

# The Appraisal Process and Recent Updates

*...to get the best outcomes from medicines for Wales...*



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All Wales Therapeutics and  
Toxicology Centre



**AWTTC**  
All Wales Therapeutics  
& Toxicology Centre

# Summary of appraisal recommendations 2016

- 25 appraisals carried out by AWMSG between April 2016 and 1<sup>st</sup> November 2016
- 23 (92%) has resulted in a full or optimised AWMSG recommendation
- Median time from agreeing the scope of a submission to ratification of 23 weeks





# Three new processes

- Orphan/Ultra-orphan medicines and medicines for rare diseases
- Review process
- One-Wales for considering specific medicines that are associated with a 'cohort'



# Latest updates

- Important documentation changes
- AWMSG appraisal of medicines not recommended by NICE
- Consideration of NICE Highly Specialised Technology advice
- NICE Accreditation
- Positive AWMSG recommendations continue to increase



Form B submitted for an orphan / ultra-orphan  
medicine or medicine developed specifically  
for rare diseases



AWTTC prepares an assessment of the evidence (the ASAR)  
and provides comment on the applicability of the orphan  
/ultra-orphan criteria



Draft ASAR sent to applicant company for comment  
ASAR may be subsequently updated in light of comments received



Preliminary appraisal by the New Medicines Group (NMG)  
Preliminary recommendation and final ASAR sent to applicant  
company for comment within 5 working days from NMG meeting



Applicant company requests a meeting of CAPIG  
following a negative NMG recommendation  
Appraisal process is suspended and a meeting of  
CAPIG is convened (an additional 8-12 weeks may  
be added to the normal appraisal timeline)



CAPIG meeting held



The information submitted by CAPIG is  
considered by AWMSG along with the usual  
meeting documentation



Applicant company accepts the NMG preliminary  
appraisal recommendation  
  
The appraisal process continues and appraisal by  
AWMSG is undertaken within normal timelines



# Orphan/Ultra orphan/rare diseases

- Five ultra orphan medicines and three orphan medicines have been appraised by AWMSG
- All were recommended or recommended for optimised use
- Two received an initial negative recommendation and were subsequently approved by AWMSG following a CAPIG meeting
- Review planned early next year involving key stakeholders



# Review Process

- Aim- all recommendations remain current and appropriate
- Always been opportunity to re-engage with significant new data (negative or restricted recommendation)
- Action taken
- All medicines with positive advice Oct 2011
- Statement of advice will be contacted in the first quarter of 2017





# Benefits to HTA as a result of One Wales process

- Intelligence strengthened links between HTA and 'cohort' requests considered by IPFR panels
- Unmet need/clinical demand
- Improves equity of access
- Three medicines have been identified as appropriate for AWMSG appraisal



# Documentation changes

- Forms have been extensively revised to enable the provision of more comprehensive information
- Guidance notes updated
- Excel-based budget impact template introduced to enable a more consistent approach



# **AWMSG appraisal of medicines not recommended by NICE**

- Process changed to allow the opportunity for an AWMSG submission- NICE non recommendation but available in England via alternative national commissioning route e.g. CDF
- Since April 2015 four medicines have been re-considered by AWMSG (three received full or optimised recommendation)



# Consideration of NICE Highly Specialised Technology advice

- Three medicines recommended by AWMSG subsequent to a positive recommendation from NICE
- Process for consideration of medicines in receipt of NICE HST advice has been refined
- Advice for Wales now issued more timely (>7 months vs. 1 month)



# NICE Accreditation

- AWMSG processes received NICE accreditation in October 2011
- Re-accreditation process is currently underway
- Early feedback is promising that processes will continue to carry the accreditation mark





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## About us

# All Wales Therapeutics and Toxicology Centre (AWTTC)

Providing prescribing and medicines optimisation services

**Why?** Create a healthier, better-informed Wales

**How?** Excellence in delivery of a portfolio of services in therapeutics and toxicology

**What?** Aim to be the authority on therapeutics and toxicology in Wales, liaising with, informing and assisting healthcare professionals, involving patients and the general public and advising Welsh Government, as well as engaging with the pharmaceutical industry

**AWTTC comprises five organisations:**



-  **PAMS**  
Patient Access to Medicines Service
-  **WAPSU**  
Welsh Analytical Prescribing Support Unit
-  **WeMeReC**  
Welsh Medicines Resource Centre
-  **WNPU**  
Welsh National Poisons Unit
-  **YCC Wales**  
Yellow Card Centre Wales



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## All Wales Therapeutics & Toxicology Centre

AWTTC delivers services in the fields of therapeutics and toxicology by bringing together, under one banner, five different NHS organisations that provide continuing support and advice relating to the safe, clinically and cost-effective use of medicines in Wales.

