Lothian NHS Board

Waverley Court
4 East Market Street
Edinburgh
EH8 8BG

Telephone: 0131 536 9000
www.nhslothian.scot.nhs.uk

Date: 11/09/2026
Our Ref: 11785
Enquiries to loth.freedomofinfomation@nhs.scot

Dear

FREEDOM OF INFORMATION – LGBT HEALTH AND WELLBEING

I write in response to your request for information in relation to NHS Lothian and LGBT Health and Wellbeing.

Question:

1. Please provide copies of any funding agreement or service level agreement between NHS Lothian and LGBT Health and Wellbeing in force during financial year 2024-25, including any schedule of agreed activities.

Answer:

NHS Lothian's contract with LGBT Health and Wellbeing was £158,500 in 2024-25.

The contract specification sets out the following key deliverables:

- Provision of a specialist telephone and online messaging advice and support service for at least 400 LGBT people in the year, offering support across a range of health and wellbeing issues including mental health, sexual wellbeing and support with finance and cost of living.

- Provision of a specialist counselling service for at least 170 LGBT people across the year.

- Provision of specialist support services for transgender adults, including advice on transitioning, one to one support, support to access services including the Chalmers Gender Identity Clinic and/or Sandyford Young People's service. This will include the delivery of group interventions, providing a range of social opportunities for at least 650 people per annum. Opportunities will be varied to meet the differing needs/populations within the LGBT+ community.

- Leading and contributing to workforce development opportunities in Lothian to enhance confidence and capability of mainstream services to deliver accessible and inclusive services for LGBT+ adults.

  The Queer Milk Group is not covered by NHS Lothian's funding to LGBT Health and Wellbeing.

Question:

2. Recorded data showing total sums paid by NHS Lothian to that organisation in each of the financial years 2022-23, 2023-24, 2024-25 and 2025-26.

Answer:

The table below summarises funding provided by NHS Lothian to LGBT Health and Wellbeing between 2022/23 and 2025/26.

Summary Funding provided by NHS Lothian to LGBT Health and Wellbeing		
Timeframe	**Amount spent (totals)**	**Purpose**
2025-2026	£158,500	Sexual health and wellbeing services for LGBT+ Adults (age 16+)
2024-2025	£158,500	Sexual health and wellbeing services for LGBT+ Adults (age 16+)
2023-2024	£158,500	Sexual health and wellbeing services for LGBT+ Adults (age 16+)
2022-2023	£158,500	Sexual health and wellbeing services for LGBT+ Adults (age 16+).

Question:

3. Copies of any guidance, policy, protocol, care pathway or patient information material held by NHS Lothian relating to induced lactation or lactation induction in non-gestational parents.

Answer:

NHS Lothian does not have any such document.

Question:

4. The current formulary status within NHS Lothian of domperidone when used to induce or augment lactation, together with copies of any Area Drug and Therapeutics Committee papers or minutes in which that use was considered, for the period January 2020 to the present.

Answer:

NHS Lothian is a partner and host organisation for the East Region Formulary, a collaborative initiative involving NHS Fife and NHS Borders. NHS Lothian Area Drug and Therapeutics Committee have delegated formulary governance to the East Region Formulary. Medicines on the formularies for these boards prior to the regional collaboration were compiled into treatment pathways for appraisal.

Domperidone; 10mg three times a day for one week, then review is a formulary approved treatment for augmentation of lactation in adults. It has the annotation 'UI" which denotes this as an unlicensed indication for this medicine.

A treatment pathway entitled 'ADULT - augmentation of lactation' was approved at the East Region Formulary Committee meeting 30/03/2022

The minutes from the East Region Formulary Committee review of the Obstetrics and gynaecology (Adults) chapter review in March 2022 can be found at the following link: Erfc-minutes-30-03-2022-final-version.pdf.

The treatment pathway was published online 18/05/2022. A further update was agreed May 2025 and the formulary was updated 31/07/2025. Formulary amendment - domperidone for augmentation of lactation was agreed at the East Region Formulary Committee in May 2025 and the minutes can be found here: erfc-28-05-25-minutes-final-revised-25-02-2026.pdf The pathway was published online 31/07/2025 and is available here: https://www.formulary.nhs.scot/east/obstetrics-gynaecology-and-urinary-tract-disorders/obstetrics/lactation/?m=augmentation-of-lactation

Question:

5. Copies of any evidence appraisal, literature review or clinical governance assessment held by NHS Lothian in relation to the material requested at points 3 and 4.

Answer:

Regarding point 3 above, there are no such documents.

Prior to the East Region Formulary, NHS Lothian delegated formulary governance to the Lothian Joint Formulary. The formulary committee received a formulary application for domperidone to treat augmentation of lactation. The summary of evidence on comparative efficacy and safety are in the attached formulary application. The formulary governance assessment was completed at the Lothian Joint Formulary Committee meeting in April 2012. Minutes are attached.

I hope the information provided helps with your request.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at https://www.foi.scot/appeal. If

you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

If you require a review of our decision to be carried out, please write to the reviewer at the address at the top of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: https://org.nhslothian.scot/FOI

Yours sincerely

ALISON MACDONALD
Executive Director of Nursing Midwifery and AHPs
Cc: Chief Executive

Enc.

FORMULARY APPLICATION FORM 3
UNLICENSED / OFF-LABEL MEDICINES

For information, refer to the ADTC 'Policy for the Use of Unlicensed (and Off-label use) Medicines in NHS Lothian' (available at www.ljf.scot.nhs.uk).

Requests to initiate unlicensed / off-label medicines in groups of patients should first be submitted by the responsible clinician, with the support of the appropriate clinical pharmacist, to the relevant Drug and Therapeutics Committee (e.g. LUHD DTC, GPPC) for provisional categorisation. The request will then be forwarded by the DTC to the Formulary Committee which will assign the drug to one of the following categories:

Red:	**Specialist use only**
Amber:	**General use with restrictions**
Green:	**Unrestricted general use**
Black:	**Not approved for use**

Section 1: Background information

Generic name of medicine: Domperidone

Brand name (if available): Motilium®

Manufacturer: Sanofi-Aventis

Formulation: Tablet and oral suspension

Route: Oral

Proposed indication: augmentation of lactation

Dosing information: 10-20mg three a day for a maximum of 8 weeks

Details of the proposed prescriber: General Practitioners

UK license status of the medicine (in terms of its proposed clinical use): Off-label

Details of the medicine's availability: Both generic and proprietory brands available in UK

Completed by:
REDACTED

Approved by:
Clinical Director (Women's Services) REDACTED
Signature:_____ **DATE:**_____

Section 2: Place of unlicensed/off-label medicine in therapy in Lothian

Please estimate for ALL Lothian use:
Prevalence (number of patients with condition): 200
Incidence (number of new patients per annum): 200
Number of patients to be treated with the medicine per annum: 200

Has a local Lothian protocol been developed? **Yes** [√] **No** [ ]

If yes, please attach a copy of the protocol with this report. (attached)

