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Review of UK and EU balance of competences:
call for evidence on research and development

The Ethical Medicines Industry Group (EMIG) is the biopharmaceutical trade association that represents the interests of over 200 companies and organisations based in the UK. Our members are commonly, but not exclusively, small to medium-sized enterprises (SMEs) and less than 20% are represented by other trade bodies.

The UK life sciences industry provides vital medicines to patients, is at the forefront of medical innovation and is a significant contributor to the UK economy. We believe that SMEs constitute approximately 90% of the total number of biopharmaceutical companies in the UK and it is estimated that 80% of biopharmaceutical innovation is derived from these companies. EMIG member companies employ approximately 20,000 people in the UK and have a combined annual turnover of £4bn.

EMIG is pleased to have the opportunity to engage in the review of the balance of competencies between the UK and the EU for research and development and its members welcome any measures which aim to incentivise and promote a prospering UK life sciences sector.

The UK has a world-class life sciences offering, which surpasses the majority of EU countries, and an established, albeit diminished, pharmaceutical research and development (R&D) presence. The continued decline of the large pharmaceutical sector's R&D footprint in the UK has, in part, been mitigated by the seemingly vibrant growth of life science SMEs. As such it is imperative the Government and European Union foster an environment which supports SMEs to grow sustainably in the UK.

Impact on national interests

1. Where has EU action had a **positive impact** for the UK on research, technological development, innovation or space? What evidence is there for this? Has EU action encouraged national action in any areas?

EMIG believes the following EU activities have had a positive impact on research and innovation in the UK:

a) The Innovative Medicines Initiative (IMI) supports collaborative research projects and builds networks of industrial and academic experts in Europe. As Europe's largest public-private partnership it aims to improve the drug development process. EMIG welcomes the programme of pre-competitive research projects supported by IMI and believes it is positive for the UK's visibility.

b) In addition, the EU's Framework Programmes (now in Framework Programme 7) supports a package of projects designed to encourage European growth in innovation and research. The Framework Programmes provide an excellent source of funding, as well as engagement opportunities for UK companies. However, navigating access to the schemes can be complex and difficult for SMEs.

c) The European Medicines Agency's (EMA) centralised application procedure provides a single marketing authorisation that is valid in all European Union countries. Overall, EMIG believes the centralisation of the procedure has made the marketing authorisation process more efficient.

d) Finally, the appointment of Máire Geoghegan-Quinn, European Commissioner for Research, Innovation and Science, is particularly beneficial to the UK life sciences industry. Geoghegan-Quinn has been a vocal supporter of the sector and her statement that she wants 'science at the centre of Europe and Europe at the centre of science' is extremely encouraging.

2. Where has EU action had a **negative impact** for the UK in these fields? What evidence is there for this? Has EU action prevented potentially useful national action in any areas?

The draft EMA policy on clinical trial data release potentially threatens UK competitiveness on a world-stage. This is due firstly, to the high profile of UK science and secondly, to the possible impact of the policy on the willingness of companies to conduct pharmaceutical research in the EU.

EMIG welcomes measures which will increase transparency in clinical research and we believe the release of raw clinical-trial data to other professionals through a suitable gatekeeper could prove to be a valuable resource in driving better-designed and more cost-effective clinical development programmes. Clinical development could benefit from properly managed open access to clinical trial data sets. It could enable clinical trial programmes to be designed more quickly and targeted more effectively to responsive patient populations and it could reduce the number of unnecessary clinical development programmes, with benefits to patient safety and the R&D portfolio budget management.

Whilst industry should be open to sharing publicly all of the data used to design, execute and report on clinical trials, once a regulatory opinion has been provided on a marketing application, EMIG believes data-sharing needs to be carried out in a controlled way, with well-constructed, prospective requests made by an 'applicant' to a future 'gatekeeper' authority. Data should not be simply released on public websites. Having a well-meaning, but less than regulatory-standard re-analysis of benefit/risk, could compromise or even seriously risk patient safety.

The EMA draft policy goes significantly further than focusing solely on 'access to clinical trial results'. It includes content beyond that which was included in the Clinical Study Report (CSR), which EMIG endorsed, and embraces large parts of the Common Technical Document (CTD). In addition, despite the EMA's stated intent to protect the public from claims resulting from inappropriate analyses of the data, the vast majority of the data will be posted on a public website with no restriction on who can access the data. Only those who are seeking access to documents for which there are personal data concerns will be asked to 'refrain from using the data to gain a marketing authorisation in a non-EU jurisdiction'.

It seems very likely that applicants for a marketing authorisation application will be asked to submit a second version of the CTD, containing 'de-identified' documents. EMIG is very concerned that initial plans suggest that if there is an inadvertent release of personal data that it will be the applicant who will be held responsible for it and not the regulator. Additionally, the EMA's draft policy does not clarify whether 'open access' CSRs will be publishable in peer reviewed journals and, if so, the safeguards that will be put in place to stop people publishing other organisation's data.

EMIG believes the EMA draft policy could collaterally damage the UK's ability to attract scientific investment from industry. It does not offer appropriate safeguards and as such could compromise patient safety and lead to costly legal action.

EMIG therefore supports the leadership shown by the Wellcome Trust in this area. Their recent report which was produced following a workshop on clinical trial transparency[1] provides a sensible and measured approach. The report advocates that 'a range of models must be explored to allow controlled access to the detailed data underpinning clinical trial findings. Controlled access, with appropriate review processes, will be necessary in order to protect personal confidentiality and to protect against the misuse of data.'[2] The Wellcome Trust's paper should be commended to the EMA as a positive way forward which will avoid further legal action and potential damage to EU, and thereby UK, competitiveness.

Future opportunities and challenges

To fully realise the potential of SMEs as wealth creators, EMIG is a sponsor of the European Health Research Innovation Network (EHRIN). EHRIN is a new pan-European health research network designed to facilitate links and funding opportunities between SMEs, academia, and allied organisations in the life sciences sector. It is currently the main driver to improving the links between EU SMEs, academia and allied organisations and thus can provide significant input to European policy makers on how to increase SME competitiveness and academia's effectiveness.

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[1] Wellcome Trust, *Developing a strategy for clinical trial transparency: Workshop report*, https://www.wellcometrustevents.org/WELLCOME/media/uploaded/EVWELLCOME/event_207/Report.pdf (19 April 2013).
[2] Ibid. pg. 4.