The Company Submission – AWTTC's role

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All Wales Therapeutics
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AWTTC
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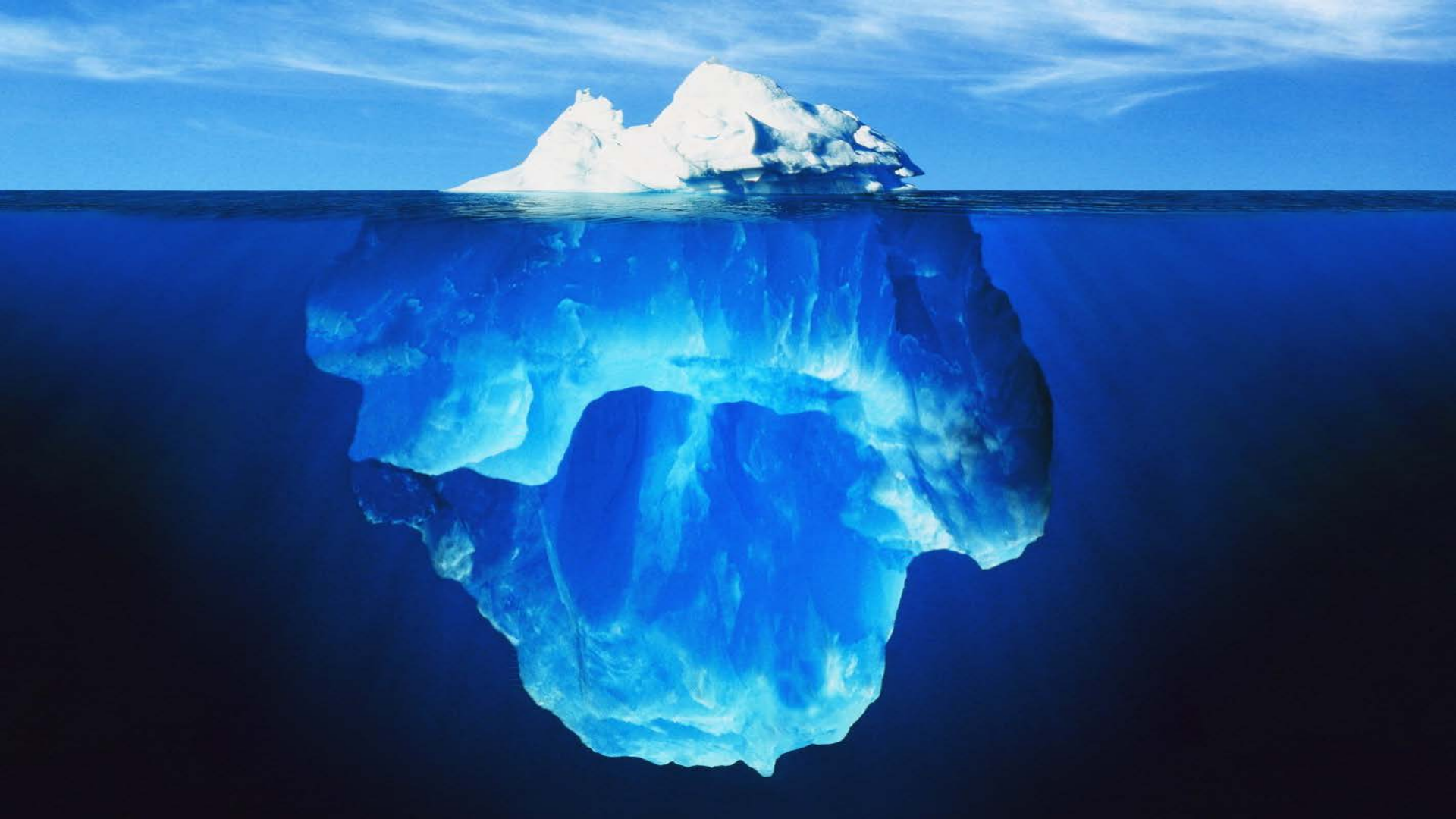
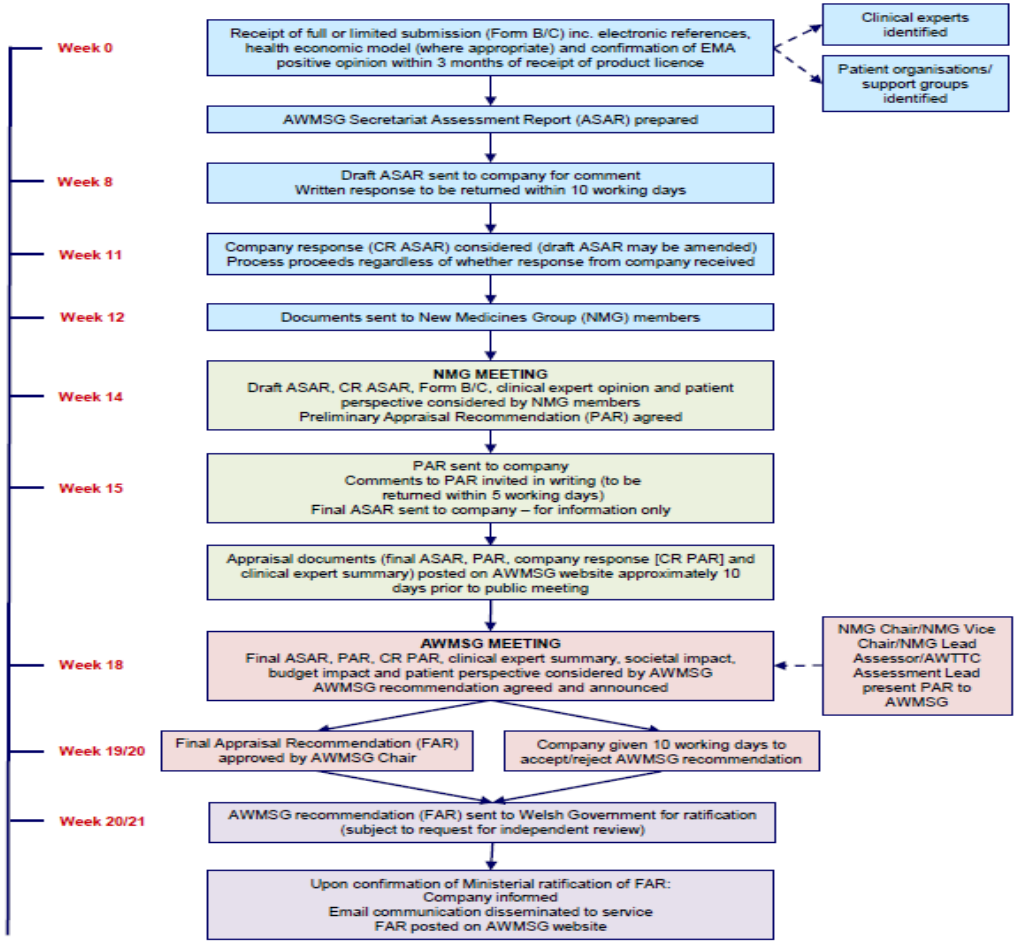
& Toxicology Centre




