Future Requirements for a World-Class UK Regulator - Perspective of the HealthTech Industry

Background

1. In the promotion and care of human health, regulation is a central, indispensable assurance. This is as true for HealthTech (devices, diagnostics and digital and AI technologies) as it is for pharmaceuticals. If a medical device is to be placed on the market, the purchaser needs to know that it fulfils a range of key requirements, such as the way it has been developed, the testing to which it has been subjected, the materials used and the clinical outcomes promoted.

2. This context is essential in determining which pathway should be promoted by the UK for regulation of the products manufactured and distributed by its HealthTech industry, a significant innovator and exporter. Thanks, in no small part to its relationship with the NHS, the industry has played a major role in setting global standards for quality, not only in design and manufacture, but also in outcomes.

3. The UK, therefore, needs to be an accomplished regulator. Furthermore, it is highly desirable that the UK is able to influence the development of the global regulatory framework, given the scale of the world market and its rate of growth. The UK Industry and Regulators have played a significant role in the development of European legislation over the last 30 years, and can again take the lead in developing a sovereign regulatory system which will be compatible with other jurisdictions.

What is needed

4. Beyond 2020, the UK will need its own, sovereign regulation for HealthTech. The new UK system and its Regulator will need to fulfil a number of criteria, which include, but are not limited to:

5. The continuing assurance of patient safety.

6. Be recognisable by Competent Authorities internationally. This would include recognition of research and mechanisms that ensure compliance, and a UK Conformity Assessment process should include provisions such that it is recognised globally, for example by the Medical Device Single Audit Program (MDSAP). MDSAP allows recognised organisations to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of all the regulatory authorities participating (Australia, Brazil, Canada, Japan and the United States).

7. The UK Regulator should contribute to global regulatory development by becoming a member of the International Medical Device Regulators Forum (IMDRF) in its own right. IMDRF is a global forum that exists to accelerate harmonisation in medical device regulation and includes all major markets (Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, South Korea and the United States). The UK should

draw on the principles developed by IMDRF when creating regulations for HealthTech, thereby providing for data compatibility and resonance with other jurisdictions.

8. Be recognisable by manufacturers in a global context, not substantially increasing complexity and cost to ensure regulatory compliance. Any sovereign UK regulation should not contain unnecessary, costly or burdensome additional requirements from those of other, established global Regulators. Data compatibility between Regulators will ensure patient access to technologies internationally, as well as maintaining the attractiveness of the UK as a market for HealthTech.

9. The Regulator should work closely with the HealthTech industry and other stakeholders, to provide transparent, collaborative and innovative approaches to UK regulation. Lessons can be learned from the swift and pragmatic approach of the MHRA to make products available during the Covid-19 pandemic, and risk-based methodologies that incorporate ethical business practise into the regulatory process. The latter will be particularly relevant to rapidly iterating digital health technologies. Establishing the UK Regulator as innovation friendly and linking the regulatory process to the adoption and spread of technologies, could make the UK a first choice market for new clinical developments.

10. Given the acute shortage of capacity, both in industry and Regulators, the UK Regulator should endorse and participate in a formal educational programme in Regulatory Science to provide more highly qualified professionals.

11. The UK Regulator needs to be appropriately resourced to be able to not only undertake its necessary tasks, but to lead innovation in global regulation. The UK Regulator should be funded by central government to maintain its independence from the sector it regulates.

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