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EU Regulation of the Life Sciences
Response from the Institute of Biomedical Science

The Institute of Biomedical Science (IBMS) is the UK professional body for biomedical science. It represents approximately 20,000 members employed mainly in NHS laboratories, NHS Blood and Transplant, Public Health services, private laboratories, research, industry and higher education.

The IBMS recognises that this consultation primarily concerns life science research, of which only a limited amount of which occurs in routine diagnostic labs, but wishes to raise a number of points for consideration.

What are the key EU regulations and frameworks that govern/influence the conduct of research and innovation in the UK life sciences?

Diagnostic labs will be greatly influenced by the up-coming CE IVD Directive, which in the field of infection, has the serious potential to stifle innovation and prevent the rapid response to new pathogens. This may not be strictly within the remit of this consultation but it is important that the implications of this up-coming directive are recognised.

Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components

Directive 98/79/ec of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices"
BS EN ISO15189:2012

In what ways do these EU regulations affect the UK life sciences? What are their benefits and the drawbacks?

They restrict and slow down products coming to the market. This can hamper small companies from competing and bringing products to the market because they are less well equipped than the larger companies to cope with the bureaucratic requirements. However,

this should not be viewed solely as a criticism as benefits are that only evidenced based products eventually make it to market.

Companies with ISO13485 accreditation can obtain CE marking much quicker, which then allows them to bring products to market more quickly. This again is more likely to benefit the larger companies and inhibit smaller ones, which can limit innovation. Products from ISO13485 companies are likely to be safer for patients overall.

There is a requirement for those laboratories using 'in-house' methods to be ISO15189 accredited.

How transparent, consultative and evidence-based are EU policy-making processes?

Anecdotally, we do not believe there is much evidence. There is certainly a lack of evidence that inspection by accreditation bodies contributes to patient safety.

To what extent is the UK able to shape regulatory processes at the EU level that affect the life sciences?

The Institute of Biomedical Science is unable to answer this question

Is the UK able to depart from the application, standards or timing of such EU regulation?

Not that we are aware of.

In conclusion, we would like to make the following points:

Data protection regulations (e.g. trial participants, clinical data used in research) seems to be a very complex and bureaucratic area, which could benefit from clarification and simplification, whilst maintaining appropriate confidentiality.

In diagnostic pathology the MHRA is essentially the UK regulator of EU directives (e.g. blood and blood products, IVD and clinical trials), which have been transposed by Government in the four UK nations into local law and regulations. It is suggested that the EU should seek to harmonise regulation between these areas and align regulations with ISO standards where appropriate.