ABHI
REGULATORY

ABHI SUMMARY REPORT: FUTURE REGULATION OF HEALTH TECHNOLOGY IN THE UK

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INTRODUCTION

Following the Medicines and Healthcare products Regulatory Agency (MHRA) consultation on the future regulation of medical devices in the United Kingdom, ABHI has taken the opportunity to reflect with its membership on some of the concepts that were either not included in the consultation, or where they wished to expand on the points made in the consultation. As such, this report should be considered in addition to the ABHI consultation response.

As with the MHRA consultation, we have considered medical devices, diagnostics (incorporating in vitro diagnostic technologies and wider diagnostic methods such as imaging) and digital health products together in all but two sections of this report.

The sections on IVDs and digital health products therefore focus only on the issues that are very specific to those product areas.

We have prepared this summary to highlight the discussions held with members and it will be used to inform the MHRA and other key stakeholders. ABHI welcomes discussion on the points raised and we will develop further position papers where necessary.

TRANSITION

The Practical Challenge

ABHI calls for the transition times of the UKCA mark to be extended to allow the necessary UK infrastructure to be developed, such that existing products can continue to be supplied, and products that are new to the market can be made available safely to patients who need them.

Practical transitional arrangements should be in place to ensure that the relevant systems and capacity of the different actors (including the MHRA, UK Approved Bodies, UK responsible person, manufacturers, importers and distributors) are in place. UK Approved Bodies must be in place with sufficient capacity. Industry then needs the appropriate time to make any necessary changes to labelling, registration and any other new requirements.

Manufacturers and/or importers should be able to place HealthTech products on the market that hold a valid CE certificate, through an extension of the current standstill agreements. From a safety point of view, it would not make sense to prioritise current UKCA certificates (UK MDR) over EU MDR/IVDR certificates.

A transition timeline that is progressive and risk-based helps to ensure that HealthTech products are continuously available for the care of UK patients.

Limits on sell-off periods risk the introduction of administrative shortfalls and excessive waste. If HealthTech products are placed on the EU or UK market, prior to the expiry of the certificate, there should be no further limit to making those products available. These products have already demonstrated their safety and performance in other jurisdictions and through post-market surveillance. Furthermore, these limits could undermine the UK's circular economy and sustainability goals, by destroying the thriving refurbishment market of capital equipment such as X-ray machines.

As a consequence of sell-off provisions, there is currently a situation where compliant stock held at EU based distribution centres becomes unavailable when a CE certificate expires, despite the same product held in a UK warehouse being available for sale.

Neither product, however, can be registered onto the UK registration database. International companies are therefore being forced to find and fill UK warehouses ahead of CE expiry, in order to avoid losing all access to stock. In addition, it should be noted that when MDD/IVDD product transitions to MDR/IVDR, the MDD/IVDD product and its associated CE all again become unavailable to the UK.

Demonstration of product safety and performance in other jurisdictions (EU, US, etc.) should be an essential component of any UKCA transition and is an indispensable part of a longer-term UK regulatory strategy. Consideration should also be given to a process for allowing legacy products beyond any transition period that are used for revision surgeries that may not be UKCA marked but that had been previously CE marked.

The MHRA proposals for grace periods for existing certificates and declarations are therefore welcome, particularly for products that already exist on the market, but they do not support the development of new and innovative products that need to undergo significant change and development during the transition period.

Non-alignment of transition dates across different regulatory regimes within the UK, and between the UK and elsewhere, need to be managed to ensure products remain available for use. Special consideration should therefore be given to the transition of products that are used in kits and procedure packs, and the transition of products that are used in combinations (e.g. with drugs, other medical devices and other regulated products).

Combination products that have received MHRA approval in the past, or have been approved by a European Competent Authority, should be grandfathered across to UKCA, with the possibility of a deferred assessment. We are concerned, however, that there would not be the capacity at the MHRA to handle a full review of all consultation dossiers, in turn leading to the unavailability of product in Great Britain when product safety and efficacy had already been established.

LABELLING

The Practical Challenge

There was no specific section on labelling in the consultation, yet this is a key industry concern. There are practical and logistical considerations on what should be included in new labels and by when. UK specific requirements for labels add to the cost of selling into the UK without adding to safety or product performance.

