Welcome to the February edition of the Area Drug and Therapeutics Committee (ADTC) Collaborative newsletter. In this edition, we'd like to share with you some exciting news about our new team members and some of our current work on behalf of ADTCs.

If you have any comments on the new look or if you have issues with viewing the newsletter, please contact us at hcis.adtc-collaborative@nhs.net.

Previous editions of our newsletters are still available on the Healthcare Improvement Scotland website here.

**PACS tier 2 National Appeal Panel (NAP)**

The National Appeal Panel (NAP), is a mechanism for the national review of PACS tier 2 appeals. Four mock panels have been held, on 20 September 23 November, 20 December and 25 January. These proved to be a valuable way to help fine tune the roles of panel members and the process and the approach panel members should follow to ensure consistency of practice for each case. Once guidance on PACS Tier 2 is launched, the panels will be held on a monthly basis and will replace appeals at local board level.

Over the next few months, work will continue on the development of National Appeal Panel processes. A number of public partners have been recruited to participate in panels and will attend an induction workshop in March.

The Scottish Government will be reissuing PACS Tier 2 guidance in the coming weeks with an implementation date of 1 June 2018. National Appeal Panel dates in 2018 are scheduled for:

- 27 June
- 25 July
- 28 August
- 26 September
- 24 October
- 21 November
- 19 December

**Biosimilars Medicines: A National Prescribing Framework**

The refresh of the Biosimilar Medicines Framework has now been published and will soon be added to the Healthcare Improvement Scotland website. The link to the document will be sent to all ADTC Chairs and Secretaries when available.

This brings guidance on biosimilars up to date and reflects on whether different approaches to biosimilar medicines are required in different clinical specialties, how biological and biosimilar
medicines should be prescribed and product details recorded, safety concerns, monitoring of all
biological medicines, how to switch from an original biological medication to biosimilar medicine and
what information should be provided to patients.

The aim of the prescribing framework is to inform clinical-decision making and support the safe,
effective and consistent use of biosimilar medicines in NHSScotland. The updated prescribing
Framework has been developed using experience to date and expertise from ADTCs and the
NHSScotland expert advisory group. The revision of this framework has been updated to reflect
learning within Scotland and UK wide over the last 2 years and will underpin the drive to improve
use of biologic medicines including biosimilars.

**Early Access to Medicines Scheme (EAMS)**

The Healthcare Improvement Scotland (HIS) website contains current EAMS operational guidance for
boards on its ADTC Collaborative webpage. Recently we have had enquiries from boards about
EAMS medicines where the guidance was not yet available on the ADTC Collaborative webpage due
to ongoing negotiations with pharmaceutical companies about various issues. To minimise delays for
patients, if boards have patients whom they feel might benefit from the use of an EAMS medicine
clinicians can access EAMS medicines without waiting for the ADTC Collaborative to issue
operational guidance by obtaining the relevant current EAMS information on the [MHRA current
EAMS scheme](https://www.mhra.gov.uk/web/default.aspx) webpage.

Operational guidance for expired EAMS medicines will be removed from the ADTCC webpage as
soon as practical after withdrawal. We will also send an email to ADTCs alerting them to the
withdrawal and attaching an annotated copy of the original EAMS guidance. To find out quickly if an
EAMS for a medicine has been withdrawn, including stop dates, check expired EAMS information on
the [MHRA expired EAMs scheme](https://www.mhra.gov.uk/web/default.aspx) webpage.

It is important that boards exercise due governance with regard to EAMS medicines. The collection
of pharmacovigilance data is mandatory for EAMS medicines. The collection of other information,
for example, real world data or patient questionnaires, is optional and subject to local board
governance considerations and approval before being undertaken. ADTCC has no powers to
undertake this governance on behalf of boards so please ensure that clinicians involved in an EAMS
understand the local process which has to be followed for the collection of patient data.

An end to end diagram of the operation of the EAMS process in NHS Scotland, including some FAQs,
is now available on the HIS ADTC Collaborative webpage.

The EAMS team had a busy time over the festive period and in January, when the details of two new
EAMS, for Emicizumab and Nivolumab, were added to the ADTC Collaborative page of the HIS
website with the existing one for Idebenone (Raxone). The nivolumab EAMS presented a new issue
of the collection of additional real world data. We would appreciate feedback to the usual email
address on any experience of collecting such data, patient views etc. This will help us work on behalf
of ADTCs in the future as real world data collection increases.
Emicizumab (EAMS No. 00031/0004) – January 2018
Emicizumab for routine prophylaxis of bleeding episodes in patients, aged one and over, with haemophilia A, with factor VIII inhibitors.