If no, please summarise in the boxes below how it is proposed that the medicine will be used in Lothian.
Please indicate proposed place of medicine in the LJF:

- Add to the LJF as first or second choice*** first [ ] second [√]
  - Add to the LJF as a prescribing note [√]

*** **non-pharmaceutical breast feeding support is first line (see guideline)**.

Please specify prescribing (primary care, secondary care or if shared care protocol (SCP) is considered appropriate): Primarily in Primary Care by General Practitioners unless if woman is an inpatient

- Add to the Additional List (i.e. useful in some patients after LJF medicines ineffective, not tolerated, LJF medicines contra-indicated, or specialist practice) [ ]
- Non-formulary: 'Not preferred' as effective alternatives available [ ]
- Unsure - leave to FC discretion [ ]

Please specify place in therapy in relation to existing medicines:

There are no licensed galactagogues in UK. Domperidone is the galactagogue of choice based on its safety and efficacy. It is not a panacea but it can be effective in augmentation of lactation when used in combination with established non-pharmacological support and breastfeeding measures and only after these measures have been failed to increase breast milk adequately.

Section 3 *(to be completed if "Add to LJF as first or second choice" has been ticked in section 2 above)* Place of medicine in the Lothian Joint Formulary (www.ljf.scot.nhs.uk)

In which section of the Lothian Joint Formulary should this medicine be placed?
Should this medicine replace one already recommended in the Lothian Joint Formulary? *(please tick appropriate box)*:

YES [ ] **NO [√]

** There is no recommended galactagogue in LJF currently

If YES, specify medicine to be replaced:
Is this medicine proposed as *(please tick appropriate box)*:
(a) first choice (b) second choice

Section 4: Summary of evidence on clinical effectiveness issues

What are the principal trials supporting the indication(s) described above and the overall results regarding outcomes (e.g. absolute or relative risk reduction or NNT) and efficacy? Please state what the principal outcome measures are and provide copies of up to 3 (max) relevant references.

There has widespread use and recommendations for over 30 years and several small studies[1-7] have investigated the effectiveness of domperidone for this off label indication for the augmentation lactation. Several reviews [8-11] have addressed its place within this clinical context. Despite certain limitations, domperidone is considered the first line galactagogue based on its safety and efficacy in the UK and in many other countries.

Petralgia et al in 1985 did a double-blinded trial in 32 women[1]. Oral domperidone 10mg three times for 4 days was given to achieve initiation of lactation in 8 out of 15 multiparous women (group 1) and for 10 days for augmentation of lactation in 9 out of 17 primigravid women (group 2). Milk yield was four times that of placebo in group1 and continued for a month in these 8 women. The milk yield almost doubled in the 9 prims and again this continued for a month compared to none in the placebo group. No side effects were reported in mothers or infants. Apart from sample size, another limiting factor in this study was that mothers were only breastfeeding 6-7 times a day and that is generally not considered optimal to produce to sufficient milk supply. Orlando da Silva et al (2001) [2] in a randomised, double blinded trial studied the effect of oral domperidone 10mg three times a day for 7 days in 16 women. Milk production was significantly higher in domperidone group and began about 48 hours after start of dosing and returned to normal after 10 days. The calculated infant dose based on measured milk level and a daily milk intake of 150ml/kg/day would be 200nanogram/kg/day well below dosage used clinically in neonates. In 1983, Hopmeyer GJ et al[3] had also reported that only small amounts of domperidone was excreted in breast milk using the same dose. A similar response in milk production was found in two other placebo controlled double blinded trial (n=20)[4,5] using the same dose as da Silva. A randomised, crossover double blinded trial[6] using dosage of 10-20mg three times a day for 1-2 weeks in women who had preterm births (n=6) found that about 66% of women had a three-fold increase in milk production using the double dose. Mean infant dose was about 0.01% at both doses. Reported side effects were dry mouth, headaches, abdominal cramps and depressed mood and these were dose related[6-7]. Wan[6] the first to address the proposed dosage range, the key limitation of this study was the small sample size. Women had non-pharmacological breastfeeding support in most of these studies and hence the pragmatic recommendation that it should be used with continued reassessment and review and for the shortest possible duration (maximum of 8 weeks) to help promote effective breast milk supply.

References

1 Petralgia F et al. Domperidone in defective and insufficient lactation. Eur J Obstet Gynae Reprod Biol 1985;19:281-7
2 Da Silva OP, Knoppert DC, Angelini MM, Forret PA. Effect of domperidone on milk production in mothers of premature newborns: a randomised, double-blinded, placebo controlled trail. CMAJ 2001;164(1):17-21.
3 Hopmeyer GJ, van Idelekinge B. Domperidone and lactation (letter). Lancet 1983:1:647
4 Gabay MP. Galactagogues: Medication that induce lactaion. J Human Laction 2002;18:274-9
5 Campbell-Yeo ML et al. Effect of domperidone on the composition of preterm human breast milk. Pediatrics 2010;125:e107-114
6 Wan EWX et al. Dose effect study of domperidone as a galactagogue in preterm mothers with insufficient milk supply and its transfer into milk. Br J Clin Pharmacol 2008;66(2):283-289
7 Wendy Jones, Sharon Breward. Use of domperidone to enhance lactation: what is the evidence? Community Practitioner 2011;84(6):35-37 (East Hampshire Primary Care Trust)
8 **UKMi Q&A 73-**3 Drug treatment of inadequate lactation. 20 April 2010. http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Drug-treatment-of-inadequate-lactation/ accessed December 2011
9 Anderson PO, Valdes. A critical review of pharmaceutical galactagogues. Breastfeeding Medicine 2007;2:229-42.
10 Christine Betzold. Is domperidone safe for breastfeeding mothers? A review. J Midwifery & Women Health 2004;49:151-4.

Section 5:Summary of evidence on comparative efficacy

What are the advantages of this medicine compared to other treatments? Consider medicines already recommended in the Lothian Joint Formulary or others in the same therapeutic class.

Breastfeeding is recognised worldwide as the optimal form of nutrition for term and preterm infants [1-3]. Apart from the nutritional and psychological benefits, breastfeeding has been shown to protect against sudden infant death syndrome, insulin-dependent diabetes, Crohn's disease, ulcerative colitis, necrotizing enterocolitis, lymphoma, leukaemia, and allergic disease. There is therefore a need to consider the place of this galactogagues to support breastfeeding.