Labelling requirements would be one of the key challenges to the transition of products that may result in the unavailability in GB of products whose safety and performance have been verified.

All HealthTech products should be labelled, and some require multiple labels due to the numerous levels of packaging, with many also requiring instructions for use (IFU). Some labelling is product specific and other products may have a generic carton, or pouch, with product parameter labelling printed on, or affixed, for example contact lenses and intraocular lenses. Therefore, a small portfolio of 10 products could become 30 artworks to update (label, carton and IFU) and a large portfolio of 5,000 products could become 10,000 on an average of two artworks per product.

These issues are further exacerbated when considering those products that require "direct part" marking. To have country specific requirements for these products requires not only consideration of part size (i.e. available real-estate), but also the engineering of new machinery and manufacturing equipment, followed by additional verification and validation exercises.

The artwork change-control process is often complex and includes:

- Approval to make the artwork change
- Mocking up new artworks
- Artwork approvals
- Sourcing and printing of new artworks
- Manufacturing and validating products with new artworks
- Moving products with new artworks to distribution centers.

When changing an artwork, a manufacturer has to consider whether they will need to scrap any stock of already printed cartons, pouches, labelling, as well as the products themselves. This has a financial cost to the manufacturer and also an environmental one.

Where possible it is desirable to deplete existing packaging stocks before moving on to the new stock.

Given the number of steps that need to take place to put a new artwork in place for one product before scaling-up to hundreds and thousands of like products, or to develop new tools for direct part marking, manufacturers typically need at least 18 months – two years to implement changes. This would allow for artwork updates to be made and the appropriate planning to be undertaken to transition products to new artworks at a suitable time and therefore reducing waste and cost.

Other areas that should be considered within the future CA marking process include:

- **Need for CA Mark on Labels**
  With CE marking a facilitator of cross-border trade and the UK having no borders, the application of a CA mark is questioned.
- **Timelines**
  To minimise duplication and cost, by ensuring that timelines for label change coincide with the corresponding changes in Europe for MDR/IVDR change.
- **E-labelling**
  The scope of the law on e-labelling should be expanded to include all HealthTech, allowing electronic solutions to be recognised.
- **Labelling Hierarchy**
  Build flexibility into the UK labelling requirements, particularly as to where any CA mark is situated and consideration of the usefulness of direct part marking.
- **Linking to Registration**
  Ensuring that a transparent registration database is used to demonstrate availability of product and of physically placing on the market by the manufacturer. Registration could also be a repository for information on other economic operators.
- **Standards/UDI**
  Any symbols on labelling should be globally recognised/ harmonised symbols in order to limit international registration impact.

IVDS

The Practical Challenge

Although one section of the consultation focused on a range of IVD-specific issues (including classification, genetic testing, companion diagnostics and distance selling), there were only two sections of the consultation that did not apply to IVDs (classification and implantables). As with the MHRA consultation, this section of the report therefore reflects only IVD specific issues. Other sections of the report include IVDs and medical devices together.

Whilst it is highly desirable that UK IVD classification aligns closely to the Principles of In Vitro Diagnostic (IVD) Medical Devices Classification from the International Medical Device Regulators Forum (IMDRF), some consideration could be given to IVD principles not yet fully considered by IMDRF, such as IVD software and risk prediction. These considerations should of course go hand in hand with a full UK engagement with IMDRF.

DIGITAL

The Practical Challenge

The consultation describes research and development but does not address the overlaps with other pieces of regulation. Also omitted is how regulation may deal with digital/device combination products specifically, although there is mention of "airlocks".

Opportunities

Reference should be made to the ABHI White Paper: Digital Health Regulatory Concepts. In general, however:

- Any regulation that is developed has to distinguish between "software as a device" and "software in a device", as well as considering aspects such as change control, cyber-security and legacy devices.
- Regulation should ideally be flexible, risk-based, and using, in particular, those guidelines published by the IMDRF. In this respect, the IMDRF has made a clear distinction between the healthcare situation and the significance of the software output, aspects which will determine overall risk. With the UK able to operate in a global setting, these guidelines should be carefully considered.
- Cyber-security risks should continue to be considered and monitored, post-market, throughout the lifetime of the product. Aspects of cyber-security to be factored in should include intended use, connectivity, use environment, functionality, shared systems, and, above all, should be linked to the risk to patients and consider the shared responsibility between manufacturer and user. The MHRA should consider definitions from other jurisdictions here, for example, those used by the Food and Drug Administration (FDA) and European Union.
- A better understanding and definition of the "airlock" would be beneficial in order to assess potential value in future regulations. Moreover, classifications of envisaged products that would benefit from the process should be developed in the short-term, to better allow for the understanding of potential approval and access programmes.
- In-house manufacture should fall under same regulatory framework, when such products are placed on the market. Health Institutions making product on an industrial scale should follow the requirements of a manufacturer to ensure performance, safety and efficacy. It is irrelevant who manufactures a product. What is important is the minimum level of safety and performance requirements as per legislation. These should be the basis to ensure patient safety, regardless of who manufactures the product.
- Clarity should be provided through guidance on the topic of distance sales and definitions of placing on the market. Definitions should be aligned with those within current regulations, particularly to avoid deviation from MDR/IVDR.
- Consideration should be given to predetermined change control plans, which appear to have some value. Any such consideration, however, should be approached on an international basis via IMDRF.

SUSTAINABILITY

The Practical Challenge

The sustainability agenda is gaining momentum and clearly has an overlap with future regulation. Any increased or proposed sustainability legislation however, that would be included within CA marking platforms, would result in a clear divergence from Europe, and potentially from other global requirements. Any such deviations would add complexity and cost to the UK and likely present the UK as a less attractive marketplace.

Opportunities

Learning from the pandemic, the MHRA and UK Conformity Assessment Bodies should adopt remote auditing as a route to ensuring compliance. Whilst the value and need for on-site audits is understood, a reliance on physical attendance is questionable, particularly with surveillance audits.

By necessity, the pandemic has opened doors to new ways of conducting business and monitoring compliance with regulatory requirements. New processes, such as remote auditing, have been demonstrated to be effective tools during specific circumstances, but also a way to modernise our regulatory systems, and provide more transparency. This also aligns with the World Health Organization's Good reliance practices in regulatory decision-making for medical products programme, and may help overcome possible capacity issues of the system.

Consideration should be given, therefore, to partial, or fully remote audits, carried out by the UK Approved Bodies on a risk-based approach. In addition, the criteria to be applied to remote or hybrid audits should provide certainty and clarity to all actors.

Consideration should be given to the long lifecycle of the medical device and IVD products which is up to 15 years. Whilst it is easier to design new sustainable products e.g. in order to eliminate substances of very high concern (SVHC, substitution of a specific substance in an existing product design can be extremely challenging.

Specific substances are selected based on their physicochemical properties, and accordingly substance by substance substitution (for e.g. SVHC) will not always work. A new product design is needed.

ABHI recognises the desire to re-use certain products, but those that are currently designed to be single-use may be hard to safely re-use. Any change to the existing regulation regarding the re-manufacturing of single-use devices needs to consider patient safety and post-marketing surveillance responsibilities. ABHI believes the current regulation should not be materially changed.

Introducing an environmental and public health impact assessment as part of conformity assessment, would introduce additional regulatory burden on manufacturers, which may be contradictory to promoting the UK as a favourable market. Ideally, environmental controls would be better managed through requirements introduced through compliance to the ISO14001 standard (or presumption of compliance).

A number of waste management responsibilities already exist within the HealthTech supply chain. Manufacturers should, however, be encouraged to consider sustainability. It should be noted that HealthTech is a complex industry and there are limits to what manufacturers can change especially in regard to specialist materials (e.g. sterile barrier systems). In other sectors, such as pharmaceuticals, there are exemptions to obligations where the requirements are unable to be met. We would like to see similar exemptions extended to HealthTech for specialist materials, such as sterile barrier systems that cannot contain recycled materials, single-use devices or multi-use devices that have a defined end of life dictated by safety profile (e.g. can no longer be cleaned to an acceptable standard).

PATIENT ACCESS TO INNOVATION AND RESEARCH

The Practical Challenge

ABHI welcomes the MHRA desire to meet the requirements of the Medicines and Medical Devices Act 2021 to make the UK "a favourable place in which to: carry out research relating to medical devices, develop medical devices, or manufacture or supply medical devices", whilst maintaining high standards of patient safety.