Week 0
Receipt of full or limited submission (Form B/C) inc. electronic references, health economic model (where appropriate) and confirmation of EMA positive opinion within 3 months of receipt of product licence
Clinical experts identified
Patient organisations/ support groups identified
AWMSG Secretariat Assessment Report (ASAR) prepared
Week 8
Draft ASAR sent to company for comment
Written response to be returned within 10 working days
Week 11
Company response (CR ASAR) considered (draft ASAR may be amended)
Process proceeds regardless of whether response from company received
Week 12
Documents sent to New Medicines Group (NMG) members
Week 14
NMG MEETING
Draft ASAR, CR ASAR, Form B/C, clinical expert opinion and patient perspective considered by NMG members
Preliminary Appraisal Recommendation (PAR) agreed
Week 15
PAR sent to company
Comments to PAR invited in writing (to be returned within 5 working days)
Final ASAR sent to company – for information only
Appraisal documents (final ASAR, PAR, company response [CR PAR] and clinical expert summary) posted on AWMSG website approximately 10 days prior to public meeting
Week 18
AWMSG MEETING
Final ASAR, PAR, CR PAR, clinical expert summary, societal impact, budget impact and patient perspective considered by AWMSG
AWMSG recommendation agreed and announced
NMG Chair/NMG Vice Chair/NMG Lead Assessor/AWTTC Assessment Lead present PAR to AWMSG
Week 19/20
Final Appraisal Recommendation (FAR) approved by AWMSG Chair
Company given 10 working days to accept/reject AWMSG recommendation
Week 20/21
AWMSG recommendation (FAR) sent to Welsh Government for ratification (subject to request for independent review)
Upon confirmation of Ministerial ratification of FAR:
Company informed
Email communication disseminated to service
FAR posted on AWMSG website