Antipsychotic agents such as chloropromazine and sulpiride have been used but safety profile is poor. Metoclopramide has a comparable efficacy to domperidone [4] but the extrapyramidal side effects as well as depression are of major concerns in this patient group. Domperidone is considered the drug of choice due to its better safety and efficacy based on short-term trials over the past 30 years [4-8]. As it is highly protein bound (90%) and has a relatively high molecular weight, transfer into milk is likely to be low (about 0.01% of maternal dose) and this has been confirmed [6-8]. Although optimal dose and duration of treatment is not known some mothers can respond in 24 hours and most within 2-3 days [6,7]. Use of domperidone is appropriate to support breastfeeding in mothers who are unwell and have preterm babies or those who wish to breast feed but have low milk supply accompanied by weight loss in their babies despite continued use of non-pharmacological measures and support. Before initiating domperidone, it is necessary to assess breastfeeding technique (including milk expressing/emptying as milk stasis inhibits milk production) and then institute corrective breastfeeding support such as use of appropriate electric pump. Stress can also play a role in these mothers so again that needs to be addressed by use relaxation or similar techniques. Domperidone should not be used alone and as first-line management. It can be useful and have a place in augmentation of lactation in combination with non-pharmacological support and measures and only after they have failed and with regular reassessment and support thereafter.

References

1 Department of Health. Infant feeding recommendation. London.2003

2 Kramer MS, Kakuma R. (2002). Optimal duration of exclusive breastfeeding. Cochrane Database Syst Rev (1) 2002:CD003517

3 Hoddinott P, Tappin D, Wright C. Breast feeding. BMJ 2008;336:881

4 Ingram J, Taylor H, Churchill C, *et al.* Metoclopramide or domperidone for increasing maternal breast milk output:a randomised controlled trial. *Arch Dis Child Fetal Neonatal Ed* 2011:F1-5

5 Anderson PO, Valdes. A critical review of pharmaceutical galactagogues. Breastfeeding Medicine 2007;2:229-42.

6 Wan EWX et al. Dose effect study of domperidone as a galactagogue in preterm mothers with insufficient milk supply and its transfer into milk**.** Br J Clin Pharmacol 2008;66(2):283-289

7 **UKMi Q&A 73-**3 Drug treatment of inadequate lactation. 20 April 2010. http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Drug-treatment-of-inadequate-lactation/ accessed December 2011

8 Wendy Jones, Sharon Breward. Use of domperidone to enhance lactation: what is the evidence? Community Practitioner 2011;84(6):35-37 (East Hampshire Primary Care Trust)

Section 6: Summary of evidence on comparative safety

Are there any safety issues regarding this medicine in comparison to existing medicines?

Antipsychotic agents such as chloropromazine and sulpiride have been used but safety profile is very poor. Metoclopramide can be effective [1] but the risk of extrapyramidal side effects and depression are of major concerns especially in this patient group. Reports of fatal cardiac arrhythmias, in very ill adults, using the intravenous domperidone has led to the warning from the FDA[2] not to use domperidone for this purpose. Despite 30 years experience of the oral domperidone, no cardiac side effects have been reported. This is not surprising as there is marked first pass loss and low oral bioavailability resulting in peak plasma concentration 60-80 fold lower compared to the intravenous route [3,4]. Nevertheless, on theoretical grounds it should be avoided in women with known cardiac disease[3-5] and possibly in those with a diagnosis or known family history of premenstrual onset of breast cancer [6]. It is best to avoid concomitant use with potent CYP34A inhibitors such as ketoconazole and erythromycin as these can reduce its metabolism and may potentially cause QT prolongation [3,4]. There are also theoretical concerns about long-term effects on the maturation of central dopamine mechanism in the newborn. To limit any possible unknown safety

issues and enhance efficacy its combined used with non-pharmacological measures such as corrective breastfeeding techniques and appropriate use of pump (milk stasis can inhibit milk production) must be advocated. Typical duration of therapy will usually be 2-4 weeks and limited to a maximum of 8 weeks and with regular (possibly weekly) monitoring of milk production and baby's weight gain. In mothers whose response is short lived or have had no response, it is essential to check other possible causes of poor milk production such as FBC (anaemia), TSH (hypothyroidism), hCG (retained placenta) and serum prolactin to exclude pituitary disease[3,5,6] .

References

1 Ingram J, Taylor H, Churchill C, *et al.* Metoclopramide or domperidone for increasing maternal breast milk output:a randomised controlled trial. *Arch Dis Child Fetal Neonatal Ed* 2011:F1-5

2 Food and Drug Administration (FDA). Domperidone. www.fda.gov/Safety/Alertsfor HumanMedicalProducts/ucm154914.htm accessed November 2011

3 **UKMi Q&A 73-**3 Drug treatment of inadequate lactation. 20 April 2010. http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Drug-treatment-of-inadequate-lactation/ accessed December 2011

4 http://www.medicines.org.uk/EMC/medicine/20011/SPC/Motilium+10/#PHARMACOKINETIC_PROPS accessed Jan 2012

5 Wendy Jones, Sharon Breward. Use of domperidone to enhance lactation: what is the evidence? Community Practitioner 2011;84(6):35-37 (East Hampshire Primary Care Trust)

6 Harvey JA et al. Increase in mammographic breast density associated with the use of domperidone. The Breast J 2004;10 (3):256-8 (case report)

7 Christine Betzold. Is domperidone safe for breastfeeding mothers? A review. J Midwifery & Women Health 2004;49:151-4.

Section 7: Summary of evidence on cost effectiveness

Please provide information on the cost effectiveness of this medicine in terms of absolute risk reduction and cost per QALY.

The health benefits of breastfeeding is considerable[1-4] ranging from physiological, psychological and long term health benefits therefore it is essential to evaluate the safety and efficacy of any treatment that can support this activity. The cost effectiveness would be difficult to assess and good quality evidence of public health interventions is limited. NICE considered interventions to be cost-effective at an incremental cost effectiveness ratio of between £20,000 and £30,000 per QALY[5]. A recent estimate from the USA was that if 90% of mothers were to breastfeed exclusively for 6 months, the United States would save $13 billion per year and prevent an excess 911 deaths, nearly all of which would be in infants ($10.5 billion & 741 deaths at 80% compliance). Such data supports that selective and appropriate use of domperidone can have considerable financial and health gains benefits.

References

1 Department of Health. Infant feeding recommendation. London.2003

2 Kramer MS, Kakuma R. (2002). Optimal duration of exclusive breastfeeding. Cochrane Database Syst Rev (1);2002:CD003517

3 National Institute for Clinical Health and Excellence. The effectiveness of public health interventions to promote the duration of breastfeeding. May 2005 www.nice.org.uk accessed November 2011).

4 Hoddinott P, Tappin D, Wright C. Breast feeding. BMJ 2008;336:881

5 National Institute for Clinical Health and Excellence. Maternal and Child Nutrition programme Economic Appraisal (NCC-WCH). Modelling the Cost-effectiveness of breastfeeding support. http://www.nice.org.uk/nicemedia/live/11677/34695/34695.pdf

6 Bartick M, Reinhold A. The Burden of Suboptimal Breastfeeding in the United States: A Pediatric Cost Analysis. Pediatrics 2010;125(5):1048-56

Section 8: Guidelines

Please include the appropriate sections from any relevant local or national guidelines e.g. SIGN, NICE

There are no national guidelines. The Breastfeeding Network (Paisley)[1] and Ayrshire & Arran (2009) guidelines advocate a similar dosage and also stress the need for it to be used in conjunction with breastfeeding support. In England, there are several guidelines but the most robust is from Somerset by the Academy of Breastfeeding Medicine[2] and again the message is comparable to our guideline.

