

# BIA response to NHS England's consultation on the NHS Commercial Framework

January 2020



## Summary

- The BIA broadly welcomes the NHS Commercial Framework and of clarifying the commercial negotiation process within the NHS.
- We are concerned that the Framework focuses on having timelier discussions as aim in itself rather than as a mechanism for securing access to medicines. This should be a key, if not the primary, aim of the Framework.
- The role of NICE in negotiations needs to be further clarified, particularly given its role in Patient Access Schemes.
- How the NHS Commercial Framework will interact with other bodies and initiatives also requires additional clarity – in particular the Accelerated Access Collaborative.
- Further clarity is also required on governance arrangements for the Commercial Framework, in particular with regard to escalation.

## Full response text

### **1. Please tell us which organisation you work for/are responding on behalf of.**

The BioIndustry Association (BIA) is the trade association for innovative life sciences in the UK. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives. Our membership includes large, multinational pharmaceutical and biotech companies as well as SMEs. Collectively, BIA members are responsible for over 90% of biotech medicines currently in clinical development in the UK.

We are pleased to be able to present this response on behalf of our members and to have had the opportunity to engage with the process thus far. This is an important piece of work and it is encouraging to see NHS England deliver much-needed direction on these vital access issues. We welcome the majority of the document but wish to highlight some issues and make some suggestions that can be incorporated in and future versions of the Commercial Framework.

**2. *Are the objectives and principles underpinning the Commercial Framework for Medicines clear?***

No

**a. *Is anything missing?***

The Commercial Framework must be understood in the context of the broader access issues at play rather focusing purely on procurement objectives. Although it is mentioned in the second bullet of paragraph 11 as the outcome of an aim to “facilitate timelier and more streamlined discussions about value, affordability and transactability”, supporting patient access to innovative medicines as a key objective is not given enough prominence. While timelier discussions are, of course, important both to industry and the NHS, this would seem to suggest that the discussions are more important than actually achieving access. Patient access should be a key aim of any commercial arrangement between industry and NHS England in its own right. It would be useful to consider these issues also in the ‘Context’ section and the ‘Core objectives and principles’ section.

We note also that in paragraph 9, encouraging “faster market entry for new treatments and support[ing] uptake and adoption where these medicines are priced fairly and responsibly” is highlighted as an aim. However, this is not explored further in detail in the rest of the document. We would welcome further detail and clarity on how the Commercial Framework will achieve this aim.

In paragraph 15, the use of ‘fully demonstrated’ with regard to simple discounts needs to be better defined as it is not clear what this means. Given that there will be differing opinions on the definition of this, we would recommend deleting the term unless a clear definition is available. The principle set out in paragraph 16 has caused confusion, with some reading it as meaning that value propositions must be towards the lower end of the NICE threshold before they are amenable to a complex commercial arrangement. We understand that the ABPI has suggested that this be amended to state that the resulting commercial arrangement should deliver a value proposition at the lower end of the NICE threshold in order to clarify this principle. We agree with this change for clarity. However, we would also like to emphasise that additional flexibility may be required in exceptional circumstances, particularly with regard to medicines for rare diseases. We hope that commercial discussions will reflect that to ensure that patients are able to access medicines.

**3. *Are the respective roles and responsibilities and the processes for engaging with NICE and NHS England clear?***

No

#### ***a. Where would further clarity be helpful?***

We are concerned that the role of NICE is not clear in the context of the commercial negotiations with NHS England. The current draft of the Commercial Framework appears to suggest that NICE will be a passive participant in the process, signposting companies to NHS England to commence commercial negotiations. This runs contrary to our understanding of the process, with NICE playing an active role in the negotiations as a third party, ensuring alignment with NICE processes. In particular, the absence of NICE's Commercial and Managed Access function is concerning, given its role in assessing the feasibility of Patient Access Schemes – i.e. through the Patient Access Scheme Liaison Unit (PASLU). As Patient Access Schemes play an important part of the process set out in this document, we would recommend including more detail on these functions within NICE and how it interacts with NHS England in commercial negotiations.

More broadly, NICE's role in supporting commercial discussions needs to be defined more clearly – for example, providing content used to underpin discussions and maintaining the link between appraisals, value assessment and commercial discussions.

