

**HPRA COMMENTS ON
DJEI CONSULTATION ON NATIONAL STRATEGY FOR SCIENCE, TECHNOLOGY AND
INNOVATION**

The HPRA welcomes the opportunity to comment on the public consultation and, in particular, the opportunity to discuss key issues relating to the health sector at the consultation workshop facilitated by the Department of Jobs, Enterprise and Innovation and the Department of Health jointly on 11 March.

Health-related research is a critical enabler of personal, economic and societal benefits to Irish people and the State. We support the focus on this area under Pillar 7 for evidence-based policy-making and technological advances. We note the need, highlighted at the consultation workshop, for basic infrastructure and resource needs to be met before the full potential for research can be realised. We support maintaining focus on the key priority areas already identified through the national research prioritisation exercise.

Under the research prioritisation programme and specifically in relation to Pillar 5, we wish to outline an important initiative we have been instrumental in setting up. It may serve as a model for collaborative efforts in other areas, one which demonstrates the ability to involve both a broad range of public sector bodies as well as the private sector in a venture which will be of benefit to the entire sector nationally and globally.

Regulatory Science Ireland

This recently formed body consists of a network of interested parties from academia, government agencies, pharmaceutical industry, medical devices industry and the medicines and medical device regulator, the Health Products Regulatory Authority (HPRA). The aim of RSI is the development of an integrated Irish response in the fields of research; education/training; and knowledge sharing that will contribute to the global regulatory science effort. Similar initiatives are already in place in the USA and Singapore.

There are four groups of founding participants:

- Academia: currently UCC School of Pharmacy and the DIT Pharmaceutical Regulatory Science Team.
- Governmental agencies: currently IDA Ireland, Enterprise Ireland and Science Foundation Ireland.
- Industry: currently Pharmachemical Ireland, Irish Medical Devices Association and specific companies.
- Regulator: currently the HPRA.

The body has been formally constituted with a Board of Directors and, in due course, Scientific Advisory Committees will be developed, as necessary, to advise on the more specialised areas. It is hoped to appoint an Executive Director in the near future.

The intention is that RSI will become a national body with membership open to all scientists and healthcare professionals working in the fields of research, education and training, and regulatory sciences, and will encourage these activities as the three main pillars of RSI.

RSI will create, through relevant research, training and communication, an environment that:

- Facilitates Irish contributions to an effective response to the increasing complexity of health products and their associated regulatory systems.
- Develops a cohort of Irish based regulatory science experts and the life sciences sector in Ireland.
- Further strengthens the value proposition of Ireland as an attractive location for health product-related activities.

The focus of the three pillars will be:

- Regulatory science research at post-graduate MSc/PhD level. Research will provide the foundation for the other two pillars.
- Education and training where the intention is to establish suitable training modules in regulatory science.
- Periodic regulatory conferences / symposia on specific topics with a regulatory science focus.

The HPRA has led on developing some research projects within RSI, the first of which will consider matters related to biosimilar medicines, including prescribing, dispensing, usage, administration and monitoring aspects. The researcher will be appointed shortly and will be co-supervised in a postgraduate programme by UCC and HPRA. Two other projects are in planning, on an implantable medical device registry and on quality defects in medicines.

RSI is holding its first major conference on March 26 and 27, 2015, in Dublin Castle, on the theme of knowledge management.

HPRA
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