References

1 The Breastfeeding Network**.** Domperidone use during breastfeeding http://www.breastfeedingnetwork.org.uk/pdfs/dibm/Domperidone_and_Breastfeeding_Jan_2012.pdf

2 The Academy of Breastfeeding Medicine (Protocol 9): Use of galactagogues in initiating or augmenting maternal milk supply.. http://www.bfmed.org/ace-files/protocol/prot9galactogoguesEnglish.pdf . Accessed January 2012

Section 9: Information on similar use elsewhere (peer support)

There is over 30 years experience with the off label use of domperidone within UK and worldwide[1,2]. For many years, use of domperidone for augmentation of lactation has been advocated by Jack Newman[3], a well recognised Canadian breastfeeding specialist[1] but the dosage and duration appears to be led by opinion rather that evaluated published studies. Guidelines from Canada[4] and New Zealand[5] are more in line with UK practice. The message is the same that it should be considered as the first line galactagogue. It is not a substitute for effective breastfeeding measures and support but should be used at the lowest effective dose in combination with these measures for 4-8 weeks and with the opportunity for regular review as this must be a mother and baby not a drug led activity.

References

1. Wendy Jones, Sharon Breward. Use of domperidone to enhance lactation: what is the evidence? Community Practitioner 2011;84(6):35-37 (East Hampshire Primary Care Trust)
2. **UKMi Q&A 73-**3 Drug treatment of inadequate lactation. 20 April 2010. http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Drug-treatment-of-inadequate-lactation/ accessed December 2011
3. NewmanJ, Kernerman E. Domperidone, getting started. www.drjacknewman.com/help/Domperidone/Getting/20started.asp accessed November 2011
4. Zuppa AA, Sindico P, Orchi C, Carducci C et al. Safety and Efficacy of Galactogogues: Substances that Induce, Maintain and Increase Breast Milk Production. J Pharm Pharmaceut Sci (www.cspsCanada.org) 2010: 13(2) 162-174
5. http://www.adhb.govt.nz/newborn/guidelines/maternal/domperidoneandbreastfeeding accessed November 2011

Section 10: Financial Information for the use of [*Domperidone (Motilium®)*] in Lothian

		No. of patients in Lothian eligible for treatment per annum	Cost per annum (£) per patient	Cost per annum (£) ALL patients**
Secondary Care	Lothian	50	REDACT	REDACT
	Non-Lothian			
Primary Care	Lothian	150	REDACT	REDACT
	Non-Lothian			
SUB-TOTAL (secondary care and primary care):				
Cost of replaced therapy	Secondary Care			
	Primary Care			
TOTAL NET COST:		200		REDACT
Other Cost Implications	e.g. Additional Medicine Therapy, X-rays, Lab Tests, etc.			

† *Note*. For Cancer medicines (SCAN) please insert separate rows for Lothian, Fife, Borders and Dumfries & Galloway. Refer also to the NHS Scotland Regional Cancer Advisory Group document '*Financial Planning of Cancer Medicines likely to be SMC approved*'.

****It is anticipated that prescribing will be mainly GP lead for outpatients and that most (99%) patients will have access to established "walk in" breastfeeding clinics within Lothian**.
http://www.nhslothian.scot.nhs.uk/Services/A-Z/BreastfeedingSupport/Pages/default.aspx

Section 11: **Conclusions & Comments**

Breastfeeding has many well-recognised health, psychological and financial benefits. Although domperidone is not a panacea for women with breastfeeding issues, it is acknowledge worldwide that it is the galactagogue of choice as benefits outweigh risks. Domperidone can contribute to augmentation of breastfeeding but it must be used in conjunction with effective breastfeeding techniques, measures and support. As this is an off label use of this drug, GPs are naturally concerned about it use especially as a "P" medicine. It can also be of concern if women were to try to purchase it from community pharmacies without the appropriate support. Lothian already has a range of breastfeeding support teams and clinics (see attachment above) and the opportunity to also utilise oral domperidone appropriately would be very beneficial. The approval of domperidone for the augmentation of lactation would therefore further facilitate seamless care and shared information across Lothian to provide a safe and effective patient-centred approach to breastfeeding.

Section 12: Declaration of Interests

LOTHIAN FORMULARY COMMITTEE
(Area Drug and Therapeutics Committee)
Policy on Declaration of Involvement and Competing Interests with the Pharmaceutical Industry

The lead clinician(s) and pharmacist(s) responsible for completing FAF3, and/or providing information to the Formulary Committee, are asked to declare and describe to the Chairman, Formulary Committee, any involvement that they may have with the relevant pharmaceutical company, or with the manufacturers of any comparator products.

1. Personal interests over the last 12 months
This involves payments* (or other support) from any one company to an individual member or their spouse/partner/cohabittee or close relative, as defined in section 22 of the Lothian Standing Financial Instructions. The main examples are consultancies, fee-paid work, travel grants or pharmaceutical company shares. (The amount of money involved does not have to be declared).

Company	**Nature or purpose of support from the company**	**Period of support From**	**To**
None			
Name of Clinician: REDACT	**Date:**		
Name of Pharmacist: REDACT	**Date:**		

* for practical purposes, payments and/or support to a value in excess of £100 annually should be declared. (Threshold of £100 chosen locally to exclude amounts for trivial items such as pens, post-its, books, etc)

2. Non-Personal interests over the last 12 months

This implies support* from any one company for your unit or place of work, as defined in section 22 of the Lothian Standing Financial Instructions. It may be financial or in kind, e.g. funding of a nurse, colleague, building or piece of equipment. (The amount of money involved does not have to be declared).

Company	Nature or purpose of support from the company	Period of support From	To
None – N/A			
Name of Clinician: REDACT		**Date:**	
None - N/A			
Name of Pharmacist: REDACT		**Date:**	

* for practical purposes, payments and/or support to a value in excess of £1000 annually should be declared. (Threshold of £1,000 chosen to concord with Scottish Medicines Consortium guidance.)