Overview

- AWTTC staff
- Data capture and engagement pre-submission
- Initial assessment of the company submission
- Writing of the assessment report
- Role of AWTTC at committee meetings
- Reviewing and updating of AWMSG advice

AWTTC ‘Front of House’

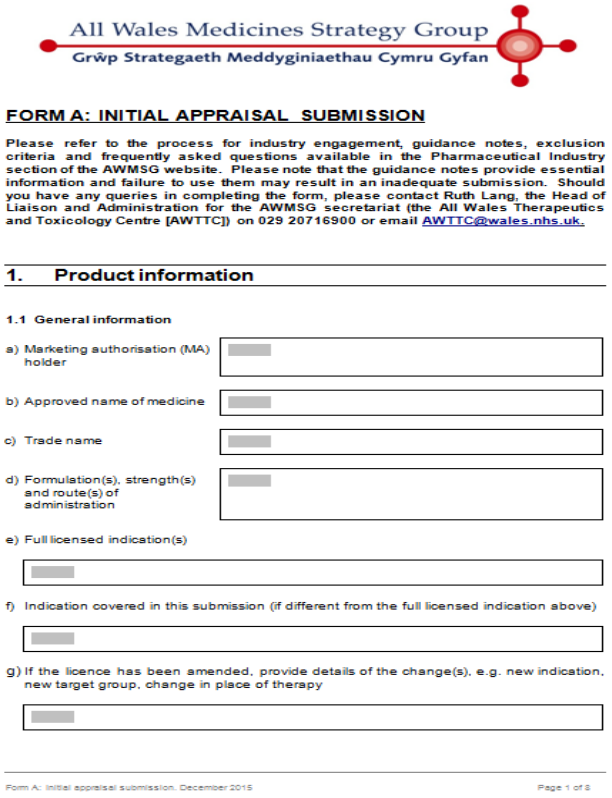
- All queries are routed via email through the AWTTC generic account: AWTTC@Wales.NHS.UK or dealt with directly by Ruth - liaison manager
- Queries requiring input from the professional team are routed to Duty Managers (appraisal pharmacist and appraisal scientist on a rota basis) supported by the senior management team as required
- Majority of enquires are replied to on the same day

Data capture

- In-house development of a database of medicines
- Currently over 3,000 records held
- Used for capturing information, enquiry answering and to generate regular reports for health boards e.g. M&T reports, Chief Pharmacist reports and Welsh Government e.g. CMO update, WG monthly reports

Pre-submission

- Although the onus is on the company to engage in the AWMSG process, AWTTC staff actively monitor for medicines approaching marketing authorisation
- Companies are contacted to submit an initial submission form (Form A) around the time of CHMP positive opinion
- Support is offered for those companies who indicate difficulties with progressing a submission



All Wales Medicines Strategy Group
Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

FORM A: INITIAL APPRAISAL SUBMISSION

Please refer to the process for industry engagement, guidance notes, exclusion criteria and frequently asked questions available in the Pharmaceutical Industry section of the AWMSG website. Please note that the guidance notes provide essential information and failure to use them may result in an inadequate submission. Should you have any queries in completing the form, please contact Ruth Lang, the Head of Liaison and Administration for the AWMSG secretariat (the All Wales Therapeutics and Toxicology Centre [AWTTC]) on 029 20716900 or email AWTTC@wales.nhs.uk.

