

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
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Summary of appraisal recommendations 2016

- 31 appraisals carried out by AWMSG between April 2016 and 31st December 2016
- 31 (91%) has resulted in a full or optimised AWMSG recommendation
- Median time from agreeing the scope of a submission to ratification of 21.5 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)**



**Applicant company accepts the NMG preliminary
appraisal recommendation

The appraisal process continues and appraisal by
AWMSG is undertaken within normal timelines**



CAPIG meeting held



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



Orphan/Ultra orphan/rare diseases

- Six ultra orphan medicines and four 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 this 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

[One Wales Process](#)

 PAMS

 WAPSU

Results

Documents **7**

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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. [Get Resource](#)

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. [Get Resource](#)

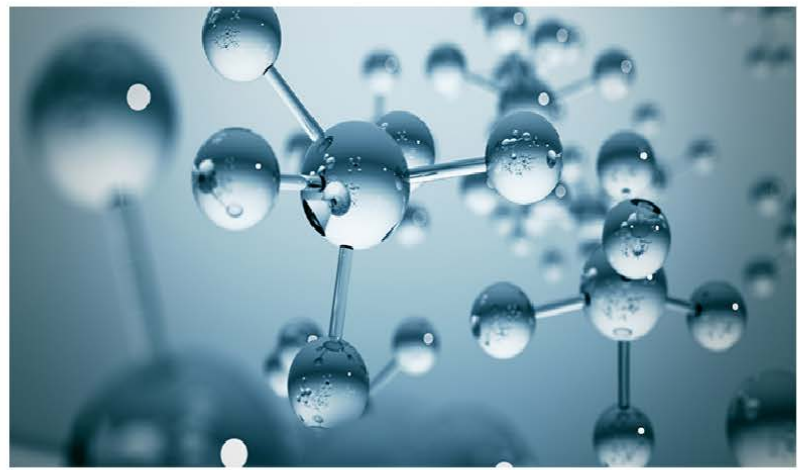
IPCG Meeting Minutes 22nd August 2016

 PAMS Last modified 26 Oct 2016

Interim Pathways Commissioning Group Meeting Minutes 22nd August 2016 [Get Resource](#)



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WAPSU
Welsh Analytical Prescribing
Support Unit



WeMeReC
Welsh Medicines Resource
Centre

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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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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