Please submit this form to the relevant Drug and Therapeutics Committee (e.g. LUHD DTC, GPPC) for provisional categorisation

Please then email the completed form, along with a note of the provisional categorisation, to prescribing@nhslothian.scot.nhs.uk

Please also post the completed form and signed declaration of interests to:

Lothian Formulary Committee
C/o Medicines Management Team
Stevenson House
555 Gorgie Road
Edinburgh
EH11 3LG

Note **This document is regularly reviewed with the aim of ensuring that it is as user-friendly as possible. Please email any comments on the documentation to prescribing@nhslothian.scot.nhs.uk**

LOTHIAN FORMULARY COMMITTEE

FORMULARY COMMITTEE

Minutes of the Formulary Committee meeting held on 18th April 2012 in Room 004, Ground Floor, Pentland House

Present:

[redacted]	Clinical Nurse Manager, Royal Infirmary of Edinburgh
Dr E Brown	Consultant Oncologist, Western General Hospital
[redacted]	Lead Directorate Pharmacist, Royal Infirmary of Edinburgh
[redacted]	Specialist Registrar in Public Health
Dr J Forbes	Formulary Committee Co-Chair and Reader in Health Economics, University of Edinburgh
Dr SC Hornibrook	General Practitioner, Lothian
Dr S Hurding	General Practitioner, NHS Lothian
Dr W Jamieson	General Practitioner, Lothian
[redacted]	Lead Pharmacist, Western General Hospital
Professor S Lawrie	Formulary Committee Co-Chair and Professor and Honorary Consultant Psychiatrist, Royal Edinburgh Hospital (***in the chair***)
[redacted]	Clinical Effectiveness Pharmacist, NHS Fife
[redacted]	Formulary Pharmacist, NHS Lothian
[redacted]	Formulary Committee Administrator
Dr D Wilks	Consultant in Infectious Diseases, Western General Hospital

Apologies for absence:

Dr J Dear	Consultant Clinical Pharmacologist, Royal Infirmary of Edinburgh
Dr H Gillett	Consultant Gastroenterologist, St John's Hospital
[redacted]	Formulary Pharmacist, NHS Borders
[redacted]	Lead Directorate Pharmacist, Royal Infirmary of Edinburgh
[redacted]	Clinical Effectiveness Pharmacist, North Cumbria Medicines Management Group
[redacted]	Lead Pharmacist, Royal Edinburgh Hospital and Roodlands Hospital
Dr R Williams	General Practitioner, Lothian

Welcome:

The Chair welcomed new member Jackie Bradie, Clinical Nurse Manager, Royal Infirmary of Edinburgh to the Committee and members introduced themselves in turn.

Declarations of interest:

The Chair reminded members to declare any interests in any of the products to be discussed.

LOTHIAN FORMULARY COMMITTEE

Minutes

1. Minutes of the previous meeting held on 7th March 2012

1.1 The minutes of the meeting of 7th March 2012 were approved as an accurate record of that meeting.

2. Matters arising from previous minutes

2.1 mycophenolate mofetil for nephrotic syndrome

2.1.1 A FAF3 submission for mycophenolate mofetil for the management of steroid-dependent nephrotic syndrome in paediatric patients was presented to Formulary Committee in September 2011. It was agreed that this treatment should be secondary care only so the draft Shared Care Protocol (SCP) provided with the submission was not supported.

2.1.2 The committee received an appeal to reconsider this decision and support the use of SCP.

2.1.3 It was noted that all of the current patients already receive mycophenolate mofetil from their GPs and there were no difficulties encountered with this so far. The GPs are familiar with prescribing this medication for transplant patients, but the use of mycophenolate in nephrotic syndrome is different and therefore a SCP would be required.

2.1.4 It was noted that patients are closely monitored and followed up by the specialist team. Those patients who are stable would be seen at clinic at 3 monthly intervals.

2.1.5 The committee agreed to change the classification on mycophenolate mofetil from RED to AMBER and to support the submission of the SCP to GPPC.

ACTION: [redacted]

2.2 bendamustine hydrochloride (Levact®) SMC No. 694/11

2.2.1 A FAF1 submission was made to Formulary Committee in March 2012. At that time, classification was deferred pending the receipt of more evidence for the use of bendamustine in combination with rituximab, although the committee acknowledged that it may only be possible through additional information on peer use by other hospitals in Scotland. Confirmation that there would be an additional benefit from the inclusion of rituximab was also required.

2.2.2 The committee noted and discussed the resubmitted FAF1 application received which included information from a current phase III German CLL trial comparing R-Bendamustine with FCR for first line therapy for CLL. An analysis of the first 100 patients was presented and it was found that response rates are similar in both arms (indicating that R-Bendamustine has a higher response rate to single agent bendamustine) with no safety concerns. However these data have not been published and have not been subject to peer review yet.

2.2.3 It was noted that there is good evidence for using bendamustine as single agent, but that until the outcomes from the German study are finalised there isn't sufficient evidence to prove the benefit of using bendamustine in combination with rituximab.

2.2.4 It was noted that no information was provided by the clinical team on whether this combination of drugs is used by other hospitals in Scotland.

2.2.5 The committee agreed to approve the use of bendamustine hydrochloride (Levact®) as per the SMC advice and to add it to the Additional List as a first line treatment.

2.2.6 Bendamustine hydrochloride (Levact®) will be **Included** on the Lothian Joint Formulary for the indication in question.

2.2.7 It was agreed that until further evidence is provided, the use of bendamustine in combination with rituximab can be undertaken via the non-formulary route.

ACTION:JP/SL

3. SMC Recommendations - FAF1s

3.1 rilpivirine (Edurant®)

3.1.1 The committee noted and discussed the previously circulated submission and SMC report. No declarations of interests were included with the application. A committee member noted a personal, non-specific interest.

rilpivirine 25mg film-coated tablet (Edurant®) **No. 758/12**

ADVICE: following a full submission:

rilpivirine 25mg film-coated tablet (Edurant®) is accepted for use within NHS Scotland.

Indication under review: rilpivirine in combination with other antiretroviral medicinal products, is indicated for the treatment of human immunodeficiency virus type1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤100,000 HIV-1 RNA copies/mL.

The non-inferiority of rilpivirine over another non-nucleoside reverse transcriptase inhibitor (when given in combination with two nucleoside reverse transcriptase inhibitors) for virological response was demonstrated in two phase III, comparative, multi-centre studies in antiretroviral treatment-naïve patients.

3.1.2 The committee noted the FAF1 submission for the use of rilpivirine 25mg film-coated tablet (Edurant®) in combination with other antiretroviral medical products for the treatment of human immunodeficiency virus type1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤100,000 HIV-1 RNA copies/mL.

3.1.3 It was noted that the evidence is based on two similarly designed phase III double-blind, randomised studies conducted in anti-retroviral naïve adults comparing oral treatment with rilpivirine 25mg once daily versus efivarenz 600mg once daily given in conjunction with a background regimen of two nucleoside reverse transcriptase inhibitors.

3.1.4 It was noted that in both studies, more patients discontinued treatment because of an adverse event (AE) in the efavirenz group than in the rilpivirine group and there were higher rates of rash, neurological and psychiatric AEs in the efavirenz group compared to the rilpivirine group.

3.1.5 The committee noted that the economic model did not take account of the virological response rate between weeks 48 and 96 of the studies and this may have been in favour of rilpivirine as the data at 96 weeks were poorer.

3.1.6 It was noted that there are 30 patients per annum to be treated with this medication and a local Lothian protocol has not been developed.

3.1.7 It was agreed to add rilpivirine 25mg film-coated tablet (Edurant®) to the Additional List for Specialist Use only.

3.1.8 Rilpivirine 25mg film-coated tablet (Edurant®) will be **Included** on the Lothian Joint formulary for the indication in question.