1. Product information

1.1 General information

a) Marketing authorisation (MA) holder

b) Approved name of medicine

c) Trade name

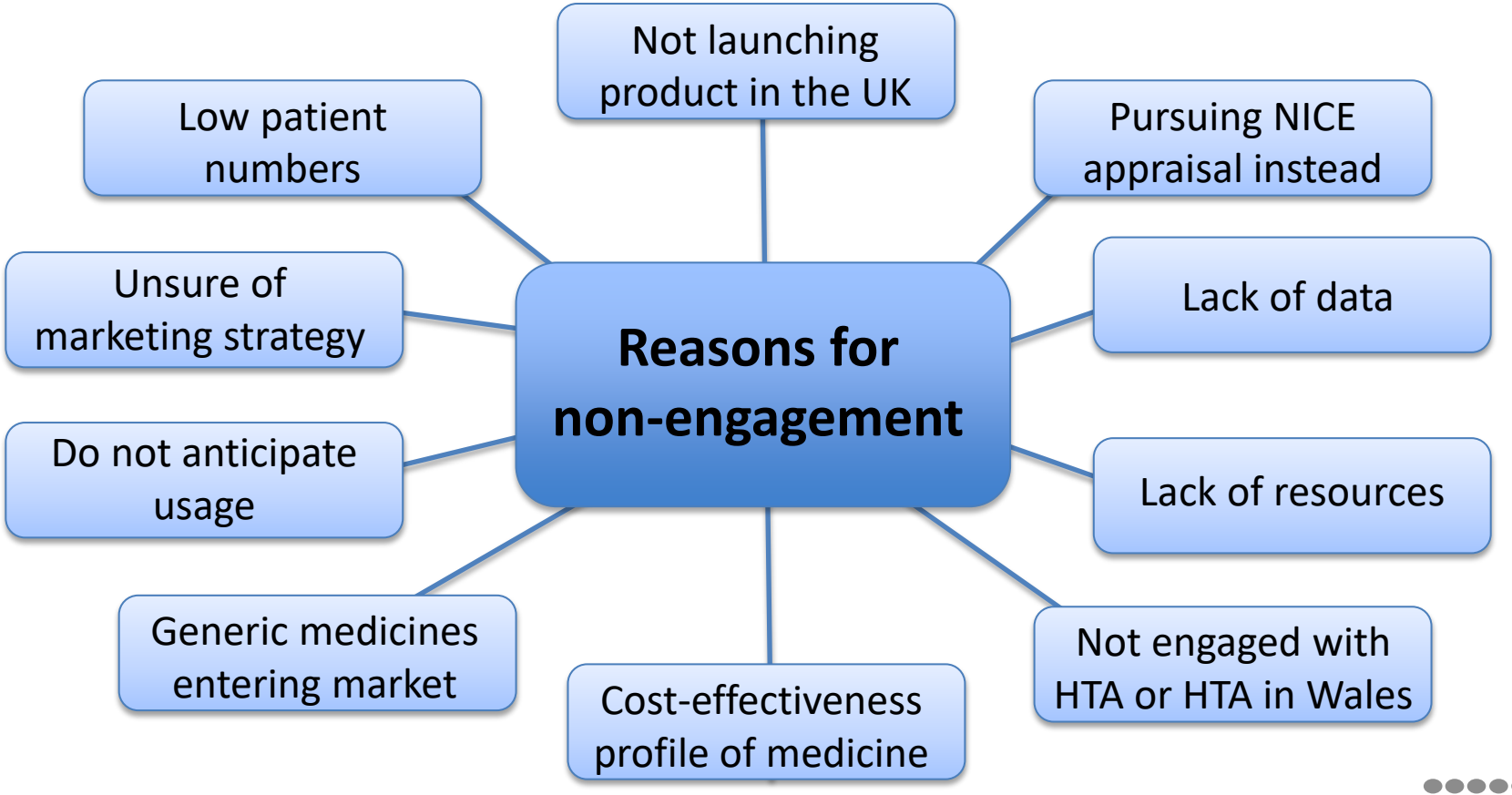
d) Formulation(s), strength(s) and route(s) of administration

e) Full licensed indication(s)

f) Indication covered in this submission (if different from the full licensed indication above)

g) If the licence has been amended, provide details of the change(s), e.g. new indication, new target group, change in place of therapy

Form A: Initial appraisal submission, December 2015 Page 1 of 8


Reasons for non-engagement
Not launching product in the UK
Low patient numbers
Pursuing NICE appraisal instead
Unsure of marketing strategy
Lack of data
Do not anticipate usage
Lack of resources
Generic medicines entering market
Not engaged with HTA or HTA in Wales
Cost-effectiveness profile of medicine

