Company engagement

AWTTC
All Wales Therapeutics & Toxicology Centre

Early engagement

1. Enables AWTTC to decide whether a medicine meets the AWMSG criteria for appraisal

2. Provides AWTTC and the applicant company with the opportunity to discuss the appraisal scope, including relevant comparators and submit a WPAS (if applicable) in a timely fashion

3. Results in medicines being appraised and AWMSG advice issued as close to licence as possible.

Timeline exercise

Form A – initial appraisal information

Submitted by the company and contains horizon scanning information. This form enables AWTTC to determine whether the medicine meets the AWMSG criteria for appraisal.

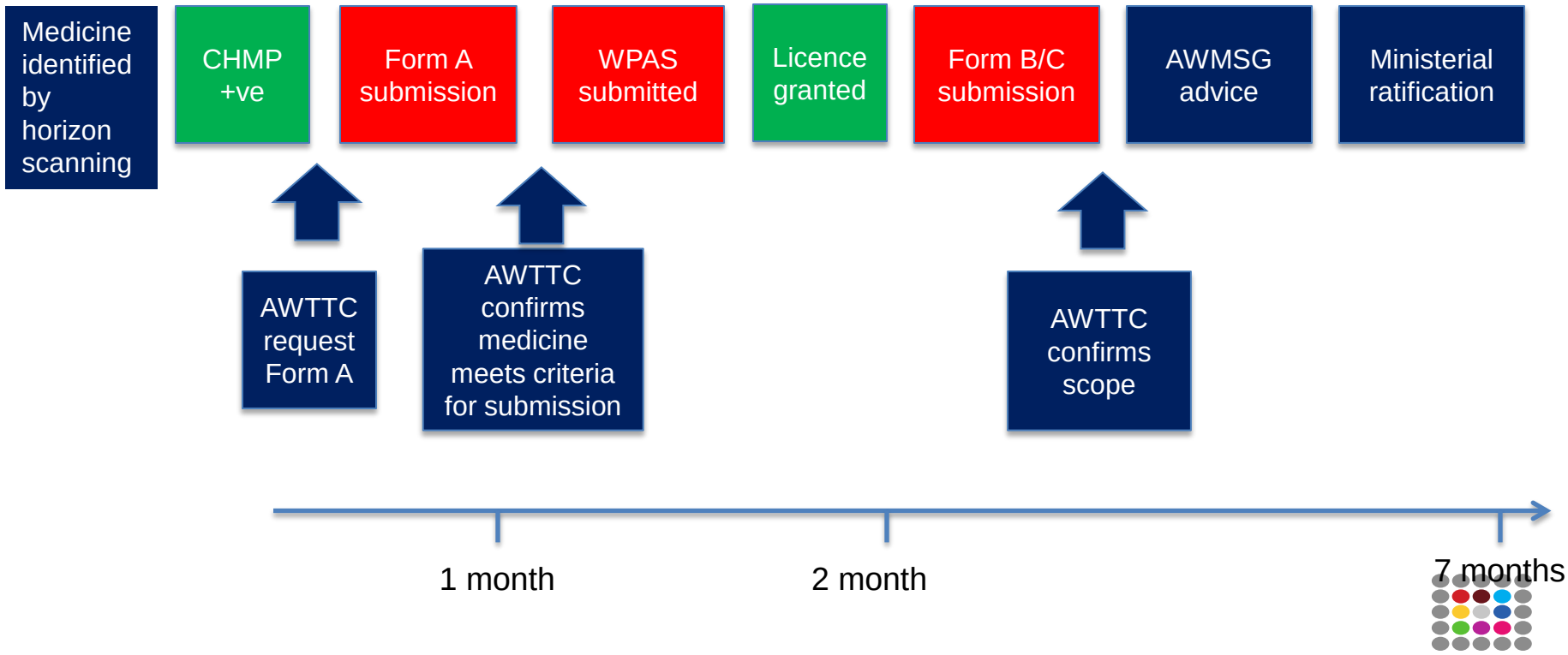
Form B – full submission

Contains clinical effectiveness, cost-effectiveness and budget impact information required for AWTTC to prepare the AWMSG secretariat assessment report (ASAR) which is considered by the New medicines Group (NMG) and the All Wales Medicines and Strategy Group (AWMSG).

Form C – limited submission

Contains clinical effectiveness and budget impact information required for AWTTC to prepare the AWMSG secretariat assessment report (ASAR) which is considered by the New medicines Group (NMG) and the All Wales Medicines and Strategy Group (AWMSG).

Timeline for engagement



Form A and appraisal process

Form A is expected within 1 month of CHMP positive opinion as this enables a decision to be made as to whether a medicine meets the criteria for appraisal.

