NHS GRAMPIAN
Minute of Formulary Group Meeting held on Tuesday 20th January 2015 in the Aspen Room, Forest Grove House

PRESENT	APOLOGIES	APPROVED
Dr D Culligan	Mr A Duncan	
Ms A Davie	Dr A MacDonald	
Ms F Doney	Mr M Paterson	
Mrs L Harper (until item 7.1)		
Dr C Hind		
Dr D Hood		
Professor J McLay (Chairman)		
Mrs L Montgomery		
Dr W Moore		
Mr C Rore		
Mr R Sivewright		
Dr A Sun		
Professor J Webster		

IN ATTENDANCE

Dr Margaret MacLeod, Consultant Neurologist, for the presentation on multiple sclerosis drugs.
Dr Callum Duncan, Consultant Neurologist, and Dr David Watson, GP with specialist interest in headache, for item 7.5.
Ms Kate Robertson, Secretary Formulary Team.

OBSERVERS VIA VIDEOCONFERENCE

Mrs Mary MacFarlane, Prescribing Advisor, NHS Shetland.
Mrs Sylvia Robertson, Primary Care Pharmacist, NHS Orkney.

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PRESENTATION

Dr MacLeod provided the Group with an update on the current treatment options for multiple sclerosis.

Note some items were taken out of agenda order

7.5 FG1 374/14 - BOTOX® - HEADACHE IN CHRONIC MIGRAINE

There were no declarations of interest recorded in relation to this product.

Dr Duncan and Dr Watson attended the meeting to present the submission for Botox® for headache management in chronic migraine. They left the meeting before decision-making. They confirmed that:

- Migraine:
  - has an estimated global prevalence of 14% making it the third commonest disease globally
  - has a heavy burden of illness for the patient and a high cost for the economy
  - is ranked by the World Health Organization seventh amongst all causes of years lived with disability
- for preventative treatment a good response is 50% reduction in headache or severity
- patients with chronic migraine, especially those failing multiple preventative treatments, represent a highly disabled population, and this is the population that the Headache service wishes to make Botox® available for
- Grampian and other Scottish Health Boards have requested Botox® on an individual patient basis via the Individual Patient Treatment Request process
- if accepted, six patients have been identified as eligible for treatment, none from Orkney or Shetland

References submitted:

1. NICE technology appraisal 260, Botulinum toxin type A for the prevention of headaches in adults with chronic migraine.
2. Sheena K, Aurora MD, Paul Winner DO, Marshall C, Freeman MD, Egilius L. et al. Onabotulinumtoxin A for the treatment of chronic migraine: pooled analyses of the 56-week PREEMPT clinical program. Headache 2011;51:1358-1373.

3. Khalil M, Zafar HW, Quarshie V and Ahmed F. Prospective analysis of the use of Onabotulinimtoxin A (Botox) in the treatment of chronic migraine; real-life data in 254 patients from Hull, UK. The Journal of Headache and Pain. 2014;15:54.
4. Glasgow Botox Audit.
5. The global burden of migraine: Measuring disability in headache disorders with WHO's Classification of Functioning, Disability and Health (ICF). Leonardi M., Steiner T.J., Scher A.T., Lipton R.B. Journal of Headache and Pain. 6 (6) (pp 429-440), 2005. Date of Publication: December 2005.
6. Migraine: the seventh disabler (Editorial). Steiner T.J., Stovner L.J., Birbeck G.L. The journal of headache and pain. 14 (1) (pp 1), 2013. Date of Publication: Dec 2013.

The Group noted:

- the poor evidence base, high placebo response and 25% failure rate
- that Botox®:
  - is the only botulinum toxin type A injection licensed for the prophylaxis of headaches in adults with chronic migraine. The manufacturer advises that botulinum toxin units are not interchangeable from one product to another.
  - is not recommended by SMC for this indication (SMC 692/11) but is accepted with restrictions by NICE (TA260 - three or more migraine preventatives have already been tried and medication overuse has been addressed)
- that use would be limited to Dr Duncan and Dr Watson working in the Headache service
- the Headache Service has drawn up selection criteria and prescribing guidance. The selection criteria are more restrictive than NICE TA260 and the prescribing guidance includes stopping rules.
- that the submission potentially underestimates the cost offset available as it does not consider the cost of injectable triptans (two injections per month ~ £40; minimum £480 per year). It was confirmed that most/all of the patients considered would be using injectable triptans as acute treatments.
- that no evidence was available to show that the use of Botox® reduces the use of preventative and/or acute migraine treatments, but the service is willing to audit the use of Botox®