ACTION: [redacted]

3.2 rilpivirine / emtricitabine / tenofovir (Eviplera®)

3.2.1 The committee noted and discussed the previously circulated submission and SMC report. No declarations of interests were included with the application.

emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) **No. 759/12**

ADVICE: following an abbreviated submission:

emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) is accepted for use within NHS Scotland.

Indication under review: treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml.

As with other antiretroviral therapies, genotypic resistance testing should inform the use of Eviplera®. This combination tablet has been shown to be bioequivalent to the individual components given separately. It is available at pro rata cost to the individual components and may be used to simplify the regimen of patients for whom this combination of HIV therapies is appropriate at the doses provided in this fixed dose combination.

3.2.2 The committee noted the FAF1 submission for the use of emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naive adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml.

3.2.3 It was noted that there are 40 patients per annum to be treated with this medication and a local Lothian protocol has not been developed.

3.2.4 The committee noted that some patients require a once daily antiretroviral formulation which is a combination of these three drugs and there are additional benefits to the patients in using this combination of medication rather than the individual components.

3.2.5 The committee agreed to add emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) to the Additional List for Specialist Use only.

3.2.6 Emtricitabine 200mg, tenofovir disoproxil (as fumarate) 245mg, rilpivirine (as hydrochloride) 25mg, film-coated tablet (Eviplera®) will be **Included** on the Lothian Joint formulary for the indication in question.

ACTION: [redacted]

4. SMC latest 'Not Recommended' Medicines (March 2012)

The committee noted the following medicine not recommended for use by SMC in NHS Scotland:

4.1 belimumab (Benlysta®), Report No. 775/12, is not recommended for use within NHS Scotland as add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g. positive antidsDNA and low complement) despite standard therapy.

4.2 tocilizumab (RoActemra®), Report No. 774/12, is not recommended for use within NHS Scotland as monotherapy in patients who are intolerant to methotrexate or where continued treatment with methotrexate is inappropriate, for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

4.3 NON-SUBMISSIONS

- **catumaxomab (Removab®), Report No. 788/12,** is not recommended for use within NHS Scotland as intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinomas where standard therapy is not available or no longer feasible.

- **everolimus (Votubia®) No. 787/12,** is not recommended for use within NHS Scotland for the treatment of patients aged 3 years and older with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery.

- **fampridine (Fampyra®), Report No. 789/12,** is not recommended for use within NHS Scotland for improvement of walking in adult patients with multiple sclerosis with walking disability.

5. Other Medicines Proposed for Use - FAF2s and FAF3s

5.1 alemtuzumab (Mabcampath®)

5.1.1 The committee noted the FAF3 submission for the use of alemtuzumab (Mabcampath®) for the treatment of relapsed chronic lymphocytic leukaemia (CLL).

5.1.2 No declarations of interests were included with the application.

5.1.3 It was noted that alemtuzumab would be given to patients via a subcutaneous injection route, which is an off label use as the license is for intravenous use.

5.1.4 It was noted that the clinical team intends to use this drug as second line treatment; however, there has never been a phase III study for the treatment of relapsed CLL.

5.1.5 It was noted that The South East Scotland Cancer Group (SCAN) has considered the available data, and recently approved the CLL clinical management guideline which includes the use of alemtuzumab in relapsed/refractory disease for selected patients. A copy of the guideline has been included in the application. A local Lothian protocol has also been provided.

5.1.6 It was noted that there are no existing medicines on the formulary for the treatment of fludarabine refractory CLL.

5.1.7 The committee noted that due to small numbers of patients (3 in Lothian) who fit the criteria, the overall cost per annum to NHS Lothian is relatively small and the drug is currently used via the non-formulary request route. However alemtuzumab is associated with CMV reactivation in 9% of recipients which could potentially cause additional costs.

5.1.8 The committee agreed to add alemtuzumab (Mabcampath®)to the Additional List, for Specialist Use only, categorised RED under the ADTC policy for unlicensed and off label medicines.

ACTION: [redacted]

5.2 methylphenidate (Concerta XL®)

5.2.1 The committee noted the FAF3 submission for the use of methylphenidate (Concerta XL®) for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in Adults (>18yr).

5.2.2 No declarations of interests were included with the application. A committee member noted a personal, non-specific interest.

5.2.3 The committee noted that methylphenidate is already approved and used under Shared Care Protocol (SCP) in children.

5.2.4 It was noted that the clinical team are proposing to add methylphenidate to the formulary as a first choice drug.

5.2.5 It was noted that the prevalence is high (15,900 patients = 3-4% in adult population) with 280 patients per annum treated in Lothian.

5.2.6 The committee noted that this medication would be used in patients with a diagnosis of ADHD requiring continuation of therapy commenced during childhood and adults diagnosed with ADHD following specialist assessment meeting criteria for trial of medication.

5.2.7 It was noted that the treatment will be initiated by specialist psychiatrist with continuation of therapy in primary care, under SCP, once the patient is stabilised on treatment.

5.2.8 It was noted that methylphenidate is used within the UK in the treatment of adults with ADHD and examples of SCPs were provided for reference. A Lothian SCP has not been provided.

5.2.9 The committee noted that the evidence is based on a few trials where some clinical effectiveness was demonstrated, but that more data is required on long-term effectiveness and in larger samples.

5.2.10 The main concern of the committee was that there is no indication about the length of treatment to be provided and therefore it is hard to predict the long-term use and safety of this drug in practice.

5.2.11 It was noted that because the duration of the treatment is not specified, and most of the patients are likely to be treated for several years, the cost implications could

significantly increase in the future. The committee would therefore like to see more evidence on the long term cost implications.

5.2.12 The committee were unclear on how the treatment would be reviewed and potentially discontinued in patients. The committee members felt that ongoing review by a specialist would be required and should be included in the SCP.

5.2.13 The committee agreed to add methylphenidate (Concerta XL®) to the LJF as a first choice drug, categorised AMBER, suitable for Shared Care Protocol use under the ADTC policy for unlicensed and off label medicines, subject to clarification of the above points.

ACTION: [redacted]

5.3 atomoxetine (Strattera®)

5.3.1 The committee noted the FAF3 submission for the use of atomoxetine (Strattera®) for the treatment of Attention Deficit Hyperactivity Disorder in Adults (>18yr).

5.3.2 No declarations of interests were included with the application.

5.3.3 The committee noted that atomoxetine is already approved and used under Shared Care Protocol (SCP) in children.

5.3.4 It was noted that the clinical team are proposing to add atomoxetine to the formulary as a second choice drug. The treatment will be initiated by specialist psychiatrist with continuation of therapy in primary care, under SCP, once the patient is stabilised on treatment.

5.3.5 It was noted that atomoxetine is used within the UK in the treatment of adults with ADHD and examples of SCPs were provided for reference. A Lothian SCP has not been provided.

5.3.6 It was proposed that atomoxetine would be used in 43 patients per annum in Lothian.

5.3.7 The committee noted that the patient criteria are the same as in methylphenidate. Atomoxetine will be considered as alternative to methylphenidate where this has been ineffective following an adequate trial, usually over 6 weeks, when methylphenidate has not been tolerated due to side effects or where co-morbidities make it a more appropriate choice. It may also be considered as first choice where there are concerns with drug misuse or the diversion of stimulants.