In Figure 2, the services offered by the Office for Market Access and Early Scientific Advice are highlighted as part of the initial engagement process. However, it is not clear from this figure that these services require a fee and are not mandatory. We are concerned that this may cause confusion and consternation, particularly for SMEs and companies working in rare diseases, where the fees to obtain these services may not be commercially possible. We recommend clarifying this, either in Figure 2 or in the supporting text, setting out the cost of these services and highlighting that they are not mandatory to engage with the process set out in the Commercial Framework. With regard to the process set out from paragraph 38 to paragraph 51, the BIA believes that the 'surgeries' set out in paragraph 43 should be better defined within the Commercial Framework. This should include examples of what is most relevant for each, timelines of engagement and what evidence or documentation companies will need to prepare to engage with the surgeries. We would also welcome greater clarity on how the Office for Market Access advice sessions and the NHS England surgeries will interact to ensure that companies understand and engage with the process appropriately.

The Accelerated Access Collaborative (AAC) is mentioned in passing, but further clarity on how the Commercial Framework will interact with its activities would be useful. In particular, we believe there is an important role for AAC in horizon scanning, with its planned single horizon-scanning platform.

While the policy has yet to be implemented, it would be useful to understand how this framework will interact with the Government's pledged Innovative Medicines Fund, which was outlined in its

manifesto. We look forward to further clarity once the details of this policy have been developed and would appreciate a timeline on an update to the Commercial Framework at that point.

**4. *Are the routes to commissioning and funding new treatments within the NHS clear?***

No

Paragraph 56 is confusing and appears to suggest that Figure 5 sets out the other routes to commissioning outside NICE appraisal, rather than the standard process. We would suggest amending this for clarity.

We would also suggest clarifying paragraph 62 to ensure that the very limited circumstances under which off-label usage is permissible are clear.

**5. *Is the framework of commercial options available clear?***

Yes

**a. *Where might further clarity be helpful?***

We welcome the list of commercial arrangements set out in Table 1. However, we would suggest expanding the list to include some of the more unusual schemes that might be used. This will be particularly relevant for ATMPs, which face very specific challenges in the context of reimbursement and long-term uncertainty. While the list should not try to be exhaustive, having additional examples of commercial schemes will help to ensure companies working in this space, or with similar challenges, will see an example of a scheme that will be suitable for their treatment.

The definition of ‘confidential’ in paragraphs 73 and 77 has the potential to cause confusion. It is agreed by both government and industry that pricing confidentiality is useful and necessary. In the context of these paragraphs, it could be construed that the final price will not be confidential in the case of a complex commercial arrangement, rather than whether a deal has taken place. It would be helpful if this were clearer.

We would welcome additional clarity in paragraph 96 on the final cost-effective price after a Managed Access Agreement. Specifically, this would need to communicate that the final price after a Managed Access Agreement may be different to the price agreed at the start of the Managed Access Agreement.

## **6. *What is missing from the commercial framework?***

As noted in our response to question two, there is very limited mention of the importance of securing access to innovative medicines. This is the rationale behind the development of the Commercial Framework and needs to be called out more clearly within the background, principles and content of the document throughout.

More broadly, the Framework should also have greater regard for the broader life sciences landscape, including the Life Sciences Industrial Strategy and the Life Sciences Sector Deal.

Data collection will be vital, both for horizon-scanning and for many of the complex commercial schemes and managed access agreements highlighted within the Commercial Framework. However, there is no discussion of how NHS England will develop a response to the shifting data landscape. This is particularly true in the case of ATMPs, which are quickly becoming a major new class of medicines and which will need to be supported by longer-term post-launch outcomes data to establish real-world performance of these therapies and ultimately to satisfy regulatory and reimbursement requirements.

At present, there is little discussion of the governance arrangements for commercial negotiations within the Commercial Framework. While we, of course, understand that NHS England wishes to maintain a level of flexibility, we believe more clarity on processes and governance – particularly with regard to escalation – will help to provide reassurance to industry and encourage early engagement with the new process. We understand that the ABPI has suggested specific governance arrangements that may be useful in supporting this process. We would be happy to work alongside the ABPI and other industry groups with NHS England on the development of these more detailed governance arrangements. As a starting point, we would suggest considering how the Life Sciences Council and its sub-committees can provide oversight of the whole system. This may be particularly useful with regard to delivering the shared priorities of the NHS Commercial Medicines Unit, NICE and the Accelerated Access Collaborative.

## **7. *What additional information could be included?***

It would be useful to see a timetable for review of this document, particularly in light of the changing policy landscape around the NICE Methods Review and the Government's proposed Innovative Medicines Fund. We would ask NHS England to ensure that representatives from industry, patient groups and the wider health economy are engaged with during any review of this and future iterations of the NHS Commercial Framework.

#### **8. Are you aware of any impact this framework might have in health inequalities?**

As noted above, fees to access the Office for Market Access and Early Scientific Advice make it harder for SMEs and companies working in the rare disease space to use them. Placing them at the beginning of the commercial negotiation process may, therefore, make it harder for their companies to engage with it, which in turn disadvantage patient with rare or ultra-rare conditions.

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