The Group acknowledged that considering a licensed medicine not recommended by SMC is not normal process. However it noted that chronic migraine is a severely disabling condition and the group of patients identified by the Headache service would be considered at the extreme end of this having failed all other appropriate preventative options. The Group agreed that Botox® for the prophylaxis of headaches in adults with chronic migraine provided the potential for significant advantages for 'responders' in the patient group identified by the Headache service.

The Group accepted the local need for Botox® for the prophylaxis of headaches in a small group of adults with chronic migraine where medication overuse has been adequately addressed and all other appropriate preventative options have failed. Acceptance is subject to the service auditing use and providing feedback to the Group at a future date. **FD**

Botox® 50, 100, 200 Allergan units is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: the prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine).
Restriction:
- where medication overuse has been adequately addressed and,
- all appropriate preventative therapies have been tried and are not effective, not tolerated or contraindicated and,
- selection of appropriate patients and provision of Botox® is restricted to the NHS Grampian Headache Service.
It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Botox® should only be administered by physicians with appropriate qualifications and expertise in the treatment and the use of the required equipment.
Patients should be informed of the risk of distant spread of toxin (see MHRA). **FTeam**

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1. APOLOGIES

The Chairman welcomed members to the meeting and apologies for absence were requested and noted. **FD**
The Chairman confirmed that a quorum was present.

2. MINUTE OF THE MEETING HELD ON THE 16TH DECEMBER 2014

The Chairman reminded the Group that membership of the December meeting did not reach a quorum. The Group ratified the decisions of the December meeting and accepted the draft note subject to minor typographical changes. **FD**

3. MATTERS ARISING

3.1. NEW PRESENTATIONS OF FORMULARY MEDICINES

At the December meeting, the Group agreed that new presentations of current formulary medicines (new combination products, formulations, medicines presented in a different device) are not automatically included on the joint formulary but an abridged submission would be acceptable for these scenarios. The example of Medabon® was drafted as an example and starting point for the principles for the abridged submission. The Group was asked to consider the 'form' and Medabon® for inclusion on the formulary.

The Group noted that the 'abridged' form was not short (2-3 pages) and ran the risk of becoming too long. The Group accepted the 'abridged' submission as presented, subject to inclusion of the recommended classification and with the proviso that additional time was provided for the Group to review the form. Suggestions for amendment to be submitted to the Formulary Team by the next meeting (17th February). **All**

SMC 913/13 - MIFEPRISTONE TABLET AND MISOPROSTOL VAGINAL TABLETS COMBIPACK (MEDABON®)

There were no declarations of interest recorded in relation to this product.

The Group noted that:

- Medabon®:
  - is accepted for use within NHS Scotland following an abbreviated SMC submission, SMC 913/13
  - provides two current formulary medicines, mifepristone and misoprostol, in a combipack licensed for an indication where there were no fully licensed medications available on the market (misoprostol is not licensed for this indication)
  - will not completely replace current usage of mifepristone and misoprostol
- a post-authorisation safety study (Quintiles study) has received research and development approval. The service will be following the same protocol for all under 63 day medical abortions irrespective of persons consenting to help with the study
- the service undertakes continuous audit for much the same outcomes as the post marketing surveillance study
- patients will return to the service for the misoprostol dose they will not be taking medicines away for home consumption. The process for patients receiving their medicines on return to the service will form part of the protocol.

The Group accepted the local need for Medabon® as per SMC 913/13.

