tablets generically or as *Requip XL* with a view to switching to branded *Repinex XL*. The estimated annual saving across the county is nearly £70,000. *Repinex XL* is approved for inclusion in the *Lincolnshire Joint Formulary.*

RAPID DRUG ASSESSMENT: *LECICARBON A SUPPOSITORIES*

A new suppository formulation for the treatment of constipation is not approved for use.

Lecicarbon A suppositories contain sodium dihydrogen carbonate (0.5g per suppository) and sodium dihydrogen phosphate (0.680g per suppository). They hold a marketing authorisation for:

- all forms of frequent constipation (habitual or chronic), especially where the rectal emptying reflex is weak.
- constipation due to low-fibre food or insufficient exercise (for example in bedridden patients).
- the stimulation of bowel movements after operations or during labour before child birth.
- evacuation of the bowel prior to surgery or diagnostic procedures.

Carbon dioxide (CO_2) is the main constituent of the gaseous products of metabolism which are formed on digestion of the intestinal contents. Of all the intestinal gases, it is the one which causes the most intense stimulation of movement of the rectum. When the *Lecicarbon A* suppository comes into contact with moisture in the intestine, carbon dioxide is liberated causing the physical induction of reflex bowel evacuation. The evacuation process occurs within 15 to 30 minutes of inserting the suppository without causing irritation, cramps or other side effects.

The product has been available in Germany for the last 80 years and has been approved for use within other member states of the European Union based on the Mutual Recognition Procedure (MRC). PACEF reviewed the evidence presented as part of the MRC and found:

- one placebo-controlled trial published in 1947.
- one paper describing an uncontrolled trial on 250 patients published in1974.
- two papers about the use of *Lecicarbon C* in children
- one paper detailing the development of *Lecicarbon A*.
- five other papers where Lecicarbon A was mentioned.
- testimonials from doctors who had used the product in Germany.

Lecicarbon A suppositories are relatively expensive in comparison with alternatives; 10 suppositories cost £8.20.

PACEF Recommendation
In view of the lack of comparative data against alternatives and the relatively high cost of the product, *Lecicarbon A* suppositories are designated RED-RED and have not been approved for inclusion in the *Lincolnshire Joint Formulary.*

RAPID DRUG ASSESSMENT: *FLUOXETINE 20MG DISPERSIBLE TABLETS (OLENA)*

Dispersible fluoxetine tablets are now a preferable option to liquid formulations in most patients with swallowing difficulties.

Fluoxetine 20mg dispersible tablets (*Olena*) are licensed for use in depression, bulimia nervosa and obsessive compulsive disorder. They should be taken dispersed in half a glass of water. The product is not recommended for children under eight years of age and is only licensed for children over 8 years for depression at an initial dose of 10mg daily. The manufacturer advises that a 10mg dose can be given as half a scored tablet.

A cost comparison with alternative liquid formulations of fluoxetine reveals that fluoxetine 20mg dispersible tablets are significantly lower cost than any formulation of fluoxetine 20mg in 5ml oral solution:

	Dose	Cost (28 days)
Fluoxetine 20mg capsules (generic)	20mg daily	£0.94
Fluoxetine 20mg dispersible tablets (*Olena*)	**20mg daily**	**£3.44**
Fluoxetine 20mg in 5ml oral solution (generic)	5ml daily	£6.94
Fluoxetine 20mg in 5ml oral solution (*Prozac Liquid*)	5ml daily	£22.24

PACEF Recommendation:
Where a patient prescribed fluoxetine has genuine swallowing difficulties necessitating the use of a dispersible or liquid formulation, fluoxetine 20mg dispersible tablets (*Olena*) are preferred. They are also indicated for children over eight years with depression at an initial dose of 10mg or half a tablet. Within licensed indications the product is designated GREEN and approved for inclusion in the *Lincolnshire Joint Formulary*. Prescribers are advised to review all patients currently prescribed fluoxetine 20mg in 5ml oral solution with a view to transferring them to fluoxetine 20mg dispersible tablets (*Olena*) where possible. The estimated potential saving across the Lincolnshire CCGs is £11,400pa.

