Association of British Healthcare Industries

HEALTHY OUTSIDE THE EU
UPDATE

JANUARY 2018

INTRODUCTION

In April 2017, ABHI published "Healthy outside the EU – Strategy for a thriving MedTech industry."

Nine months on, and in the light of developments such as the publication of the UK Government's Position and Future Partnership papers, and the Industrial Strategy, we have revisited our initial 36 recommendations.

Whilst we believe all are still valid, we have focused on a smaller number of "essentials" for the sector as we approach March 2019. The recommendations remain aligned to our five, original themes: Regulatory Stability, Trade, Skills, SME Support and Enhanced Collaboration with the NHS.

The latter is particularly, and increasingly important. For the NHS to play its full role as an engine for economic growth through the adoption and spread of innovation, and the MedTech sector to maximise its contribution to NHS efficiency, a collaborative, rather than confrontational approach, will be essential.

There are reasons to be optimistic; the MedTech sector deals announced as part of the Industrial Strategy, the Government's response to the Accelerated Access Review, and the development of the Innovation National Network for MedTech, are all positive measures.

Set against this, the financial pressures on the NHS are driving short-term, transactional and hostile behaviour in the procurement of goods and services. Many such initiatives run counter to the positive policy intent evident elsewhere. A continued weakness of the pound and the prospect of new border arrangements post-Brexit, for an industry with complex, international supply chains, will continue to increase the costs of doing business for MedTech companies. Yet the NHS seems to believe that it should be immune from the cost pressures faced by its suppliers.

Whilst considerable uncertainty remains about the final outcome of Brexit negotiations, it is clear to us that the most important consideration for the NHS is that its patients should be guaranteed continued access to life saving and enhancing medical technologies. This requires a fully functioning system for the movement of MedTech products and a recognised regulatory regime for the market authorisation of such products on day one. Our two, overarching recommendations are therefore:

1. All products used in healthcare should be exempt from any new customs, tariff or VAT arrangements, and afforded pre-shipping clearance and fast track access across any new EU / UK borders
2. There should, at least initially, be continued compliance with the current CE marking system for medical devices and the continued validity of products currently in the market place (grandfathering).

THE RECOMMENDATIONS

Regulatory Stability

1. The UK remaining part of the CE marking regime for MedTech. This requires mutual recognition of the CE-mark between the UK and EU and, where practicable, similar arrangements with other jurisdictions
2. UK Notified Bodies (NBs) remain within the existing European network and oversight mechanisms. They should continue to be designated to assess devices for the EU and UK markets
3. Authorised representatives of manufacturers based outside the EU should still be allowed to be domiciled in the UK
4. MHRA to remain formally engaged with the European Commission's new stakeholder body, the Medical Devices Co-ordination Group (MDCG), and has full access to the Eudamed database, so retaining insight and influence over the EU regulatory system.

Trade

5. All products used in healthcare should be exempt from any new customs, tariff or VAT arrangements
6. Increased MedTech specialists in the overseas consulates and embassies
7. Launch a MedTech export campaign – a designated, long-term, country-by-country strategy for UK MedTech companies, led by market specific MedTech champions.

Skills

8. Ensure the continued availability of skilled labour and access to the best talent globally.

SME Support

9. Cabinet Office targets for spend on SMEs should be included as part of the inspection regime for all NHS organisations
10. Appoint a high-profile, cross-government MedTech SME Champion to address policy anomalies.

Enhanced Collaboration with the NHS

11. A statement of intent, from the highest level of both NHS England and NHS Improvement, to leverage the full potential of the service to drive economic growth

12. Cost increases associated with Brexit affect all sectors of the economy, including those which supply the NHS. The NHS should work with its suppliers to manage these pressures in a collaborative way. The price of some inputs will increase, and it is unrealistic for the service simply to deny this. For example, with respect to any increase in the cost of goods

13. It is important, therefore, to utilise whole systems thinking to inform the intelligent, outcomes-based procurement of MedTech, recognising that potential savings are often not realised in-year, but accrue over time. As noted in their submission to the House of Lords Science and Technology Committee's inquiry into the Life Sciences and the Industrial Strategy,

> "NHS England is also particularly interested in 'substitutive innovations' that simplify pathways and take out cost. However, the benefits of these only accrue when local NHS systems do the redesign, integrate the innovations, and genuinely take out cost. These are unlikely to be achieved through simple national procurement."

14. The NHS should pursue a more strongly data-driven approach to procurement that is less reliant on the use of intermediaries and remove duplicative procurement arrangements, ensuring that any such intermediaries provide added value

15. Urgently implement the recommendations of the Accelerated Access Review and make full use of the new Innovation National Network for MedTech led by the Academic Health Sciences Networks

16. Use payment and incentive systems to support the adoption of MedTech via individual technology tariffs, reconfigure the NICE Technology Appraisal programme to support wider inclusion of MedTech and the funding mandate, and introduce a "comply or explain regime" for all NICE guidance.

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