SMC 913/13 - Mifepristone tablet and misoprostol vaginal tablets combipack (Medabon®) is included on the Grampian Joint Formulary for the indication; restricted use.
Indication under review: for medical termination of developing intra-uterine pregnancy of up to 63 days of amenorrhoea.
For patients in whom mifepristone and misoprostol is an appropriate choice of therapy, Medabon® provides the two components in a single pack at a lower cost than the individual components. It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only.
Medabon® can only be prescribed and administered in accordance with the countries national laws and regulations. **FTeam**

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3.2. NICE (M)TA323 ERYTHROPOIESIS-STIMULATING AGENTS (EPOETIN AND DARBEPOETIN) FOR TREATING ANAEMIA IN PEOPLE WITH CANCER HAVING CHEMOTHERAPY (INCLUDING REVIEW OF TA142)

At the December meeting the Group noted that NICE TA323 (http://www.nice.org.uk/guidance/TA323) represents a material change in the recommendations for use of erythropoiesis-stimulating agents (epoetin alfa, beta, theta and zeta, and darbepoetin alfa) for treating anaemia in people with cancer who are having chemotherapy. Advice is still awaited from the oncology service regarding the local need for erythropoiesis-stimulating agents for this indication. However choice of agent becomes a procurement rather than formulary decision. The financial implications of this change will be brought to Group when available. Any changes to local guidance/guidelines will be considered by the Medicine Guidelines and Policies Group. **FD CH**

The Group ratified the recommendations of NICE TA323:

- erythropoiesis-stimulating agents (epoetin alfa, beta, theta and zeta, and darbepoetin alfa) are recommended, within their marketing authorisations, as options for treating anaemia in people with cancer who are having chemotherapy
- if different erythropoiesis-stimulating agents are equally suitable, the product with the lowest acquisition cost for the course of treatment should be used **FTeam**

3.3. SCOTTISH PALLIATIVE CARE GUIDELINES

It was confirmed that the Palliative service is working to update the local intranet site and relevant sections of the NHSG Palliative and Supportive Care Plan to bring doses into line with national recommendations. Locally the official launch of the Scottish Palliative Care Guidelines is planned for the end of March.

3.4. BUDGET ALLOCATIONS FROM DECEMBER 2014 MEETING

This item was discussed under item 6.2.

3.5. FG1 SMC 1003/14 AFLIBERCEPT

At the December meeting a query was raised regarding the evidence available to support sequencing of intravitreal vascular endothelial growth factor inhibitors. The service has confirmed that if a patient fails with one vascular endothelial growth factor inhibitor a trial with the other would be offered. It is unknown what proportion is likely to respond to the second agent.
The service considers the suggestion not to offer a patient an alternative licensed treatment, where another has failed, unethical.

It was confirmed that the licence for both agents (ranibizumab and aflibercept) and subsequent SMC acceptance does not preclude sequencing.

4. FORMULARY GROUP DECISIONS DECEMBER 2014 – PUBLISHED 29/12/2014

The Group ratified the advice as published.

5. CMO(2012)1 REPORTING FOR SCOTTISH MEDICINES CONSORTIUM (SMC) ADVICE - 2014/15 YTD

It was confirmed that for the SMC accepted medicines published April to December 2014 the Formulary Group audit standard for CMO(2012)1 reporting (90%) was achieved for the following criteria:

- Local decision on SMC accepted medicine published within 90 days: 54 of 54 - 100%
- FG decision published within 14 days of the decision being reached: 54 of 54 - 100%

6. OTHER BUSINESS

6.1. NICE MULTIPLE TECHNOLOGY APPRAISAL GUIDANCE - NONE

6.2. FINANCE UPDATE

FORMULARY GROUP ALLOCATION

The Group noted the FG budget allocation for 2014/15 is £1million, which is considered as the ‘in-year’ spend on specific managed service approved medicines, it is not the ‘full year’

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funding required for the introduction of these medicines.
It was reported that to date £760,000 has been drawn down for spend on specific managed service formulary approved medicines. As several 14/15 formulary approved medicines remaining 'unfunded' a financial risks document will be drafted and brought to the February meeting. **FD/RS**

FORMULARY GROUP COST PRESSURES 2015/16

It was reported that the Formulary Group budget cost pressures estimates were included in the 2015/16 Budget Paper as appendices. The information is based on information from SMC Forward Look. The estimated cost pressure is £8million (£3-4million in-year cost). The Group was reminded that the estimates are based on full year costs (annual costs or cost per course as appropriate including VAT) but make no allowance for patient access schemes.
The Group noted that medicines for rare conditions represent an additional risk as the SMC impact templates make no allowance for these medicines. In addition, it is not clear if funding of these medicines will be considered under the New Medicines Fund, and the fund is only guaranteed until the end March 2016.