NICE TECHNOLOGY APPRAISAL 308: *RITUXIMAB IN COMBINATION WITH GLUCOCORTICOIDS FOR TREATING ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODY-ASSOCIATED VASCULITIS* (MARCH 2014)

Rituximab, in combination with glucocorticoids, is recommended as an option for inducing remission in adults with anti-neutrophil cytoplasmic antibody [ANCA] - associated vasculitis (severely active granulomatosis with polyangiitis [Wegener's] and microscopic polyangiitis), only if:

- further cyclophosphamide treatment would exceed the maximum cumulative cyclophosphamide dose or
- cyclophosphamide is contraindicated or not tolerated or
- the person has not completed their family and treatment with cyclophosphamide may materially affect their fertility or
- the disease has remained active or progressed despite a course of cyclophosphamide lasting 3–6 months or
- the person has had uroepithelial malignancy.

PACEF Recommendation:
Rituximab infusion (*MabThera*) holds a marketing authorisation for use in combination with glucocorticoids for the induction of remission in adult patients with severely active granulomatosis with polyangiitis (Wegener's) and microscopic polyangiitis. Following NICE approval, it is designated RED for this indication and approved for inclusion in the *Lincolnshire Joint Formulary*. Rituximab is also licensed for Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and the treatment of rheumatoid arthritis and is also approved by NICE for all of these indications.

NICE TECHNOLOGY APPRAISAL 309: *PERMETREXED MAINTENANCE TREATMENT FOLLOWING INDUCTION THERAPY WITH PERMETREXED AND CISPLATIN FOR NON-SQUAMOUS NON-SMALL-CELL LUNG CANCER* (APRIL 2014)

Pemetrexed is **not recommended** for the maintenance treatment of locally advanced or metastatic non-squamous non-small-cell lung cancer (NSCLC) in people whose disease has not progressed immediately following induction therapy with pemetrexed and cisplatin.

PACEF Recommendation:
Despite the fact that pemetrexed injection (*Alimta*) is not approved for the maintenance treatment of locally advanced or metastatic non-squamous non-small-cell lung cancer by NICE it is still listed on the *National Cancer Drugs Fund List* (July 2014). As a result of this, pemetrexed injection (*Alimta*) is designated RED for this indication and approved for inclusion in the *Lincolnshire Joint Formulary.*

NICE TECHNOLOGY APPRAISAL 310: *AFATANIB FOR TREATING EPIDERMAL GROWTH FACTOR RECEPTOR MUTATION-POSITIVE LOCALLY ADVANCED OR METASTATIC NON-SMALL-CELL LUNG CANCER* (APRIL 2014)

Afatinib is recommended as an option, within its marketing authorisation, for treating adults with locally advanced or metastatic non-small-cell lung cancer only if:

- the tumour tests positive for the epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation and
- the person has not previously had an EGFR-TK inhibitor and
- the manufacturer provides afatinib with the discount agreed in the patient access scheme.

PACEF Recommendation:
Afatinib 20mg tablets (*Giotrif*) are designated RED for this indication and approved for inclusion in the *Lincolnshire Joint Formulary*.

NICE TECHNOLOGY APPRAISAL 311: *BORTEZOMIB FOR INDUCTION THERAPY IN MULTIPLE MYELOMA BEFORE HIGH-DOSE CHEMOTHERAPY AND AUTOLOGOUS STEM CELL TRANSPLANTATION* (APRIL 2014)

Bortezomib is recommended as an option in combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adults with previously untreated multiple myeloma, who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.

PACEF Recommendation:
Bortezomib injection (*Velcade*) is designated RED and approved for inclusion in the *Lincolnshire Joint Formulary* for this indication. It has been previously approved by NICE for use as monotherapy in the treatment of relapsed multiple myeloma and for use in combination with thalidomide for the first line treatment of multiple myeloma.

NICE TECHNOLOGY APPRAISAL 313: *USTEKINUMAB FOR TREATING ACTIVE PSORIATIC ARTHRITIS* (MAY 2014)

Ustekinumab is **not recommended** within its marketing authorisation for treating active psoriatic arthritis, that is, alone or in combination with methotrexate in adults when the response to previous non-biological disease modifying antirheumatic drug (DMARD) therapy has been inadequate.

PACEF Recommendation:
Ustekinumab injection 90mg/ml (*Stelara*) holds a marketing authorisation for the treatment of psoriatic arthritis (PsA) in adults, alone or in combination with methotrexate when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. As NICE have not recommended ustekinumab for this indication, it is designated RED-RED and not approved for inclusion on the *Lincolnshire Joint Formulary.* Ustekinumab (*Stelera*)

also holds a marketing authorisation for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate or PUVA (psoralen and ultraviolet A) and is approved by NICE for this indication. It is designated RED within this context and included in the *Lincolnshire Joint Formulary* for this indication.