[Find out more](#)



**PAMS**

Improving access to medicines



**WAPSU**

Analysing prescribing data and developing medicines optimisation resources



**WeMeReC**

Providing education in therapeutics, prescribing and behavioural change



**WNPU**

Part of NPIS, providing 24hr poisons advice to healthcare professionals



**YCC Wales**

Monitoring adverse drug reactions

### News

#### One Wales Interim Commissioning Advice:

Arsenic trioxide (TRISENOX®) in combination with all-trans retinoic acid is supported for the

### Events

AWTTC will be hosting the AWMSG Masterclass on 23rd November 2016

AWTTC is supporting the AWMSG training day on 18th January 2017

### Resources

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### Adalimumab (Humira®) for uveitis in adults: One Wales Interim Commissioning decision

 PAMS Category: News and events, Advice Last modified 10 Nov 2016


Adalimumab (Humira®) for the treatment of adult patients with severe refractory non-infectious uveitis. Advice date: October 2016.  
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### Adalimumab (Humira®) for uveitis in children: One Wales Interim Commissioning decision

 PAMS Category: News and events, Advice Last modified 10 Nov 2016

Adalimumab (Humira®) for the treatment of paediatric patients with severe refractory non-infectious uveitis. Advice date: October 2016.  
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### IPCG Meeting Minutes 22nd August 2016

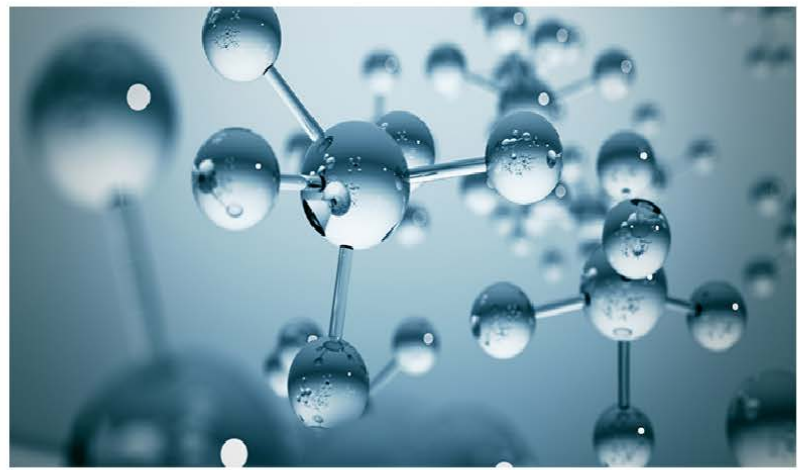
 PAMS Last modified 26 Oct 2016

Interim Pathways Commissioning Group Meeting Minutes 22nd August 2016  
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Welsh Analytical Prescribing  
Support Unit



**WeMeReC**  
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Patient Access to Medicines Service (PAMS) aims to ensure that



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**WNPU**

The Welsh Analytical Prescribing Support Unit (WAPSU) aims to



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## About us



**The Welsh Medicines Resource Centre (WeMeReC) is a source of independent information for all healthcare professionals and advisors working in Wales.**

We provide education in therapeutics, prescribing, and behavioural change through a combination of digital



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# Our work



**Welsh National Poisons Unit**



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### The Yellow Card Centre Wales

YCC Wales is one of five regional adverse drug reaction monitoring centres, acting on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA). YCC Wales has a vital educational and communicating role to encourage suspected adverse reaction reporting via the Yellow Card Scheme (spontaneous reports of suspected adverse drug reactions) to both patients and local health professionals in Wales. Staff at YCC



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# Thank you



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