6.3. PATIENT ACCESS SCHEMES (UPDATE, DYMISTA® PRICE REDUCTION)

The Group noted that Meda Pharmaceuticals has temporarily reduced the price of Dymista®. The list price is below the patient access scheme (PAS) price so the PAS has been suspended from 1st January 2015 to 31st December 2016. It was confirmed that there is some (non-formulary) use of the product locally and the relevant primary care PAS rebate is being recouped. **FD/RS**

7. NEW PRODUCT REQUESTS

7.1. FG1 375/14 - GANCICLOVIR - OCULAR HERPES SIMPLEX

There were no declarations of interest recorded in relation to this product.

The Group noted:
- that aciclovir eye ointment is the first-choice agent. However due to a manufacturing problem and recent product recall supplies of aciclovir are limited.
- ganciclovir ophthalmic gel:
  - is approximately double the costs of aciclovir
  - is requested as a second-choice agent
- when aciclovir stocks are exhausted ganciclovir would be available for first-line use
- the submission is supported by the Antimicrobial Management Team

The Group accepted the local need for ganciclovir eye ointment as a second-line option for the local treatment of ocular herpes simplex infection.

Ganciclovir 0.15% eye gel (Virgan®) is included on the Grampian Joint Formulary for the indication in question.
Indication under review: local treatment of herpes simplex infection (ocular).
Restriction: to use as a second-line agent.
It was classified 1a - available for general use and 8d - treatment may be initiated in the community on the recommendation of a consultant/specialist. **FTeam**

7.2. FG1 SMC 1009/14 - TRIUMEQ® ▼ - HUMAN IMMUNODEFICIENCY VIRUS

There were no declarations of interest recorded in relation to this product.

The Group considered the submission for Triumeq® ▼, a new combination tablet containing the three antiviral agents dolutegravir (50mg), abacavir (600mg) plus lamivudine (300mg).

The Group noted that:
- the submission is from the adult service but Triumeq® ▼ is licensed for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age. The paediatric service has confirmed that it would be a useful additional for adolescent patients.

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- the submission is supported by the Antimicrobial Management Team
- several new HIV medicines and new combination tablets have been accepted to formulary over the past few years but no medicines have been removed from the formulary. A review of current formulary medicines and prescribing guidelines will be requested via the Medicines Guidelines and Policies Group. **CH**
- the financial implications of the introduction of Triumeq® ▼ are unclear

The Group accepted the local need for Triumeq® ▼ for the treatment of HIV infected adults and adolescents above 12 years as per SMC 1009/14. A Formulary Group budget allocation was not issued due to uncertainties with the potential costs/offset, advice will be sought from the Antibiotic Pharmacists. **FD/AbPh**

SMC 1009/14 - Dolutegravir 50mg, abacavir 600mg plus lamivudine 300mg (Triumeq® ▼) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents above 12 years of age weighing at least 40 kg.
In patients for whom this combination is appropriate, it offers a single tablet at a lower cost per dose compared with the individual components.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of Triumeq® ▼ and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Therapy should be prescribed by a physician experienced in the management of HIV infection. **FTeam**

7.3. FG1 SMC 999/14 – POSACONAZOLE 100MG GASTRO-RESISTANT TABLETS

There were no declarations of interest recorded in relation to this product.

The Group noted that:
- posaconazole oral suspension is already included on the formulary for this indication
- the formulary request is based on an abbreviated SMC submission, which notes "*Posaconazole plasma concentrations are generally higher following administration of posaconazole tablets than posaconazole oral suspension. The tablet and oral suspension are therefore not to be used interchangeably. While the tablets are cost saving when administered for treatment they are significantly more expensive than the oral suspension when administered for prophylaxis*."
- the majority of use locally will be for prophylaxis

It was confirmed that other Boards have already moved to the tablets, and the cost difference between tablets and oral suspension for prophylaxis may not be as large as intimated in the SMC abbreviated submission.