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY: *DRUG SAFETY UPDATE* (JUNE 2014)

Combination use of medicines from different classes of renin-angiotensin system blocking agents: Risk of hyperkalaemia, hypotension and impaired renal function

Combination use of medicines from different classes of renin-angiotensin system (RAS) blocking agents is associated with an increased risk of hyperkalaemia, hypotension, and impaired renal function. New warnings have been agreed following an EU-wide review. In particular, prescribers are advised that people with diabetic nephropathy should not be given an ACE-inhibitor with an angiotensin-receptor blocker as they are already prone to developing hyperkalaemia. Combining aliskiren with an ACE-inhibitor or angiotensin-receptor blocker is contraindicated in people with kidney impairment or diabetes.

Advice for healthcare professionals:

- Combination use of medicines from two classes of RAS blocking agents (ACE-inhibitors, ARBs, or aliskiren) is not recommended.
- In particular, prescribers are advised not to give patients with diabetic nephropathy an ACE-inhibitor with an ARB since they are particularly prone to developing hyperkalaemia.
- The combination of aliskiren with an ACE-inhibitor or ARB is contraindicated in patients with kidney impairment or diabetes.

Patients with heart failure

- Some patients with heart failure may have a medical need for treatment with an ACE-inhibitor and an ARB. Candesartan and valsartan are licensed as add-on therapy to ACE-inhibitors for people with symptomatic heart failure who require such a combination despite optimal therapy.
- The triple combination of an ACE-inhibitor, ARB, and a mineralocorticoid receptor antagonist or other potassium-sparing diuretic is not recommended.

Patients currently taking a combination of RAS blocking agents

- Review the treatment of all patients currently taking a combination of RAS blocking agents at a routine appointment. Carefully consider if combination use is appropriate.
- If combination use is considered absolutely necessary, it must be carried out under specialist supervision and with close monitoring of blood pressure, renal function, and electrolyte levels (particularly potassium). Consider monitoring patients when combination use is started and on a monthly basis thereafter, and also after changing dose or during inter-current illness.

PACEF Recommendation:
Prescribers are advised to review all patients currently taking a combination of renin angiotensin system (RAS) blocking agents (i.e. a combination of two of the following:

ACE inhibitors, angiotensin II receptor antagonists or aliskiren) at their next routine appointment. The MHRA do not recommend the combination use of these agents and specifically contra-indicate the use of a combination of RAS drugs in particular patient groups

Ivabradine – emerging evidence of increased cardiovascular risk

Ivabradine (*Procorolan*) is used to treat symptoms of long-term stable angina in adults with coronary heart disease who have a normal heart rhythm. It is also used in patients with long-term heart failure who have a normal heart rhythm but whose heart rate is at least 75 beats per minute (bpm). The SIGNIFY trial investigated the efficacy of ivabradine compared with placebo in people with coronary artery disease. The trial included a pre-specified subgroup analysis of participants with symptomatic angina of Canadian Cardiovascular Society Class II or more. Preliminary results have shown a small but statistically significant increase in the combined risk of cardiovascular death and non-fatal myocardial infarction with ivabradine compared with placebo in this subgroup that may be associated with a target heart rate below 60 bpm.

The European Medicines Agency is reviewing the data from SIGNIFY to determine how these findings impact on the balance of benefits and risks with ivabradine. In the meantime MHRA advice is as follows:

- The starting dose of ivabradine is 5 mg twice daily; the maintenance dose should not exceed 7.5 mg twice daily.
- Patients should be carefully monitored for bradycardia or its symptoms (e.g., dizziness, fatigue, and hypotension).
- If resting heart rate decreases persistently below 50 bpm or if the patient experiences symptoms of bradycardia, the dose can be down-titrated to 2.5 mg twice daily if necessary.
- Ivabradine treatment should be stopped if resting heart rate remains below 50 bpm or symptoms of bradycardia persist.
- Only increase the dose to 7.5 mg twice daily after 3 to 4 weeks of treatment and if the 5 mg dose is well tolerated, but insufficient. Carefully monitor the effect of a dose increase on heart rate.
- Avoid concomitant use of ivabradine with heart rate-reducing calcium channel blockers such as verapamil or diltiazem.
- Review the treatment of patients currently using ivabradine where appropriate.