‘Form A’ stage: NSDF

- NSDF = New Submission Decision Form
- This is the decision process for deciding whether a medicine meets criteria for appraising and if so, whether it should be a full or a limited submission
- Aim is to provide a decision within two weeks of receipt of Form A
- Each submission is checked against the latest exclusion criteria, the decision process for a full or limited submission and projected costs are verified

‘Form A’ stage: Difficulties

Areas of difficulty can include:

- Does it meet exclusion criteria? e.g. biosimilar, very minor licence extension, overlap with current or upcoming NICE guidance
- Acceptance of a limited submission: companies will often argue the case for a pragmatic approach to be taken
- Is there a PAS/WPAS associated with the medicine?
- Is budget impact considered significant?
- Is the comparator appropriate?
- Consistency with previous decisions

The Form B/C submission

- If the AWMSG exclusion criteria are not met, AWTTC request a full (Form B) or limited (Form C) submission from the company
- Upon receipt, the company submission is reviewed by the AWTTC medical advisor, appraisal pharmacist and a health economist at Bangor University

Is the submission appropriate for the licensed indication?

Have the correct comparators been used?

Has the company restricted their submission?

Is the health economic model present and complete?

Does the End of Life criteria apply?

Is the health economic measure/model appropriate?

Does the orphan/ultra-orphan policy apply?

Is the population data appropriate for Wales?

Is the information on budgetary impact satisfactory?

Strengthening the Form B/C submission

- AWTTC highlight any areas where the company may strengthen their submission; examples include:
  - Choice of comparator may not reflect Welsh practice
  - The need for a full rather than limited submission
  - Choice of health economic model; CUA versus CMA
  - Improved evidence surrounding EoL or orphan/ultra-orphans
- The company are informed that AWTTC can only advise on their approach and it is the decision of the committees to decide on whether their approach is justified

The ASAR

- Evidence from the company submission is summarised and critiqued to produce the AWMSG Secretariat Assessment Report (ASAR). Additional evidence considered include the company references, clinical expert input and results of an independent literature search
- The clinical section of the ASAR is written over a 5 day period and is subsequently edited by a clinical editor (Pharmacist) and a technical editor (Appraisal Scientist).
- A pool of health economists are available to write the health economic section of the report which is peer reviewed by the health economic team at Bangor University
- Proofed by member of the AWTTC management team

AWTTC at NMG

- Assessment lead provides notes containing key points for NMG chair
- Assessment lead presents any issues raised by applicant company and clinical experts and responds to any queries regarding process/clarify evidence
- Points raised by NMG members are documented and form part of the AWMSG briefing notes for the AWMSG Chair and Head of HTA/Patient Access
- ASAR may be updated in line with comments or corrections provided by committee members

AWTTC at AWMSG

- Assessment lead highlights key points and presents any issues of importance
- Responds to any queries regarding process or provide clarification of the evidence
- Ensure that there is consistency with wording and process
- Liaises with the company representatives before, during and subsequent to the meeting

Reviewing/Updating of AWMSG advice

- Following recommendations from NICE accreditation a review process has now been developed and a review team has been set up within AWTTC
- All advice is now reviewed after three years of the initial advice being issued
- Literature search conducted and close liaison with the applicant company and clinical experts takes place
- Consideration is now given as to whether it is appropriate to amalgamate advice

Updating AWMSG advice

Recommendation of AWMSG

Insulin detemir (Levemir®) is recommended as an option for use within NHS Wales for the treatment of diabetes mellitus in children aged 2–5 years.

- Licence extended to include 1-2 year olds
- Advice reviewed and updated

Recommendation of AWMSG

Insulin detemir (Levemir®) is recommended as an option for use within NHS Wales for the treatment of diabetes mellitus in children aged 1–5 years.

- Changing landscape within NICE
- New Treatment Fund and closer engagement with Pharma and NHS Wales for horizon scanning and financial forecasting
- Earlier engagement with companies with further refinement of the appraisal process to ensure advice is timely
- Strengthen links between HTA and One-Wales processes

Thank you

AWTTC
All Wales Therapeutics & Toxicology Centre