August 2019

Green Paper

Future UK Regulatory Frameworks Post Brexit

Executive Summary

The general principles from the International Medical Device Regulatory Forum (IMDRF) for medical technology regulation, are borne from the 'New Legislative Framework' in Europe, which is the basis for the Medical Device Directive (MDD), In-vitro Diagnostics Directive (IVDD), Medical Device Regulation (MDR) and In-vitro Diagnostics Regulation (IVDR). If any future UK regulatory system was to be based on IMDRF principles, it could ensure that;

- The system will be recognisable to manufacturers, therefore resulting in no substantial increase in costs or complexity with regards to regulatory compliance,
- Research and Compliance work conducted in the UK would be recognisable to global competent authorities.
- Flexibility and speed can be built into UK compliance processes to ensure that the UK remains competitive post-Brexit.
- Future UK regulatory compliance can include a 'UK Compliance Mark', potentially providing for UK based 'Third Party Conformity Assessment bodies.'
- Regulation could include references to Ethical Business Practice and Regulation (EBP&R), in order to pre-empt longer-term compliance initiatives and activities.
- Input into the global regulatory discussion by the MHRA will maintain their position as a preeminent regulatory authority.

August 2019

Introduction

The MHRA has indicated that irrespective of the outcomes of political discussions[1], the UK will accept the European CE Mark as a route to placing medical technologies on the UK market. The MHRA has further qualified this position, by insisting that this acceptance will be for a 'time-limited period', which is expected to be no greater than 2 years.

This 'Green Paper' describes a potential basis for a future alternative regulatory strategy based on application of principles outlined by the IMDRF. This paper further advocates the increased input and influence of the MHRA in this international forum, thereby ensuring that the UK maintains its current global presence and reputation.

Background and Proposal

The IMDRF was constituted in February 2011 as a forum to discuss future directions in medical device regulatory harmonisation. It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonization and convergence.

http://www.imdrf.org/index.asp

Current members of the IMDRF include Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, South Korea and the United States.

The IMDRF (and the former GHTF) has produced many documents that straddle global regulatory systems, and include much of the MDD/MDR backbone, such as 'essential principles', 'conformity assessment', 'risk and quality management', 'application of standards' and most importantly, 'manufacturer responsibility' and subsequent 'declaration of conformity'.

As the IMDRF is a global forum, its documents have to be flexible to allow national Competent Authorities latitude in defining any resulting national laws and practices. Furthermore, the requirements in the IMDRF documents are similar, if not the same, as the European 'New Legislative Framework' or CE Marking scheme. As a result, therefore, and as an overall aim of the forum, a product's technical data stipulated through application of the IMDRF, will be largely identical to those of CE-Marking.

To maximise any future advantages afforded by application of IMDRF principles, the MHRA could be advised to become independently involved as a member of the forum. This would ensure firstly that the UK's voice and comments are considered, and secondly, that the UK can influence the direction of international regulation.

It is recognised that the IMDRF is the driving force behind the MDSAP (Medical Device Single Audit Programme), which has been identified by the MHRA and industry alike, as a potential positive, post-Brexit. IMDRF is also working with FDA on aspects of software, which will offer the potential for collaborations between the UK and US.

[1] https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario

August 2019

A consequence of the UK leaving the EU CE-Marking process, has been that the indigenous Conformity Assessment organisations (Notified Bodies) have migrated to mainland Europe. A UK-based regulatory system based on IMDRF principles however, could provide a platform for the rejuvenation of these bodies, specifically aimed at future specific UK marking.

Gap Assessment; IMDRF Documents vs. MDR

A preliminary 'gap assessment' between the current MDR requirements and those of the IMDRF guidance, has been carried out.

It is important to note however, that the IMDRF only produces guidelines, so the UK legislators would have to transform these into UK law. This should potentially not be too difficult to achieve, as the principles are not too different from those already enacted for the MDD, IVDD, MDR and IVDR.

Further to ensuring that any indigenously developed regulation is compatible with global trends, consideration could be given to the introduction of EBP&R as part of the UK adaptation of IMDRF principles. This would ensure that future regulation would be at the forefront of development for many years to come.

Aspects of the EU Medical Device Regulation are covered to a large extent, by the documents produced by the IMDRF. As an example, the 'Summary Technical Documentation (STED)' document philosophy used for data format is well established and used globally for the development of technical documentation files, including within the EU. Furthermore, the IMDRF also defines Risk, Classification, Essential Principles and Conformity Assessment, which are again the main elements of the 'New Legislative Framework'.

A 'preliminary gap assessment, however, identifies the following as being within the EU Medical Device Regulation but not within IMDRF guidelines. The colour coding refers to the potential solution for their inclusion in future regulation;

- Placing on the market requirements
- Distance sales
- Common Specifications (could these be added to the sections on Standards?)*
- Obligations on manufacturers
- Persons Responsible for Regulatory Compliance
- Single-use devices and their reprocessing
- Parts and Components
- MD Nomenclature (as relates to UDI)
- UDI Database / EUDAMED
- Electronic systems for registration of EO's
- Details on NBs, although discussed as Regulatory Reviewers
- Clinical Investigations in Emergencies / damage compensation / application or submission of clinical trials / Clinical Investigation of products that have the CE Mark / provision of results (etc),
- Post-Market Surveillance other than vigilance and vigilance reporting, including PSURs etc., **
- Custom-made devices,

- Clinical provisions covered by ISO 14155
- Scrutiny procedure

Notes;

Orange = National provision / requirement
Purple = Standards or International guidelines
Red = UK guidance
Black = International requirement

* It should also be noted that the IMDRF Principles, as with the 'New Legislative Framework', depend on the application of recognised standards. They do however, as a result of being the International Regulators Forum, reference International Standards Organisation (ISO) standards rather than Europeanised ISO standards. A strategic decision would have to be made within the MHRA and UK Conformity Assessment bodies, as to whether European Norms (EN) or more global ISO documents are referenced, or applicable.

** Future Post-Market Surveillance activities could be dependent on the outcomes of the 'Cumberledge Review', by including elements of registries and initiatives such as 'Beyond Compliance'. Note also that ISO is currently working on an International Technical Report dealing with Post-Marketing Surveillance, which could also form the basis of future requirements.

Potential Drawbacks

Some potential drawbacks to this approach may be;

- The processes being developed by the IMDRF are guidelines and will require careful transposition by the MHRA in order to ensure mutual recognition of regulatory processes, particularly with the EU. Indeed, the overriding caveat from industry, is that any system would have to include a recognition by other jurisdictions to ensure continued trade without adding to the current administrative and financial burden.

- The increase in MHRA regulatory involvement in IMDRF activities may lead towards a 'fee-for-service' approach, reflecting the added resource and greater 'centralised activities' in the UK.

- The divergence from the EU CE Mark, may lead towards a 'UK Compliance Mark'. This may lead to additional level of regulation that industry must comply with, particularly with respect to labelling.

- The overlaps with EBP&R, for which the greatest benefits will be realised is a process that will require cultural shifts within the industry and by all stakeholders within the medical technology sphere. Such cultural shifts require commitments from all stakeholders, including patients, and will not be achievable in the short-term.

Conclusions

The IMDRF process and the guidelines they produce, can be used as the basis for developing a UK specific regulatory system. Having been subject to the 'New Legislative Framework' in the UK for regulation of medical devices since the early 1990's, this transition is potentially not onerous for either regulators or industry, providing elements of continuity.

Such application would also allow sufficient flexibility to include future compliance methods such as EBP&R. The use of the IMDRF principles, which are increasingly being used globally, would be compatible with regulatory systems around the world, including the European Union and United States.