There should be alignment with EU MDR/IVDR for clinical evidence requirements, but for the approval of clinical investigations and performance studies to take a more flexible approach that relies on clear processes and guidance with comprehensive UK standards to support UK patient access to new and innovative devices.

The use of real-world data (when aligned with IMDRF) and the recognition of patients' lived experience of HealthTech can be important elements of clinical evidence

To make the UK a favourable place to develop products, the clinical evidence outputs from UK studies will need to be transferable across to other regulatory jurisdictions.

ABHI supports the intention to encourage device development through the use of new pathways, such as passports and the Innovative Devices Access Pathway (IDAP). Innovation is important for the HealthTech industry across the UK, including small, medium and large companies. This is in-line with the ABHI messages on innovative products that were presented to the MHRA Board last year.

The IDAP proposal for an innovative pathway is an excellent idea and would allow manufacturers to get innovative devices to the market whilst maintaining patient safety. IDAP, however, should not only be open to SMEs but for all manufacturers, especially if the technology is a 'game changer', with a clear patient need. It is unclear how restricting this pathway to SMEs promotes innovation and in many cases could be seen as counterproductive.

There is an opportunity for the MHRA to introduce a mechanism for the issue of exemptions for the clinical evidence requirements for low-risk categories of products. This could take the form of a common specification, or a monograph, where certain parameters or special conditions are met and manufacturers have shared and pooled their clinical data of that type of product with the MHRA. The common specification, or monograph approach, could improve standards and ease access to market.

With regards to lived experience of HealthTech, a further MHRA-led consultation with the public and patient groups would be helpful. Given the vast range of products, an automatic requirement to have patient/public involvement is justifiable. Such a wide-ranging consultation would have the benefits of bringing a number of stakeholders together, in order to set a frame of reference to remove any ambiguity as to whether manufacturers were engaging with the relevant patient/public groups.

DOMESTIC ASSURANCE/ GLOBALISATION

The Practical Challenge

Central to the MHRA proposal is the concept of domestic assurance, equating to access to the UK market for products with approval from certain other international regulators, particularly those regulators aligned with principles developed by the IMDRF.

If implemented appropriately, then domestic assurance could allow products that have already demonstrated acceptable safety and performance (e.g. via the Medical Device Single Audit Program (MDSAP) or CE marking) to be made available to UK patients. Simple access routes to the UK market that protect patient safety can make the UK a favourable place to manufacture and supply HealthTech.

Critical to this success will be common sense requirements for importers, distributors and other economic operators including the Responsible Person, to ensure for manufacturers, there is no duplication of efforts unnecessarily across the UK and EU.

One potentially ambitious implementation of the domestic assurance route would be a greater reliance on the use of the MHRA's registration database. With greater access, combined with increased public transparency, there would be no need for individual UKCA marks on product labelling.

This could even be combined with a new UK e-labelling system, in a process that would benefit manufacturers, patients, end-users and regulators, whilst simplifying and accelerating products and innovations into the UK health system.

Opportunities

Defining the Roles of Economic Operators, Including the Responsible Person

The role of all Economic Operators should also be assessed, including the importer, distributor and Responsible Person. Again, specifically, their roles around product release and control should be considered and clearly defined.

In order to ensure the attractiveness of the UK health market, regulatory approaches that minimise unnecessary regulatory burden on all stakeholders involved should be developed. Such a system should ensure timely access to safe, effective, and innovative HealthTech, whilst increasing patient confidence in the quality and safety of the products they use.

With a trend towards global regulatory harmonisation and recognition, future regulation will need to consider the roles of Economic Operators in the timely and safe supply of technologies.

Recognition of Regulatory Approvals from Different Jurisdictions

UK HealthTech regulation should seek consistency and recognition with other major and developed regulatory and standards frameworks, such as those promoted by the IMDRF, EU MDR, EU IVDR or US FDA and international standards bodies such as ISO, and CEN. Consistency would ensure the supply of HealthTech to the UK market, enhancing the quality and safety of products and increasing access to existing, new, and innovative technologies.

IMDRF Principles and MDSAP as a Positive

The MHRA's active involvement in shaping the global regulatory environment, for example via IMDRF, is supported by the HealthTech industry. To facilitate this, there should be an appropriate level of competent resources within the MHRA, to build trust with those international partners. Such cooperation and involvement will ultimately ensure that the UK becomes a more attractive market whilst enhancing the supply of safe products to the UK.

