

NICE / PHARMA INDUSTRY COUNCIL

DRAFT MINUTES

Wednesday 2nd November 1.30pm – 3.30pm

ATTENDEES

Professor David Haslam, Chairman, NICE

Sir Andrew Dillon, Chief Executive, NICE

Professor Carole Longson, Executive Director, NICE

John Kearney, President ABPI and General Manager, Amgen

Richard Erwin, Chair ABPI Value & Access Workstream & General Manager, Roche

Mike Thompson, Chief Executive, ABPI

Richard Torbett, Executive Director, Commercial, ABPI

Paul Catchpole, Value & Access Director, ABPI

Item 1: Introductory remarks

ABPI highlighted industry concerns about the downward direction of travel regarding the use of new medicines by the NHS with prices being at the lower end of most European countries and further commercial controls being applied or planned which taken in the round were very significant. There was a need more than ever for a constructive partnership between industry and NICE.

ABPI explained that we were entering a pre-industrial strategy period where there was major discontinuity that would bring about very significant change. There are three big issues: Brexit, an unaffordable NHS, and the volume and profile of the innovation that the industry is bringing to market. Brexit discussions appear to confirm that the UK will unlikely be a regulatory gateway to Europe in the future and the UK will have to stand on its own. Access to data would be key as regulatory pathways change with more adaptive licensing based on real world evidence. In the absence of an effective industrial strategy, short-cycle decisions might quickly become apparent such as reducing the clinical trials footprint in the UK and changes in the launch sequence for new medicines, with the UK moving backwards. Longer-cycle decisions such as reducing investment in infrastructure and facilities might take more time to emerge.

Whilst strong messages of support for life sciences had emerged from No. 10 this now needed to be followed through with a strong industrial strategy. Everything was on the table, and everything was at risk.

Industry fully supports NICE as an independent HTA body but is concerned that the independence of its appraisal committees and the overly academic rigour built into NICE methods limits flexibility. Industry does not feel it is a customer of NICE but if a different relationship could be achieved then it may be willing to pay for appraisals. Without any changes being put in place, then charging for appraisals are seen only as an additional tax that companies do not support.

NICE stated that it found these introductory remarks helpful and recognised the volatile environment, the so far unknown consequences of Brexit and the understandable perception about the changing regulatory pathway. In terms of independence, NICE has always relied upon cost effectiveness analysis to manage value for money but recognises that affordability now needs to be handled within the system. Alongside arguing for more money from Treasury and DH (which is seen as impossible to achieve at present), a sensible managed approach to handling affordability challenges is believed to now be appropriate through the introduction of a budget impact threshold. NICE's relationship with the NHS has not changed but as there is no more money the system cannot be destabilised. The NHS will need to continue to implement NICE guidance and the proposals will not make NICE any less independent.

Item 2: Charging for Appraisals

NICE considers that there is regulatory precedent in the UK which provides an arguable case for progressing with charging for appraisals. It had not been assumed that the proposals would be welcomed by industry and the feedback made by the life sciences trade associations was currently being considered.

NICE stated that it intended to proceed with the proposals for charging for appraisals. The proposals would be taken to the NICE Board on 16th November followed by discussions with DH and Treasury before Christmas in order to allow the required changes to NICE Regulations to be prepared in the New Year.

NICE confirmed that a full cost recovery approach would have to put in place unless DH would agree to a marginal approach. Similarly, DH agreement would be needed for any differential pricing approach for SMEs. NICE considered our comparisons with international benchmarks to be unhelpful since there were no other comparable bodies to NICE which matched the approach used in the UK.

A discussion took place about what industry might require in order to support the introduction of charging for appraisals. The key points were:

- Commit to support the introduction of charges for a one year period only, followed by a review
- Provide a mechanism to discuss the priority areas raised by ABPI in the response to the discussion paper and clarify how and when these can be formally considered by NICE
- Provide a greater level of detail on how the proposed charges are made up
- Deliver on a commitment to forensically examine costs to ensure that charging levels are absolutely no higher than is necessary
- Companies to be able to choose, in discussion with NICE, what the right timing is for undertaking an appraisal including the option to not proceed if the company chooses not to make a medicine available in the UK
- NICE to support dialogues with DH about the need for flexibility in the system to find solutions for multi-indication and combination pricing.

If these commitments could be agreed then ABPI will share these with its membership.

Item 3: Consultation on linking value and affordability

NICE considers that the consultation will help better manage the planned introduction of technology appraisal guidance into the NHS and will be enabling.

ABPI pointed out that the PPRS is the primary mechanism for managing affordability in the system and that the consultation taken together with other changes being introduced such as the Cost of Medicines Bill and the introduction of a Strategic Commercial Unit into NHSE, as proposed by the AAR, has the potential to significantly undermine it. ABPI considered that there was a loss of trust in the intent of the proposals and that companies had a right to expect a reasonable return on their investments during the period of the patent life of their medicines. NICE on the other hand considered that securing a shared approach to managing the adoption of some technologies could be helpful and in the context of new commercial models, such as price/volume agreements, could help secure more predictable uptake.

Budget impact threshold

NICE clarified that the budget impact threshold of £20m that is being consulted on had been set by NHS England based on a retrospective analysis of appraisals and that it would apply to technology appraisals and not just those commissioned directly

by NHS England. ABPI considered the threshold to be too low given that the dialogue around affordability had been based around the hepatitis C medicines where budget impact challenges are of an order of magnitude of around £200m. The importance of undertaking earlier horizon scanning was highlighted.

ABPI would be seeking a dialogue with the NHSE CFO to explore further.

Fast track appraisals

ABPI and NICE shared the view that having a fast track mechanism available for some medicines was positive but ABPI challenged that the current proposal would not fast track the right medicines through the system. These should be major breakthroughs and truly innovative medicines which the entry criteria for the fast track approach would currently select out. ABPI accepted that the fast track proposal was positive but different criteria were required to make it valuable.

Cost effectiveness threshold for HSTs

NICE explained that the introduction of a threshold for HSTs should be regarded primarily as a trigger mechanism to signal the point at which the funding direction would apply for HST approved medicines. Notwithstanding this it was difficult to see how the introduction of such a threshold would do anything other than give legitimacy to the use of cost effectiveness analysis for HSTs which ABPI strongly disagreed with. An alternative proposal would be tabled by ABPI in its consultation response.

NICE confirmed that it had not considered any alternative approaches to introducing a budget impact threshold and a cost effectiveness threshold for HSTs in developing the consultation proposals.

Item 4: AOB

It was agreed that the optimum timing for the next Industry Council meeting would be in March 2017.