PACEF Comment
Ivabradine tablets (*Procoralan*) are currently approved for use through the *Lincolnshire Joint Formulary* for two indications:
1) The treatment of patients with chronic stable angina in normal sinus rhythm who have a high heart rate and who (i) cannot tolerate beta blockers or calcium channel blockers or (ii) for whom beta blockers and calcium channel blockers are contra-indicated.
2) The treatment of chronic heart failure NYHA II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥75 bpm (beats per minute), in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contraindicated or not tolerated.
For both indications it is classed as AMBER (without shared care) appropriate for prescribing in primary care following initiation of treatment by or on the advice of a consultant.

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY: *DRUG SAFETY UPDATE* (JULY 2014)

DRUGS AND DRIVING: BLOOD CONCENTRATION LIMITS TO BE SET FOR CERTAIN CONTROLLED DRUGS IN A NEW LEGAL OFFENCE

The Department of Transport has introduced a new offence, due to come into force on the 2nd of March 2015, of driving with certain controlled drugs above specified limits in the blood-stream. Drugs that might be used for medicinal purposes that are included in the new offence are:

- Cannabis (tetrahydrocannabinol, THC)
- Cocaine
- Morphine
- Diamorphine
- Methadone
- Ketamine
- Amphetamine
- Flunitrazepam
- Clonazepam
- Diazepam
- Lorazepam
- Oxazepam
- Temazepam

Anyone found to have any of these drugs in their blood above the specified limits will be guilty of an offence, whether their driving was impaired or not. However, there is a defence for people taking the drugs for medical reasons, if their ability to drive was not impaired. The conditions of the medical defence state that the individual is not guilty of an offence if: (1) The medicine was prescribed, supplied, or sold to treat a medical or dental problem,and (2) It was taken according to the instructions given by the prescriber or the information provided with the medicine. The individual may need to provide written evidence to satisfy the points above (e.g., the tear-off section of a prescription or the medicine's patient information leaflet). If the individual's driving is impaired, they can be found guilty of an offence under current law, which has no statutory medical defence and will not change.

Although only a few benzodiazepines and opioids are included in the list above, all benzodiazepines and opioids can impair driving ability. The risk of driving impairment is increased if the medicine is taken with alcohol. Warnings on the risks of driving impairment are already in the patient information leaflets.

PACEF Comment:
PACEF will provide more information to prescribers on this issue when this new offence becomes law early in the new year. Standard advice to patients is that it is currently against the law to drive if your driving ability is impaired by any medicine that you are taking.

TRANSDERMAL FENTANYL PATCHES: REMINDER OF POTENTIAL FOR LIFE-THREATENING HARM FROM ACCIDENTAL EXPOSURE, PARTICULARLY IN CHILDREN

Accidental exposure to transdermal fentanyl can occur if a patch is swallowed or transferred to another individual. A recent EU-wide review emphasized the need for safe handling of patches. To date, the MHRA have received three Yellow Card reports describing accidental

contact with or transfer of fentanyl patches. Children are at risk as they may touch, suck, chew, or swallow a patch that has not been disposed of properly. Also, children have a lower threshold for fentanyl overdose than adults. Two of the three Yellow Card reports received to date concerned children.

Clear information must be provided to patients and caregivers regarding risk of accidental patch transfer and ingestion of patches, and the need for appropriate disposal of patches. If a patch is transferred to another person, it should be removed and the individual should get medical help immediately. If a patch is swallowed, the individual should get medical help immediately

EUROPEAN MEDICINES AGENCY: ***LEVONORGESTREL AND ULIPRISTAL REMAIN SUITABLE EMERGENCY CONTRACEPTIVES FOR ALL WOMEN, REGARDLESS OF BODYWEIGHT*** **(JUNE 2014)**

A recent review by the European Medicines Agency has concluded that there is no definite proven link between decreasing efficacy of emergency contraception and increasing body weight. As a result of this, emergency contraception (specifically levonorgestrel (*Levonelle 1500*/ *Upostelle*) and ulipristal (*EllaOne*)) can continue to be used to prevent unintended pregnancy in women of any weight or body mass index.

Acknowledgements

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