5.3.8 The committee noted that some clinical effectiveness was demonstrated but that more data is required on long-term effectiveness. It was noted that atomoxetine can affect blood pressure and heart rate, suicide-related behaviour and adversely effect patients with history of seizure. Therefore atomoxetine should be used with caution.

5.3.9 It was noted that, as with methylphenidate the main concerns of the committee were the duration of the treatment, long-term safety implications, review of patient treatment and the cost implications.

5.3.10 The committee agreed to add atomoxetine (Strattera®) to the LJF as a second choice drug, categorised AMBER, suitable for Shared Care Protocol use under the ADTC policy for unlicensed and off label medicines, subject to clarification of the above points.

ACTION: [redacted]

5.4 dexamphetamine (Dexetrine®)

5.4.1 The committee noted the FAF3 submission for the use of dexamphetamine (Dexetrine®) for the treatment of Attention Deficit Hyperactivity Disorder in Adults (>18yr).

5.4.2 No declarations of interests were included with the application.

5.4.3 The committee noted that dexamphetamine is already approved and used under Shared Care Protocol (SCP) in children.

5.4.4 It was noted that the clinical team are proposing to add dexamphetamine to the formulary as a third line therapy where other stimulant and non-stimulant medication has failed.

5.4.5 It was noted that the treatment will be initiated by specialist psychiatrist with continuation of therapy in primary care, under SCP, once the patient is stabilised on treatment.

5.4.6 It was noted that dexamphetamine is used within the UK in the treatment of adults with ADHD and examples of SCPs were provided for reference. A Lothian SCP has not been provided.

5.4.7 It was proposed that use would be in 7 patients per annum in Lothian.

5.4.8 The committee noted that the patient criteria are the same as for methylphenidate.

5.4.9 The committee noted that the evidence is based on one short-term randomised, double-blind, placebo-controlled study demonstrating the clinical effectiveness of dexamphetamine. The only significant side effect was weight loss. However studies of long-term efficacy have not been carried out yet.

5.4.10 It was noted that, as with the previously discussed ADHD drugs, the main concerns of the committee were the duration of the treatment, long-term safety implications, review of patient treatment and the cost implications.

5.4.11 The committee agreed to add dexamphetamine (Dexetrine®) to the LJF as a prescribing note, categorised AMBER, suitable for Shared Care Protocol use under the ADTC policy for unlicensed and off label medicines, subject to clarification of the above points.

ACTION: [redacted]

5.5 etonogestrel (Nexplanon®)

5.5.1 The committee noted the FAF3 submission for the use of etonogestrel (Nexplanon®) for the treatment of:

- Postpartum contraception for women with substance use issues whose lives are chaotic, find it difficult to access services and who are at high risk of an unintended pregnancy. For insertion within first 72 hours post delivery.
- Postpartum contraception for all other groups of women who find it difficult to access services and who are at high risk of an unintended pregnancy. For insertion within first 72 hours post delivery.
- Following abortion or miscarriage in second trimester – insertion within first 72 hours of abortion or miscarriage for all other groups of women who find it difficult to access services and who are at high risk of an unintended pregnancy.

5.5.2 One declaration of interest (personal specific) was included with the application.

5.5.3 It was noted that currently Depo-Provera, an injectable progestogen, is used immediately after delivery but it does require further injections every 12 weeks where Nexplanon® provides effective reversible contraception for 3 years.

5.5.4 The committee noted that Nexplanon® is currently the first choice contraceptive implant (only progestogen implant method available).

5.5.5 It was noted that the there is a safety concern about bleeding after implant but there is no evidence that off label insertion within 72 hours of delivery would enhance this problem.

5.5.6 The committee agreed to add etonogestrel (Nexplanon®) to the Additional List, for Specialist Use only, categorised RED under the ADTC policy for unlicensed and off label medicines.

ACTION: [redacted]

5.6 domperidone (Motilium®)

5.6.1 The committee noted the FAF3 submission for the use of domperidone (Motilium®) for the augmentation of lactation.

5.6.2 No declarations of interests were included with the application.

5.6.3 It was noted that there are no licensed galactogogues in the UK. Domperidone is the galactagogue of choice based on its safety and efficacy. It can be effective in augmentation of lactation when used in combination with established non-pharmacological support and breastfeeding measures and only after these measures have failed to increase breast milk adequately.

5.6.4 It was noted that the evidence is based on a several small studies which proved that the milk production was significantly higher in women taking domperidone.

5.6.5 The committee noted that no cardiac side effects have been reported during the studies however use of domperidone should be avoided in women with known cardiac disease and those with a diagnosis or family history of premenstrual onset of breast cancer. There are also theoretical concerns about long-term effects on the maturation of central dopamine mechanism in the newborn.

5.6.6 It was noted that the applicants have drafted guidelines for domperidone for augmentation of lactation. It was suggested that it would be beneficial to involve a group of GPs in this work to finalise the guideline.

5.6.7 The committee noted that Medicines and Healthcare products Regulatory Agency has issued a warning regarding the use of domperidone which should be included in the maternity guidelines.

5.6.8 The committee agreed to add domperidone (Motilium®) to the formulary, categorised AMBER under the ADTC policy for unlicensed and off label medicines.

5.6.9 It was noted that this classification is provisional, pending the D&TC minutes being homologated.

ACTION: [redacted]

6. SMC Abbreviated Submissions

6.1 adrenaline tartrate pre-filled syringes (Jext®)

adrenaline tartrate 150 and 300 microgram solution for injection in a pre-filled pen (Jext®) **No. 687/11**

ADVICE: following an abbreviated submission:

adrenaline tartrate pre-filled syringes (Jext®) is accepted for use within NHS Scotland.

Indication under review: emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis.

For patients at risk of anaphylaxis and requiring adrenaline, this is a new presentation of adrenaline for emergency use. It has an extended shelf life (24 months) compared with some existing products.

6.1.1 It was noted that an amendment to the LJF section has been approved at the meeting in March 2012.

6.1.2 The committee agreed to add adrenaline tartrate pre-filled syringes (Jext®) to the Lothian Joint Formulary.

6.1.3 Adrenaline tartrate pre-filled syringes (Jext®) will be **Included** on the Lothian Joint Formulary for the indication in question.

ACTION: [redacted]

6.2 bupivacaine + fentanyl (as citrate) (Bufyl®)

bupivacaine HCL 1.0mg/mL and 1.25mg/mL plus fentanyl (as citrate) 2 microgram/mL solution for infusion (Bufyl®) **No. 738/11**

ADVICE: following an abbreviated submission:

bupivacaine HCL 1.0mg/mL and 1.25mg/mL plus fentanyl (as citrate) 2 microgram/mL solution for infusion (Bufyl®) is accepted for use within NHS Scotland.

Indication under review: epidural analgesia to relieve pain during labour and to control post operative pain.