AWTTC considers this information and informs the company of their decision.

The following documentation should be referred to when completing a Form A:

- Form A guidance notes
- AWMSG exclusion criteria
- AWMSG decision process for full and limited submission

All Wales Medicines Strategy Group
Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Search
Home | About us | Contact us

About AWMSG | Appraisals | Medicines management

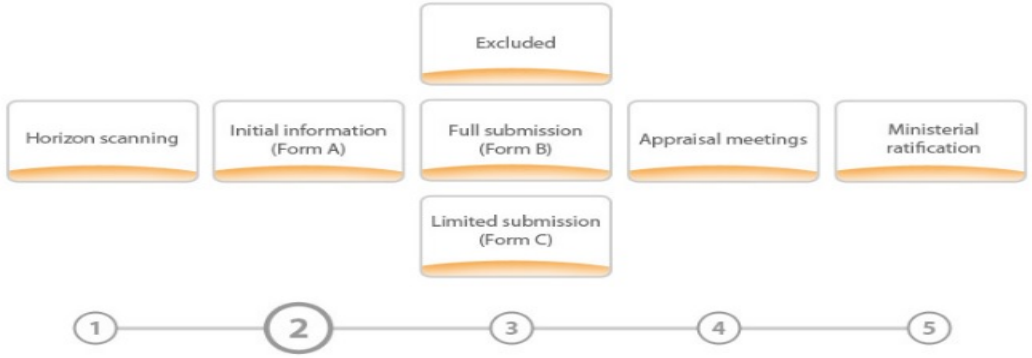
Pharmaceutical industry

Appraisal information

- About
- Appraisal process
- Wales Patient Access Scheme
- AWMSG in relation to NICE
- Orphan, ultra-orphan and rare diseases
- All appraisal documents

Appraisal process

Click on each of the stages below for a brief overview of the AWMSG appraisal process and to obtain the relevant documentation. For the full process diagram please refer to the appraisal principles and process flow chart.



Initial information (Form A)

Why?
Form A should be completed for **all newly licensed medicines**, each new indication and/or formulation. Form A provides the information required by the AWMSG Steering Committee to decide whether a medicine requires appraisal.

When?
Form A should be submitted before marketing authorisation is received, and ideally within one month of receipt of positive opinion from the Committee for Medicinal Products for Human Use (CHMP)

How?
Form A should be completed using the documents provided in the **Form A submission pack** and submitted to AWTTC.

Form A submission pack

- Form A
- Form A guidance notes
- AWMSG decision process for full & limited submissions
- AWMSG exclusion criteria
- AWMSG process for industry engagement
- FAQ's

Exclusion? Form B? Form C?

1. trottia/kennesen (Velofastium®) licensed for improved cycling

-Product comprises two medicines: trottia and kennesen which were originally licensed individually for improved cycling in 2008 and 2009.

EXCLUDE

2. trampolinuzab licensed for improved bouncing from aged six years

- trampolinuzab was recommended by AWMSG in June 2010 for use in adults and children aged 12 years and upwards.

LIMITED SUBMISSION

3. Fastboatibag licensed for improved sailing in adults

- In 2011 fastboatibag was recommended for use to improve rowing performance in adults.

FULL SUBMISSION

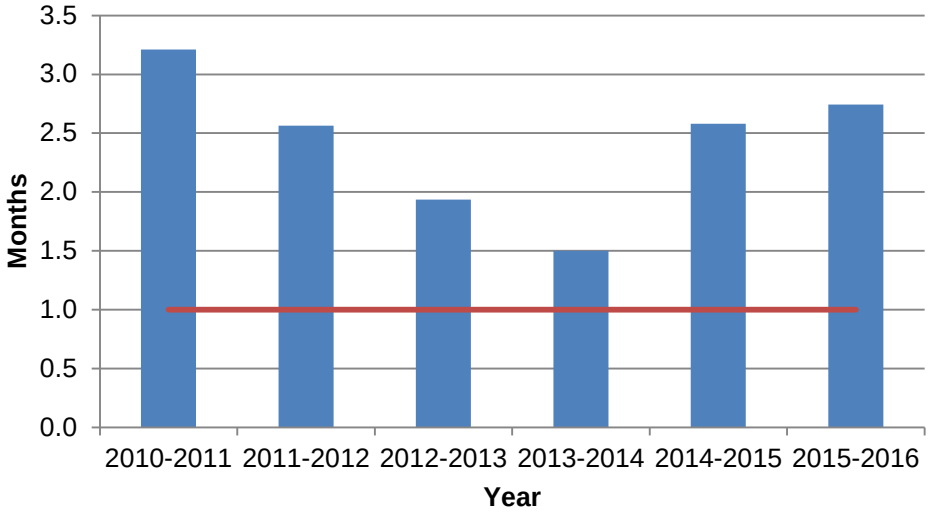
4. Speedylegsium subcutaneous injection licensed for long distance running improvement in adults

- Speedylegsium IV was licensed for the same indication in 2011.