Industry support also extends to the active MHRA involvement in shaping rules and implementation of MDSAP in the global regulatory environment. In a global market moving more towards a global technical document review process, it is critical to reduce the number of regulatory and quality system audits, which is the consequence of inconsistent regulatory approaches and application of disparate technical requirements.

The use of remote audits should be considered for use, even when not in special circumstances such as a global pandemic.

The Conformity Assessment Process

To ensure the effectiveness of alternative methods, a minimalist approach to an abridged assessment and the appropriate levels of scrutiny should be employed. Reliance based on recognition enables the UK to maximise the opportunity to leverage work already done in other jurisdictions. Other reliance models should enable minimal additional work to be done, such as checking that the appropriate certificates from other major regulatory regimes exist and conduct of enhanced post-marketing surveillance processes.

The MHRA should especially consider how it can designate Approved Bodies outside the British territory without adding pro forma administrative burdens regarding physical presence. Setting the framework for Approved Bodies to conduct joint audits on different regulations is a best practice to use synergies and build on all existing capacities, which is currently under peak pressure due to multinational regulatory changes (e.g. EU regulations).

Drug-Device Combination (DDC) Products

Under the EU MDR marketing authorisation holders (MAHs) of DDC products shall assure that the device constituent of such combination fulfils the relevant General Safety and Performance Requirements (GSPRs) of Annex I of Regulation 2017/745 related to the safety and performance of the device part.

The MAH must seek a notified body opinion (NBOp) on the conformity of the device part with the relevant GSPRs issued by a Notified Body (NB) designated in accordance with the EU MDR. The MAH is responsible for submitting the NBOp in conjunction with the Marketing Authorisation Application (MAA) to the medicines competent authority.

Defining a Regulatory Path for DDC Products in the UK: General Principles

Whilst the EU MDR introduces new requirements to ensure patient safety, it also creates an unnecessarily tortuous regulatory pathway, increasing the overall time to market, in the process missing certain key topics, such as the assessment boundaries between the approval bodies and product life cycle management requirements.

In summary an optimum scenario in the UK for DDC products would see:

- Alignment of the UK essential requirements to the GSPRs of the EU MDR.
- No need for a UK conformity assessment review of the device constituent: the assessment of compliance of the device constituent to the GSPRs, which in the EU is performed by a NB, might be in the UK under the MHRA. In this scenario, the MAH would submit the MAA to the European Medicines Agency (EMA) only, as done so far.
- The defining of a regulatory path for DDC products in the UK, for example when a specific case when same device constituents are used with different drug constituents.
- A DDC product manufacturer may choose to use the same or very similar device constituents to contain and administer different medicinal products. This is the case, for example with most pre-filled syringes. The same syringe may be used by the same pharmaceutical company in combination with various medicinal products. Also, those syringes, can be supplied by external HealthTech companies as components to numerous pharmaceutical companies.

Under the EU MDR, the conformity of the device constituents to the GSPRs is assessed at first time registration for each of those DDCs and once again when a change to the device constituents triggers an updated NBOp.

Although the device part technical information and the data to demonstrate compliance to some GSPRs are identical for each of those DDCs, in the scope of the initial or an NBOp update, the NBs will have to review the same information many times.

An alternative approach is proposed below for the UK market that may help to streamline the review process and potentially bring innovative DDC products to patients in a more expedited manner.

A general (core) GSPRs checklist is prepared for the device constituent part accompanied by all related technical documentation. The core checklist is focused on the device manufacturing, controls, risk analysis, biocompatibility aspects and performance data (obtained by testing the device empty or with an analogous drug surrogate).

When a MAA is submitted for the first time for a DDC including that device part, the core GSPR checklist is submitted by the pharmaceutical company* to the MHRA, together with the drug eCTD file. An integration to that core GSPR checklist will also be submitted to demonstrate compliance to some requirements that may be affected by the specific DDC or by some additional manufacturing steps.

The MHRA will review the GSPR checklist on the device and provide an opinion, if needed.

When another MAA is submitted for a DDC containing the same device constituent, the MHRA will not review again the GSPR checklist, but only those requirements that are potentially affected by the combination with the new medicinal product.