For patients in whom the combination of bupivacaine and fentanyl is an appropriate choice of therapy, Bufyl® provides two fixed-dose, pre-mixed preparations.

6.2.1 The decision made regarding this drug are no longer relevant, as following the meeting further information became available. This item will be brought back to the next FC meeting.

ACTION: [redacted]

7. Formulary Additions and Amendments

7.1 Formulary Additions

None.

7.2 Formulary amendment request forms

7.2.1 Pentasa 1g tablets

7.2.1.1 The committee noted the request to amend the gastrointestinal section of the LJF where Pentasa tablets are currently as first choice for the treatment of mild to moderate exacerbations of ulcerative colitis and the maintenance of remission of ulcerative colitis. It was requested to add Pentasa 1g strength to the formulary.

7.2.1.2 No declarations of interest were included with the application.

7.2.1.3 The committee noted that Pentasa 1g tablets offer less (half) tablet burden to patients compared to Pentasa 500mg tablets. Currently patients have to take 8 tablets daily for treatment of an acute attack of colitis and 4 tablets for maintenance treatment. As a result, patients are often switched to Mezavant XL or Pentasa granules as these preparations allow less tablet burden.

7.2.1.4 It was noted that although Pentasa 1g tablets are slightly more expensive then Pentasa 500mg, this will be offset by less patients being switched to Mezavant XL which is a significantly more expensive preparation.

7.2.1.5 The committee agreed to amend the gastrointestinal section and add Pentasa 1g strength to the formulary.

ACTION: [redacted]

7.2.2 Lidocaine 5% medicated plaster

7.2.2.1 The committee noted the request from paediatric pain team to change lidocaine 5% medicated plaster from second line treatment to first line for the treatment of neuropathic pain in children.

7.2.2.2 No declarations of interests were included with the application.

7.2.2.3 It was noted that lidocaine plasters are well tolerated, effective and often facilitate weaning of other medications.

7.2.2.4 The committee noted that lidocaine plasters will be obtained from secondary care outlets only and patients will remain under regular review by the pain management team while lidocaine patches are being prescribed.

7.2.2.5 It was noted that lidocaine is more expensive than the current first line treatment but this may be balanced by a likely reduced number of out patient appointments and possibly a decrease in the use of other analgesics if the treatment is successful. It also has a more patient friendly side-effect profile and has less effect on patients' daily routines.

7.2.2.6 The committee agreed to amend the pain management section of the paediatric LJF, section 4.7 analgesics and move lidocaine 5% medicated plaster to first choice.

ACTION: [redacted]

7.2.3 Magnesium aspartate (Magnaspartate®)

7.2.3.1 The committee noted the formulary amendment request to replace magnesium glycerophosphate capsules with magnesium aspartate (Magnaspartate®).

7.2.3.2 No declarations of interests were included with the application.

7.2.3.3 It was noted that Magnaspartate® is licensed as a food supplement whereas magnesium glycerophospate is an unlicensed special medicine.

7.2.3.4 It was noted that Magnaspartate® has also reduced dosing, at 2 sachets per day, as compared to magnesium glycerophosphate capsules at 12 capsules per day. It was noted that potential cost savings in secondary care, based on the 2010/11 usage could be £7,000 per annum.

7.2.3.5 The committee noted that the oncology GP information sheet would need to be reviewed with a view to changing it to cover other clinical areas. Magnaspartate® does have high sugar content; therefore, keeping some glycerphosphate for diabetic patients may need to be considered.

7.2.3.6 The committee agreed to amend the section 9 of the LJF and replace magnesium glycerophosphate capsules with magnesium aspartate (Magnaspartate®). It was noted that the oncology GP information sheet needs to be reviewed.

ACTION: [redacted]

8. NICE/SIGN/NHS QIS Clinical Guidance

March 2012

8.1 CG 139 Infection control – prevention and control of healthcare-associated infections

8.1.1 The committee noted and discussed the above NICE clinical guideline.

8.2 TA 249 Atrial fibrillation - dabigatran etexilate

8.2.1 The committee noted and discussed the above NICE technology appraisal guideline.

April 2012

8.7 TA 250 Breast cancer (advanced) - eribulin

8.7.1 The committee noted and discussed the above NICE technology appraisal guideline.

9. Drug Safety Issues – MHRA Advice

March 2012

9.1 MHRA Drug Safety Update, Volume 5, Issue 8, March 2012
http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con146571.pdf

9.1.1 The committee noted the drug safety update.

9.2 Ketoprofen-containing topical formulations
http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con146472.pdf

9.2.1 The committee noted the updated information.

9.3 Victrelis (boceprevir)
http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con146861.pdf

9.3.1 The committee noted the updated information.

9.4 Rasilez (aliskiren)
http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con146473.pdf

9.4.1 The committee noted the updated information.

9.5 Halaven (eribulin)
http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con146474.pdf

9.5.1 The committee noted the updated information.

9.6 Benlysta (belimumab)
http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con146915.pdf

9.6.1 The committee noted the updated information.

9.7 Onglyza (saxagliptin)
http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con146917.pdf

9.7.1 The committee noted the updated information.

9.8 Perfalgan (intravenous paracetamol)
http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con146920.pdf

9.8.1 The committee noted the updated information.

9.9 Samsca (tolvaptan)
http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con146921.pdf

9.9.1 The committee noted the updated information.

10. Antimicrobial Management Team Minutes

The committee noted the following AMT minutes for information:

- 15th February 2012

11. For Information Only

11.1 Formulary Committee Reports and Letters

The committee noted the following Formulary Committee reports and letters:

- boceprevir (Victrelis®) and telaprevir (Incivo®)
- levobupivacaine, sodium chloride, ketorolac and adrenaline
- prilocaine hydrochloride (Priloketal®)
- bendamustine hydrochloride (Levact®)
- erlotinib (Tarceva®)
- botulinum toxin type A (Botox®)
- epoetin (Eporatio®)
- exenatide (Byetta®)
- filgrastim (Nivestim®)
- filgrastim (Zarzivo®)
- iron isomaltoside (Monofer®)
- moxifloxacin (Avelox®)
- ticagrelor (Brilique®)
- valganciclovir (Valcyte®)
- valsartan (Diovan®)
- magnesium sulphate

12. AOCB

12.1 Formulary Management Audit

12.1.1 Further to the Formulary Management Audit Terms of Reference circulated to the FC members it was noted that the audit will commence from Monday 23rd April.

12.1.2 It was noted that it is not clear yet whether there would be any implications for FC members on an individual basis.

12.2 Formulary Committee Annual Reports for 2010/11 and 2011/12

12.2.1 It was noted that the annual reports were finalised and will be circulated to the FC members for their information.

13. Date of Next Meeting

13.1 The committee noted that the next meeting would be held on Wednesday 30th May 2012. *(The deadline for submission of papers for this meeting is close of play Tuesday 15th May 2012.)*

Apologies: Jenny Carson, Dr Philip Conaglen, Professor Stephen Lawrie