Technology Appraisals

Proposals to increase capacity in the TA programme

Feedback from Phase 1 consultation
Outline of Phase 2 consultation

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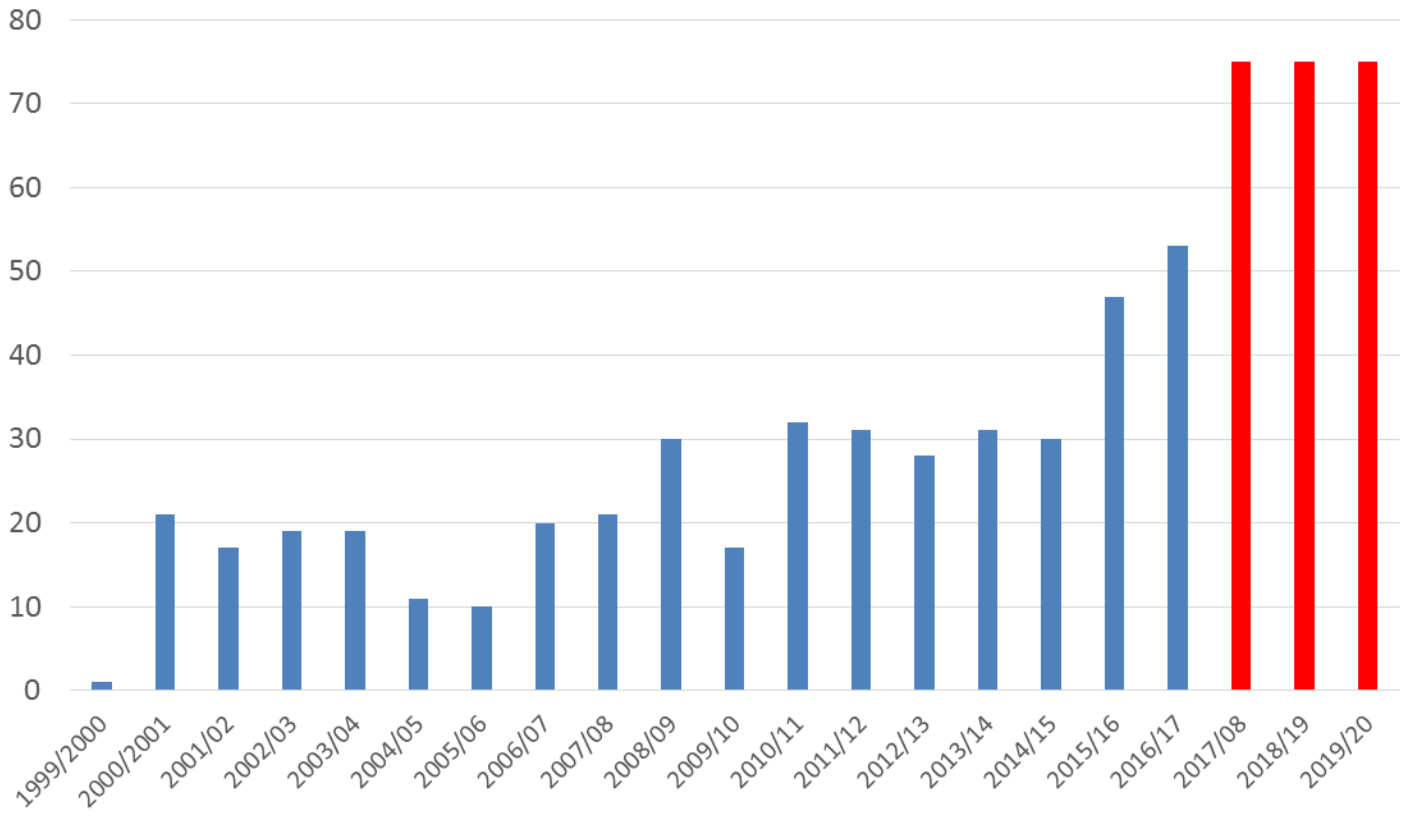
Background

The TA programme is developing and publishing more guidance than ever before



Reasons for increase in demand

- Regulators are granting marketing authorisations at earlier stages in development and for more products
- Some cancer products now receive marketing authorisation for more than 10 indications.
- EAMS designation and the Cancer Drug Fund imposes strict requirements for priority scheduling and timely publication of cancer topics