We have just received a communication that emicizumab has now received marketing authorisation (MA) for routine prophylaxis of bleeding episodes in patients with haemophilia A with factor VIII inhibitors.

As a result, MHRA has withdrawn the early access to medicines scheme (EAMS) scientific opinion on 28th February 2018. However, for those patients who have been considered for emicizumab EAMS at the time of marketing authorisation, the MHRA has agreed to extend the enrolment period until 14th March 2018. Therefore, you will have until 14 March 2018 to submit applications for these patients. When you submit the EAMS application, you will be requested to confirm that the patient was under consideration for EAMS on or before 28 February 2018.

Patients already enrolled into this EAMS will continue to receive free emicizumab until reimbursement. Any re-supply request should be sent to welwyn.emicizumabeams@roche.com using the re-supply form provided in your physician pack.

Nivolumab (EAMS No. 15105/0008) – January 2018
Nivolumab for the treatment of adult patients with advanced or recurrent Gastric or Gastro-esophageal Junction (GEJ) adenocarcinoma after two or more prior systemic therapies.

Idebenone (Raxone) (EAMS No. 46555/0001) – July 2017
Idebenone (Raxone) for Duchenne muscular dystrophy operational arrangements for NHS Scotland.


Medicines and ADTC Collaborative new team members
We’re delighted to welcome two new National Clinical Leads and a Project Officer to the Medicines / ADTCC Team; Ewan Bell, the National Clinical Lead (Medical), and Stephen Bowhay, the National Clinical Lead (Pharmacy), will provide support for the National Appeal Panel (NAP) PACS Tier 2 work. They will be working closely with the ADTC Collaborative team. Karen King is the Project Officer for the ADTC Collaborative and NAP.

Ewan Bell

Having graduated from Glasgow University in 1990, I spent the next seven years as a Junior Doctor in just about all the Glasgow hospitals, dabbling in Acute Medicine, Diabetes and a bit of research. In 1997 I became a West of Scotland SpR in Clinical Biochemistry, again rotating through just about all the Glasgow hospitals. Bored with Glasgow, I moved to Philadelphia in 2000 for two years to work as a Post-doc researcher, using my research in islet transplantation as the basis for my MD in 2004. A Consultant Clinical Biochemist post in NHS Dumfries and Galloway beckoned in 2005 and thereafter I pursued medical management culminating in an exhausting but worthwhile
two years as Associate Medical Director for Acute and Diagnostics! Now that I can breathe (and think) I Chair the D&G ADTC and lead on Realistic Medicine. I am excited to be given this opportunity to be National Clinical Lead for the NAP. In my spare time I am house-husband to my wife Kirsty, dad to two lads (Keir and Ruaraidh) and a step-daughter (Holly), and dog walker of three whippets (Poppy, Daisy and Belle). All that’s enough to keep me busy and out of trouble!

Stephen Bowhay

I have been Lead Clinical Pharmacist for Hospital Paediatrics and Neonatology in Glasgow for the last 10 years. Prior to this I had appointments in both clinical and managerial roles in both Forth Valley and Lanarkshire. I have gained experience in IPTR, PACS and ULM processes in my areas of clinical interest, namely, neurology, respiratory and metabolic medicine.

At present, I am Chair of the Scottish Neonatal and Paediatric Pharmacists group (SNAPP) and works nationally in managed clinical networks for paediatric, endocrine and metabolic medicine. Throughout the United Kingdom, I am a member of the UK-wide Paediatric Chief Pharmacist Network. I am the professional secretary for the GGC Paediatric Drugs and Therapeutic Committee.

Karen King

Currently on secondment from SIGN, I joined the team as Project Officer to work for both the ADTC Collaborative and the National Appeal Panel. Prior to joining HIS, I had a number of admin roles within the financial sector and NHS Fife. In 2011, I gained a B.Sc in Business Management.

In my spare time, I am a non-acting member of the management committee for Limelight Productions, a local amateur theatre company in Dunfermline.

Dates for your diary

Single National Formulary Network Meeting

The next Formulary Network meeting is scheduled to take place on 25 April 2018. More details to follow.

Access to new medicines bi-monthly WebEx for ADTC Chairs and Professional Secretaries

This WebEx series is open to any ADTC members who wish to attend and these are scheduled at the following times for 2018:

- 14 March 2018 – 2pm-4.30pm
- 9 May 2018 – 2pm-4.30pm
- 11 July 2018 – 2pm-4.30pm
- 12 September 2018 – 2pm-4.30pm
- 14 November 2018 – 2pm-4.30pm

To provide feedback, unsubscribe or contact us for more information:

hcis.adtc-collaborative@nhs.net

ADTCC Collaborative · Delta House · 50 West Nile St · Glasgow, G1 2NP · United Kingdom