MAP BioPharma response to the House of Lords Select Committee on Science and Technology inquiry into the future of UK Life Sciences

MAP BioPharma works with over 70 global biopharmaceutical and medical technology companies and a growing number of health charities. We have relationships with many companies which develop products for rare diseases. MAP BioPharma's aim is to accelerate patient access to innovative medicines, devices and diagnostics.

Industrial strategy

1. One of the major challenges with the industrial strategy is the disconnect between the Department of Health and government policy on life sciences and the adoption of innovation within the NHS. For the UK to retain a position as a leading economy for investment in pharmaceutical innovation and development, companies will need reassurance that there is a significant chance of routine patient access being achieved.

2. Earlier and informed commercial discussions with NHS England, led by the commercial team, may improve patient access to medicines but should not undermine the role of NICE in assessing clinical and cost-effectiveness independently and should not delay patient access to new treatments.

3. Initiatives such as the £20 million budget impact test recently introduced by NICE and the introduction of new thresholds for highly specialised technologies (HSTs) based on incremental cost-effectiveness ratios (ICERs) may delay access for patients. Depending on how they are implemented, these measures may also deter companies from prioritising England for medicines launches, particularly in light of the uncertainty caused by the UK's decision to leave the European Union.

4. The industrial strategy from Professor Sir John Bell makes limited reference to price but the nature of pricing agreements between the Department of Health and the industry are important to support predictability for companies and Government. The nature of the 2014 Pharmaceutical Price Regulation Scheme (PPRS) meant that the level of payments has changed substantially through the years of the agreement, making it harder for companies to plan. Although the industry agreed to offset any growth in the medicines bill, company payments into the NHS were not redirected to the medicines budget. This missed an opportunity to invest further in access to innovative treatments – something which should be addressed if a similar mechanism is used for the 2019 agreement.

Accelerated Access Review (AAR)

5. Reference within the industrial strategy to the Accelerated Access Review (AAR) is welcome. The success of the industrial strategy will be dependent on widespread implementation of its recommendations.

6. Industry, regulatory agencies, NICE and the NHS will need to work together to support early access to innovative products. Examples of managed access agreements and other commercial agreements which have been agreed after protracted periods of negotiation between NHS England and companies should be used as a reference point for newer products to support earlier patient access to treatments.

7. Reviewing how the NHS introduces new medicines also provides an opportunity for NICE and NHS England to consider how orphan products are assessed, including the interchange between the single technology appraisal, HST and NHS England clinical commissioning policy processes. It is important that orphan drugs do not fall between the gaps and are made routinely available on the NHS so that patients with conditions where there is unmet need are not disadvantaged.

Responsibility and accountability

8. The decision to remove a dedicated Life Sciences Minister from the Government risks fragmentation in the implementation of industrial strategy recommendations for life sciences. In the absence of a Ministerial lead, the Office for Life Sciences may suffer from a lack of momentum. The delay in there being a formal response to the Accelerated Access Review may be a reflection of this.

Brexit

9. Brexit brings considerable uncertainty for the pharmaceutical and medical technologies sectors. Reassurance, such as the recent confirmation from Lord O'Shaughnessy that new EU medical devices regulations will be followed in the UK after Brexit is welcome. In line with most voices in the sector, MAP supports close collaboration with regulatory agencies after Brexit to provide consistency and avoid the UK losing its place as a priority location for the launch of new innovative products.