Proposed solution

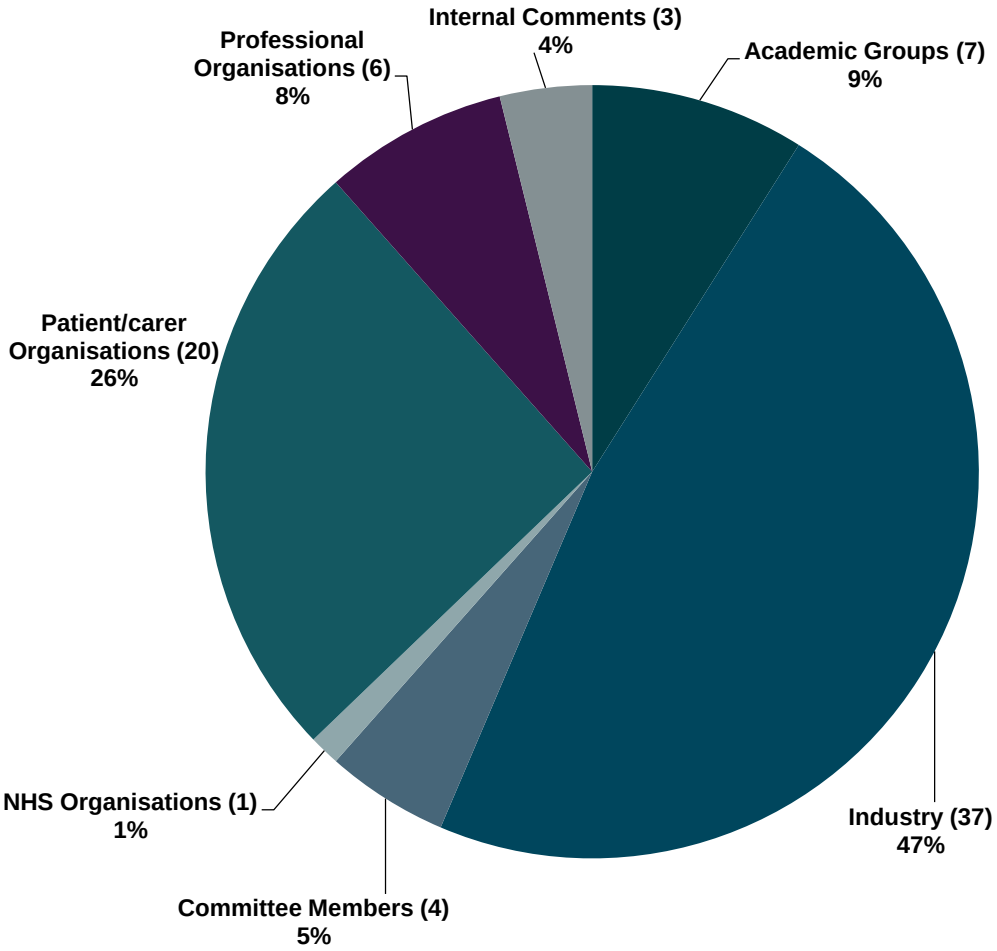
- Front load the process as much as possible
- Do more with existing appraisal committee capacity
- Aim to ‘get it right’ first time

Proposals issued for consultation

- Provide clear, recognisable milestones for companies linking them to key stages in regulatory pathways
- Provide more time for NICE to engage with companies early in the appraisal process
- Develop capability for meaningful commercial discussions as early as possible
- Release capacity for the appraisal committees as more of the scientific and technical elements are pulled forward in the process.

Stakeholders - Engagement and involvement

- Phase 1 – a 6 week public consultation - received 78 responses
- A webinar for stakeholders (80 people) and a face-to-face event in Manchester (40 people)
- A number of individual meetings with key stakeholder groups



Consultation response

- The consultation received a generally supportive response to the proposals put forward.
- The proposals for involvement of clinical experts and patient representatives at the committee meeting as the (only) key exception.
- We propose to make the following changes post consultation:
  - membership of the 'technical team';
  - attendance of clinical expert and patient expert representatives at the appraisal committee
  - arrangements for consultation on optimised recommendations, and;
  - publication of final appraisal guidance relative to marketing authorisation.