This regulatory pathway has many advantages, including centralised review, protection of confidentiality, a smooth lifecycle management and limitation of dossier creations and submissions.

A similar approach is already in place in the United States. The Center for Drug Evaluation and Research is responsible for the review of combination product applications and is requiring the Center for Devices and Radiological Health to review the device component information.

The device information is submitted by the device supplier to the FDA in the form of a device master file. The supplier provides a letter of authorization to the MAH, and the MAH files the medicinal product dossier together with the LoA to the FDA for assessment.

**When the device constituent is supplied by another company, the core GSPRs checklist could be submitted to the MHRA by the device supplier, this will also help manufacturers of device components in protecting proprietary information. The same approach could be used for changes affecting the device constituent.*

Device Incorporating Ancillary Medicinal Substances

As for the Medical Device Directive 93/42/EEC, during the certification process for devices containing an ancillary medicinal substance, the NB must review device aspects and seek the opinion of a European competent authority in relation to the ancillary medicinal substance incorporated in the device. Prior to seeking the opinion of the competent authority, the NB must verify the usefulness of the medicinal substance incorporated in the device. The competent authority will provide the NB with a scientific opinion on the quality and safety of the substance, considering the clinical benefit/risk profile of the incorporation of the medicinal substance into the device. The review of the medicinal substance by the competent authority may take up to 210 days.

Considering the current regulatory path, to be able to launch those type of products in EU and UK, manufacturers will have to apply to a UK-based Conformity Assessment Body that has a presence both in the UK and the EU. This will limit the choice of NBs and may, at least in the short-term, overburden the few currently available.

The NB will have to request a scientific opinion on the medicinal substance to both the MHRA and an EU competent authority (or EMA). To avoid delay in the assessment, the review of the medicines competent authorities should be synchronised as much as possible. It is advisable to have a formal process coordinated by the NB to receive questions from the medicines authorities and provide feedback to streamline communications. A process similar to the current work-sharing procedure in place for variations could be envisaged to avoid duplication of work from the medicines competent authorities. This will also facilitate the lifecycle management activities (e.g. the need for updated scientific opinions further to changes affecting the ancillary medicinal product).

In an ideal scenario, at least for devices containing well-established medicinal substances used in the same approved indication, it will be beneficial to have a mutual recognition of the scientific opinion on the medicinal substance quality and safety between the EU competent authorities and the MHRA.

EQUALITY, DIVERSITY AND INCLUSION (ED&I)

The Practical Challenge

The concepts of ED&I were not a separate component of the MHRA consultation. Whilst we would agree that the requirements of ED&I run through many, if not all, aspects of product regulation, ABHI would like to draw attention to some particular concerns.

Requirements for ED&I should drive access in otherwise under-represented populations. Improved access can support improved health outcomes.

Regulatory requirements for clinical evidence, product development, authorisation and post-market activities should explicitly ensure that products are suitable for the intended target patient groups as stated by the manufacturer.

As no single approach can represent all populations (e.g. ethnicity, gender, learning difficulties etc.), regulatory requirements should not be proscriptive to the population.

CLEAR REQUIREMENTS

Summary

The current proposals for the legislative text are a series of additional amendments that will make the regulatory framework in the UK potentially unworkable and inaccessible. Developers, users and suppliers of HealthTech in the UK need to be clear on their legal obligations so that they do not risk inadvertently falling foul of UK requirements. Only a clear accessible and consolidated text from an authoritative UK source will allow people to understand and follow UK requirements.

There should be sufficient expertise within MHRA to provide such scientific and regulatory advice.

Guidance, standards and specifications all underpin the UK legislation. These non-legislative solutions need to be consistent, clear, unambiguous and workable for the HealthTech industry in the UK and be available in good time prior to implementation. MHRA regulatory and scientific expertise is important to ensure good quality guidance.

Access to good regulatory advice is critical for industry in the UK. This includes clear contact points, and reasonable timescales.

It is important for the MHRA to work closely with other UK regulators and healthcare stakeholders, such as the National Institute for Health and Care Excellence, the Care Quality Commission and the United Kingdom Accreditation Service, to ensure the whole UK regulatory framework for medical devices is proportionate and streamlined.

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