FULL SUBMISSION OR LIMITED SUBMISSION OR EXCLUSION

Engagement

Time taken from receipt of CHMP positive opinion to receipt of Form A

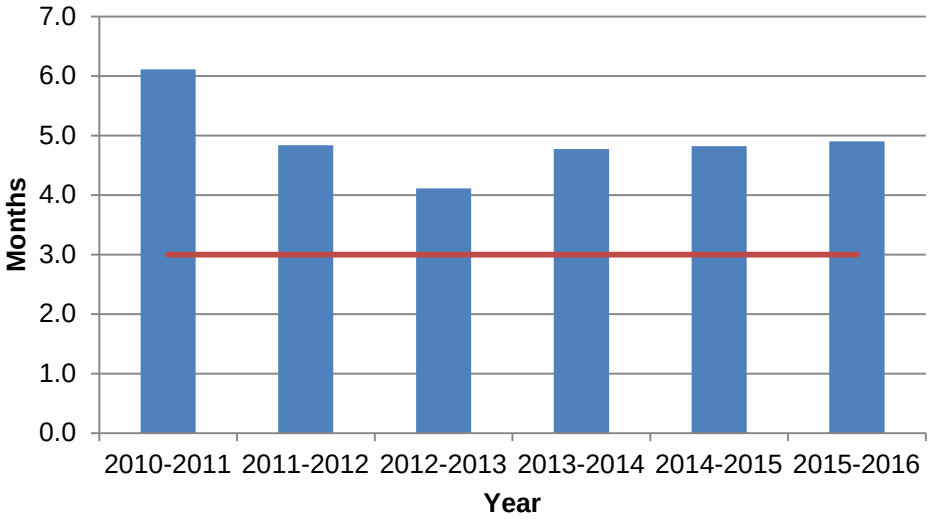


- Median time taken for receipt of Form A following CHMP positive opinion in 2015/2016 was 2.5 months

- This suggests that Form A's are submitted on receipt of licence

Engagement

Time taken from UK licence to receipt of Form B/C



- Median time taken for receipt of Form B/C following UK licence in 2015/2016 was almost 5 months

- This suggests that there is a 5 month delay to the appraisal process and that a number of medicines are therefore receiving statements of advice 3 months post licence.

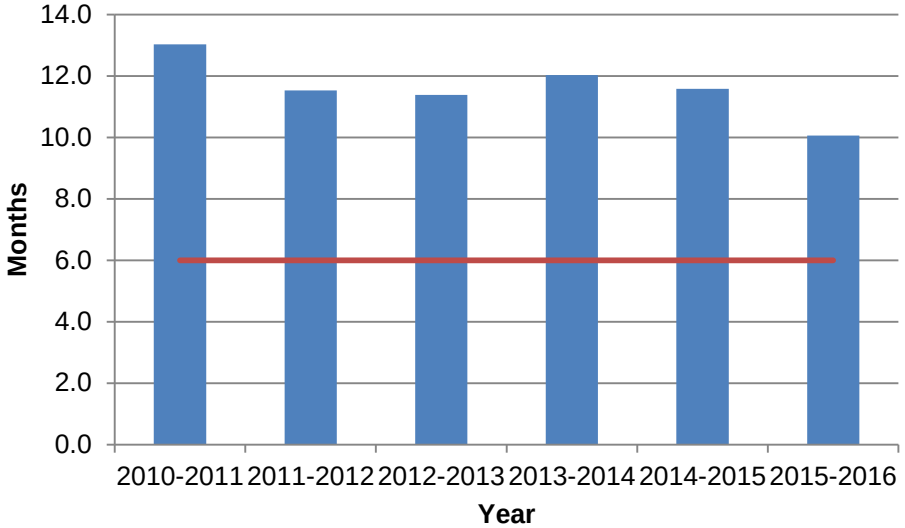
2015/2016

Minimum = 1 day

Maximum = 349 days

Working together to improve engagement has enabled patients in Wales timely access to medicines?

Time taken from UK licence to Ministerial ratification



- Median time taken from UK licence to Ministerial ratification in 2015/2016 was 10 months

- As the appraisal process takes 5–6 months this suggests that there is a 4–5 month delay to the appraisal process which may be accounted for by the delay in receipt of Form B/C

2015/2016

Minimum = 5.7 months

Maximum = 15 months

Thank you