The Group accepted the local need for posaconazole 100mg gastro-resistant tablets (Noxafil®) as per SMC 999/14 subject to clarification of costs associated with introduction. **FD**

SMC 999/14 - Posaconazole 100mg gastro-resistant tablets (Noxafil®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: in the treatment of the following fungal infections in adults:
- Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products;
- Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B;
- Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole;
- Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products.
for prophylaxis of invasive fungal infections in the following patients:
- Patients receiving remission-induction chemotherapy for acute myelogenous

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leukaemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropaenia and who are at high risk of developing invasive fungal infections;
- Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high risk of developing invasive fungal infections.
Restriction: to patients in whom there is a specific risk of Aspergillus infection or where fluconazole or itraconazole are not tolerated on the advice of local microbiologists or specialists in infectious diseases.
Posaconazole plasma concentrations are generally higher following administration of posaconazole tablets than posaconazole oral suspension. The tablet and oral suspension are therefore not to be used interchangeably.
It was classified 1b – available for restricted use under specialist supervision and 8b – recommended for hospital use only. Treatment should be initiated by a physician experienced in the management of fungal infections or in the supportive care in the high risk patients for which posaconazole is indicated as prophylaxis. **FTeam**

7.4. FG1 SMC 1017/14 - OMALIZUMAB – CHRONIC SPONTANEOUS URTICARIA

A member declared a personal, non-specific interest in relation to this product.

The Group noted that:

- omalizumab (75mg and 150mg injection) is already included on the formulary for restricted use for severe persistent allergic IgE-mediated asthma (6 years and over)
- the formulary submissions were from adults service, Immunology and Dermatology, but omalizumab 150mg injection for chronic spontaneous urticaria is licensed for patients 12 years and above
- prescribing for chronic spontaneous urticaria will be limited to the specialist areas
- costs include the provision of adrenaline autoinjectors
- initial injections require a couple of hours monitoring for allergic effects so introduction has additional service implications
- there is a potential gap in provision for adolescents 12-16 years. The relevant specialists will be contacted to confirm local need. **FD**

The Group accepted the local need for omalizumab 150mg solution for the treatment of chronic spontaneous urticaria in adult and adolescent 12 years and above as per SMC 1017/14. A budget allocation was not issued as the anticipated costs were below the Formulary Group funding level.

SMC 1017/14 - Omalizumab 150mg solution for injection (Xolair®) is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.
Restriction: use in adults and adolescents with chronic spontaneous urticaria who have an inadequate response to combination therapy with H1 antihistamines, leukotriene receptor antagonists (LTRA) and H2 antihistamines, used according to current treatment guidelines.
The addition of omalizumab to combination therapy with H1-antihistamines, and/or leukotriene receptor antagonists and/or H2-antihistamines was more effective than placebo in reducing the weekly itch severity score (ISS) at 12 weeks.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost effectiveness of omalizumab and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Omalizumab treatment should be initiated by physicians experienced in the diagnosis and treatment of chronic spontaneous urticaria. **FTeam**

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7.6. FG1 SMC 972/14 – POMALIDOMIDE – MULTIPLE MYELOMA

A member declared a personal, non-specific interest in relation to this product.

The Group noted:

- that pomalidomide provides another line of treatment (fourth-line agent) for patients with relapsed and refractory multiple myeloma (third-line for those unable to tolerate or have contraindications to thalidomide)
- there is currently no standard of care after progression, treatment is tailored to patients
- that evidence comes from one study, MM-003, that compared the efficacy and safety of pomalidomide plus low-dose dexamethasone with high-dose dexamethasone in patients with refractory or relapsed and refractory multiple myeloma. The primary outcome was progression-free survival (PFS) and the median PFS was 16.5 weeks and 8.2 weeks respectively; secondary outcome overall survival (OS) and the median OS was 12.7 months and 8.1 months respectively.
- the high cost of treatment (£8,945 per 28-day cycle, ex VAT, ex PAS), and costs are supplementary as this is additional line of therapy
- no prevalent patients require treatment as the Individual Patient Treatment Request route has been used when eligible patients were identified

