NICE / PHARMA INDUSTRY COUNCIL

MINUTES

Thursday 22nd October 2018

11.00am to 1.00pm

NICE LONDON

ATTENDEES

Sir Andrew Dillon, Chief Executive, NICE
Meindert Boysen, Director Centre for Health Technology Evaluation, NICE

Erik Nordkamp, President, ABPI and UK Managing Director, Pfizer
Richard Erwin, Co-Chair, ABPI V&A Workstream and General Manager, Roche
Richard Torbett, Executive Director Commercial Policy, ABPI
Paul Catchpole, Value & Access Director, ABPI

Apologies

Professor David Haslam, Chairman, NICE
Tim Irish, Non Executive Director, NICE
Mike Thompson, Chief Executive, ABPI

AGENDA ITEM POINTS

Item 1: Welcome / introductions

It was the turn of the ABPI President to chair the meeting.

Meindert Boysen, in his new role as Director of CHTE, was welcomed on to the Council.

Item 2: Agreement of minutes and matters arising from last meeting

NICE requested a change to the minutes of the meeting of 22nd February 2018 to make clear that the phrase 'NICE executive' in paragraph 2 referred to a NICE manager position within CHTE rather than a NICE Executive Director. This was agreed. **(Action: ABPI)**

Item 3: PPRS Update (including NICE charges for appraisals)

The PPRS negotiations were ongoing and a heads of agreement had not be reached at the time of the meeting. ABPI had made clear that any reduction in the cost effectiveness threshold represented a red-line for the industry. The upcoming NICE Methods Review in 2019 would be an important opportunity to take forward any changes required in value assessment that had been discussed as part of the PPRS discussions.

These discussions had brought into focus that having clarity about the respective roles and responsibilities of NICE and NHSE would be extremely important going forwards. NICE's role was to undertake value assessment in the context of a clear description of uncertainty, and this should not need to be revisited by NHSE. The new Commercial and Managed Access Programme (CMAP) group could play a key role in ensuring good alignment and integrated working between NICE, NHSE and companies.

ABPI tabled the Budget Impact Test (BIT) process as an early example of an area that needed some attention in this regard. Greater clarity was needed about the roles and responsibilities across the NICE TA team, the NICE RIA team, NHSE and companies in terms of how and where each participant should contribute to the process. There were some examples of parallel discussions which were circumventing the process. ABPI supported NICE being the independent arbiter of budget impact recognising that this was not an exact science. NICE stated it was progressing work on the operational handling of the BIT process. It was agreed that it would be helpful to clarify the process with NHSE **(Action: NICE)** and to evaluate the lessons learned from the process in due course.

In relation to NICE charges for appraisals, ABPI had responded to the recent DHSC consultation and proposed an aggregate top-up payment mechanism to be administered as part of the PPRS. In doing so, the risks that were inherent in the proposals for individual charges for appraisals could all be addressed. NICE confirmed that regardless of where the payments came from NICE would make work any solution agreed by DHSC, ABPI and industry. NICE acknowledged the ABPI consultation comment that the charges proposed were amongst the highest in the world but noted that for Canada, only 40% of the costs are recharged to companies.

NICE shared that the pay-as-you-go individual solution was problematic in any case because it would take until 2020/21 to reach a steady state with a deficit of £1.3m predicted for 2019/2020. ABPI's aggregate payment proposals addressed this issue.

The alignment of non-oncology and oncology appraisal timelines was discussed and it was noted that transition and alignment would likely take place over a number of financial years before steady state was reached. NICE would need to be clear about the circumstances for any delays in appraisals agreed with companies and ensure that KPIs reporting on appraisal performance in terms of timelines were suitably flexible. A further challenge to NICE receiving in each financial year the income it needed from appraisals might arise as a result of changes to the licencing and launch timelines for medicines as a consequence of Brexit. Changes in global launch sequences were expected and this presents a further risk.