Membership of the technical team and technical engagement

- Key scientific and technical issues addressed before the first appraisal committee meeting by the 'Technical Team'
  - Proposed to be Committee Chair, committee members and NICE staff and *ERG*
- Some stakeholders, particularly the ERGs themselves, indicated that ERG should be advisory to the technical team
  - We will remove the ERG from the technical team membership
- Release of unredacted technical report to stakeholders for comment at the technical engagement step
  - NICE needs to release of confidential clinical information and economic analyses to stakeholders to provide meaningful engagement
  - Stakeholders sign a confidentiality agreement providing a 'confidentiality club' to allow us to distribute the information to them

Arrangements for consultation on optimised recommendations

- We proposed to alter consultation arrangements for 'optimised' (narrower than marketing authorisation) recommendations
  - 10 working day targeted consultation with consultees and commentators only
  - Consultation responses reviewed by the technical team and amendments presented electronically to committee members for review and endorsement
- This received varying levels of support
  - Suggestion to increase to 15 days
  - An 'optimised' recommendation should be subject to the same consultation standards as a 'no'
  - Proposals for committee to apply a 'light touch' to consultation responses if they lead to the incremental cost effectiveness ratio being low enough to allow a positive recommendation
- In response
  - We will retain the standard 20 working day consultation
  - In circumstances where the committee is clear about its expectations after the 1st meeting, and where the company responds with an updated commercial offer, the Chair (and technical team) can decide that a face to face appraisal committee meeting is not required and final recommendations agreed by the appraisal committee electronically.

Publication of final appraisal guidance relative to marketing authorisation.

- We proposed to align the timeliness targets for ***all*** technology appraisal output, with guidance within 90 days of marketing authorisation for all new drugs
  - Currently in place for cancer drugs
- The proposal was welcomed by most respondents
  - Noted the link to recommendations in the Accelerated Access Review and the vision captured in the Life Sciences Industrial Strategy
  - The Department indicated that it wishes to consider the proposal to align the publication schedule for non-cancer and cancer topics in the forthcoming renegotiation of the Pharmaceutical Price Regulation Scheme (PPRS)
- In view of the DH position, we will not proceed with the proposal to align the publication schedule for non-cancer and cancer topics at this time.

Attendance of clinical experts and patient experts at the appraisal committee

- It may not always be necessary for experts to attend the committee meeting
  - Proposed a needs assessment made by the technical team to inform request for experts to attend
- Virtually all stakeholders raised concern with this proposal
  - A 'needs assessment' was thought to be unacceptable
  - Some indicated that where direction of travel is clear from the technical engagement step, they would be willing to reconsider their attendance at the committee meeting
- In response
  - The intention was to increase patient and clinical input into the appraisal process at a much earlier point, not to remove input altogether!
  - We will re-instate the opportunity to attend committee meetings but also provide an 'opt-out' of attendance at the meeting experts feel their views are adequately reflected in the technical report and attendance in person may not add additional benefit.
  - We will need to ensure that expert attendance at committee is not regarded a substitute for input into the technical engagement stage

Additional step for involvement

Aim:
To resolve as many scientific issues and uncertainties as possible before the committee meeting, to reduce the need for second or more meetings.

Technical team:
Committee chair, cost, clinical, lay person, NICE staff.

Technical report
Produced by the technical team with participation from experts.

Consultation (on the technical report)
20 working day consultation with stakeholders

Patient involvement
Patient organisations and patient experts
- participate in technical engagement (experts only)
- comment on the technical consultation

The consultation

Opened Friday 19th January 2018

Closes 5pm, Thursday 1st March 2018.

https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/technology-appraisal-guidance/consultation-on-changes-ta-programme-phase-2

How to comment

1. Read the draft process guide (PDF) and the consultation summary paper (PDF)
2. Fill in the consultation proforma (Word)
3. Email your completed proforma and queries to TAconsultation2018@nice.org.uk

Engagement events

Held by other groups

- Patients Involved in NICE, 19 January
- **Cancer 52, 24 January**

Held by NICE

- Face to Face - London: Thursday 08 February, 2pm – 5pm
- Face to Face - Manchester: Wednesday 28 February, 10am – 1pm
  - send the nomination form to TAconsultation2018@nice.org.uk deadline Thursday 1 February 2018
- Webinar: Thursday 22 February, 10am – 11am
  - Register via the consultation page on the website.

Next steps

- Board for final approval for the changes (anticipated) on
  - 21 March 2018
  - Westlands, Yeovil, BA20 2DD
  - Register https://www.nice.org.uk/event/marchpublicboard_2018

- **Implementation from 01 April 2018**, subject to Board approval