The Group noted the uncertainty in survival estimates and the high cost-effectiveness ratio (ICER ~ £57k/QALY gained) that was accepted by SMC in the context of the SMC decision modifiers. [*The Committee considered the benefits of pomalidomide in the context of its decision modifiers that can be applied when encountering high cost-effectiveness ratios or where there is increased uncertainty. The committee concluded that the criteria for a substantial improvement in life expectancy and absence of other treatment options of proven benefit were met.*
After application of the appropriate modifiers, the Committee accepted pomalidomide for use in NHS Scotland].

The Group noted pomalidomide is accepted for use within NHS Scotland for the indication in question and accepted the local need as directed in SMC 972/14. To allow the introduction of pomalidomide for the treatment of multiple myeloma as per SMC 972/14 a full year cost estimate of £400,000 was agreed and will be highlighted with finance **RS**

SMC 972/14 - Pomalidomide 1mg, 2mg, 3mg and 4mg hard capsules (Imnovid®) ▼ is included on the Grampian Joint Formulary for the indication in question; restricted use.
Indication under review: in combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.
Pomalidomide plus dexamethasone significantly increased progression-free survival compared with high-dose dexamethasone in patients with refractory or relapsed and refractory multiple myeloma.
This advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of pomalidomide and is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment must be initiated and monitored under the supervision of physicians experienced in the management of multiple myeloma. **FTeam**

The Group discussed the implications of funding medicines with high cost-effectiveness ratios. It was confirmed that the route for accessing New Medicines Fund monies was not clear, or if pomalidomide would be eligible for New Medicines Fund monies. Professor Webster and Ms Doney to draft a letter to Shona Robison MSP, Cabinet Secretary for Health, Wellbeing and Sport. **JW/FD**

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8. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE – ISSUED JANUARY 2015

The Group noted the SMC provisional advice issued January 2015.

If published next month the negative SMC recommendations for abiraterone acetate (Zytiga®) SMC 873/13 and colestilan (BindRen®) SMC 939/14 will not be included on the Grampian Joint Formulary for the indications in question. **FTeam**

It was confirmed that from 1st January 2015 Mitsubishi Tanabe Pharma Europe ceased all UK sales, promotion and marketing activities for BindRen® tablets and granules. In due course it will request a voluntary withdrawal of the marketing authorisation.

9. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED JANUARY 2015

The Group noted the SMC advice published January 2015.

Following publication of the negative SMC recommendation for bevacizumab (Avastin®) SMC 806/12 it will not be included on the Grampian Joint Formulary for the indication in question. **FTeam**

The following SMC accepted medicines have not been processed within a 60-day timescale:

- aztreonam lysine (Cayston®) SMC753/12
- olodaterol (Striverdi® Respimat®) SMC 974/14
- cetuximab (Erbitux®) SMC 1012/14 (submission expected)
- brimonidine (Mirvaso®) SMC 1016/14
- peginterferon-beta-1a (Plegridy®) SMC 1018/14 (submission received)
- canagliflozin plus metformin (Vokanamet®) SMC 1019/14

Local advice for these medicines and indications will be included in the January 2015 decisions as: "**not included on the Grampian Joint Formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine for the indication in question**." **FTeam**

10. GENERAL INFORMATION FROM SMC JANUARY 2015

This item was noted.

11. DOCUMENTS FOR INFORMATION

Items 11.1 (Drug Safety Update December 2014) and 11.3 NHS Grampian pregabalin letter (dated 19th December 2014) were noted.

ITEM 11.2 – DRUG SAFETY LETTERS

It was confirmed that a monthly summary has not been issued since the release of the Information sent to healthcare professionals in October. The MHRA will be contacted to confirm if this is a temporary delay or if this advice is no longer issued by the MHRA. **FD**

12. AOCB - NONE

DATE OF NEXT MEETING

The date of the next meeting was confirmed as Tuesday 17th February 2015 starting at 14.30 in the Aspen Room Forest Grove House.

CHAIRMAN'S SIGNATURE **DATE 17th February 2015**