Item 4: NHS Long Term Plan

NICE shared that the 10YP is likely to have a big impact on the NICE TA Programme. This is because a key focus throughout the 10YP will be on technology and innovation, particular in relation to MedTech and digital. Whilst the funding direction applies to TAs, this programme is reserved essentially only for medicines. A substantial amount of work will now be needed by NICE to gear up its programmes for MedTech and digital and there are capacity concerns.

ABPI proposed that the 10YP was an opportunity to anchor pathways for innovation into the system. Could we take a few areas and work together on how to extract value and signal the impact for other areas (delivering in practice the theoretical gains that we describe in economic models in NICE submissions)? Working together on system preparedness focussing on the future pipeline seen as a crucial activity to extract value and become more comfortable with managing risk. (NICE noted that the maximum appetite for managing risk is presently within the CDF. In the NICE Commissioning Support Programme (CSP) and MedTech Programmes there was no risk appetite at present). ABPI noted that piloting some areas that illustrate different problems in the system would be beneficial.

NICE welcomed and was supportive of the opportunity and described in this context a major new initiative which is intended to pro-actively align different parts of the system through real time presentation of pathways which would enable better matching up of programmes and work from horizon scanning to implementation.

The delivery of this initiative would tie into NICE's 20th Anniversary Plans in 2019. Starting in diabetes there would be a roll out to 15 – 20 other pathways. Other areas might include CVD and COPD in due course. It was agreed that a separate meeting would be arranged to discuss this further with Gillian Leng. A new NICE Pathways Committee had already been set up and ABPI would be represented **(Action: NICE / ABPI).**

Item 5: LSIC, AAC & PMAP

It was noted that the AAC could enable the piloting of new approaches to accelerating uptake along with a better understanding of how to prepare the system for absorbing learnings. NICE was supportive of a forum to reflect what is working well and less well, along with the mechanisms proposed to support rolling out learnings to benefit all medicines.

Item 6: EU Joint Clinical Assessments

NICE will where possible utilise the outputs of Joint Clinical Assessments in its work programmes involving medicines. Timing considerations remain the main factor that will make the JCA less useful in the TA programme. A discussion was held on the likely impact of Brexit on the regulatory system with knock on effects into the NICE TA work programme. NICE may face some unexpected workload changes in the TA Programme due on the one hand to some new medicines approvals being brought forward (time between EU CHMP approval to UK licencing decision) and some being potentially delayed (because full dossiers for new medicines might need to go through an MHRA led process). And companies will be reviewing global launch sequences which may change as a consequence of Brexit. In some areas the UK could go earlier if there was no risk to EU approvals (e.g. new formulations, OTC switches, genomics). Further clarity is needed from MHRA and a joint follow-up meeting with MHRA might be sought. **(Action: NICE/ABPI).**

There are multiple other issues too that need to be resolved including confidential data handling, intellectual property requirements, and availability of pricing information.

Item 7: NICE Methods Review

A discussion was held on the process to be used for the upcoming NICE Methods Review and on the scoping of the topics to be included. This is currently in the planning stage at NICE. It would be helpful if a more pragmatic approach could be found to undertaking the review including potentially making use of a two-stage consultation process similar to that used for the NICE Process Review in 2018.

There were a number of buckets under which topics could be considered including: industry proposals and thinking which had already been done on extended value assessment; challenges with the application of the current Methods Guide (as identified by NICE and industry); dealing with uncertainty/risk; and use of real-world evidence. Further discussions would be held in due course. **(Action: NICE/ABPI).**

Item 8: Antimicrobial Resistance

A discussion was held on the status of the work currently underway on AMR. Industry was keen to progress piloting of the reimbursement and evaluation model with a greater sense of urgency. Nick Crabb is preparing a paper which will be discussed with the NICE senior management team and the NICE Board setting out the role that NICE will play in taking this initiative forwards. ABPI will follow up further with Nick **(Action: ABPI).**