BIA submission to the Royal College of Surgeon's Commission on the Future of Surgery

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UK BioIndustry Association

Introduction

1. Established in 1989, the BioIndustry Association (BIA) is the UK trade association for innovative bioscience enterprises. The BIA represents over 300 member companies, including innovative start-ups and small and medium-sized enterprise (SME) bioscience companies, large pharmaceuticals, academic research and philanthropic organisations, and service providers to the UK bioscience sector. Our members are responsible for over 90% of biotechnology-derived medicines currently in clinical development in the UK and are at the forefront of innovative scientific developments targeting areas of unmet medical need. Our goal is to promote innovative bioscience in the UK for the benefit of global public health by enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.

2. Within our membership we have a community of companies developing and manufacturing advanced therapy medicinal products (ATMPs). The BIA's Cell and Gene Therapy Advisory Committee (CGTAC) represents the majority of the UK's regenerative medicine industry with over 30 UK companies (SMEs and big pharma) and key organisations including the Cell and Gene Therapy Catapult, and the Knowledge Transfer Network (KTN) and Innovate UK. We have drawn on the expertise of this group to inform this submission, which relates to the impact advances in regenerative medicine will have on the future of surgery.

Definitions

3. The terms regenerative medicine, advanced therapy, ATMP, and/or cell or gene therapy are used interchangeably to some extent. The term 'regenerative medicine' refers to methods to replace or regenerate human cells, tissues or organs in order to restore or establish normal function. These can include 'advanced therapies' as well as more traditional treatments involving pharmaceuticals, biologicals and devices.

4. Advanced therapies are medicines based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering). Advanced therapies can offer ground-breaking new opportunities for the treatment of a number of diseases or injuries, such as in burns victims, cartilage defects, Osteoarthritis and inflammatory bowel disease. An advanced therapy medicinal product (ATMP) is a medicinal product which is either a gene therapy medicinal product, a somatic cell therapy medicinal product or a tissue engineered product, as defined in the ATMP Regulation (EC) No 1394/2007.

The potential of regenerative medicine in the UK

5. Regenerative medicine involves the use of some of the most advanced therapeutic technologies of the 21st century. It offers revolutionary new approaches to treating a growing number of diseases, with improved options for patients that can save and improve lives and the rapid pace of the supporting science is likely to see its application across ever increasing field of clinical practice.

6. The field also presents great potential for companies to grow and benefit the UK economy. UK regenerative medicine is underpinned by excellent science, growing infrastructure for R&D and manufacturing, and supportive government policies to date. The rapid pace of the supporting science is likely to see its application across ever increasing fields of clinical practice.

7. There are numerous factors that mean that the UK is well-positioned as a leader in regenerative medicine, including among others:

   a) The UK is a world leader in the development of advanced therapies, contributing to the growth of the nation's life sciences industry. This in underpinned by a strong academic and commercial early-stage bioscience research base, in addition to access to clinical trial infrastructure and patients in the NHS, and significant levels of financial support and engagement from medical research charities and the UK research councils.

   b) UK government initiatives have helped foster innovation in the life sciences sector. Innovate UK, the UK's innovation agency, has awarded funding support to a number of regenerative medicine companies. The Cell and Gene Therapy Catapult, supported by Innovate UK, was established in 2012 to bridge the translational gap between early stage research and late stage clinical development and build a world-leading industry in the UK.

   c) The UK benefits from having the Medicines and Healthcare products Regulatory Agency (MHRA), a leading national regulator recognised at both a pan-European and global level. A 'one stop shop' for regulatory advice on regenerative medicine, hosted by MHRA's Innovation Office, was launched in October 2014 to provide a joined up.

8. Yet despite these strengths, a key commercial challenge for companies developing ATMPs in the UK as well as the rest of Europe is that of working out how they will fit into the current healthcare system and infrastructure and reimbursement models.

Implications for the future of surgery

9. ATMP manufacturing processes and surgical procedures will need to become increasingly interdependent and integrated if advances in regenerative medicine are to become embedded into routine healthcare and result in improved cost-effectiveness and patient outcomes.

10. Surgeons will require a solid understanding of the different ATMPs available and the aspects that contribute to their success e.g. tissue handling for biopsies, conditions for transport and how the cells are cultured or the tissues are grown, in order to identify and diagnose diseases that are amenable to regenerative medicine approaches, select the most appropriate therapy for the patient and administer it correctly. The surgeon's role is likely to become increasing integrated in the manufacturing and supply chain for some biopharma and more ATMPs, particularly those that involve end-point customisation e.g. bioprinted implants or organ substitutes.

11. In addition, the exquisite sensitivity of some ATMPs to the conditions in the chain of custody (temperature control, pauses in supply and administration, shear sensitivity to some forms of handling, ingress of adventitious organisms) will probably result in the introduction of technology designed to log and report back to the manufacturer on the product experience up to the point of administration, which surgeons will be required to use.

12. Conversely, the role of technical sales/support teams for product manufacturers will become much more closely associated with that of the surgeon (as indeed it is now with, for example, advanced orthopaedic procedures) as the surgeons will need an ever deeper understanding of product behaviours under different conditions in order to facilitate safe and efficacious use.

13. Subsequently, training for future surgeons should include an understanding of aspects of manufacture to ensure they can select, receive and apply ATMPs with confidence and with maximum benefit to the patient. In order to address this requirement manufacturers may establish training centres for surgeons to gain experience in specialist administration alongside the developers, however, this is unlikely to address the broader requirement for regenerative medicine training for surgeons. Universities, the NHS, the General Medical Council and professional membership organisations, such as the Royal College of Surgeons, all have a role to play, alongside ATMPs developers.

14. In addition to direct impacts on the role of the surgeon, and the relationship between surgeons and manufacturers, advances in regenerative medicine will require changes to the current healthcare infrastructure. In the longer term, flexible regulatory and reimbursement schemes, such as the Early Access to Medicines Scheme or the forthcoming Accelerated Access Pathway may result in collaborative enterprises between manufacturers and specialist surgical centres to ensure tight alignment of manufacture and harvest of goods with theatre access. Patient scheduling will need to include repeat visits for some products (multiple dose or case examination followed by treatment) and the patients will be pre-qualified for more personalised medicine. Migration towards specialist treatment centres is to be expected with the proviso that manufacturing may be carried out at the centre giving rise to a hub-and-spoke model for delivery of ATMPs. Innovate UK's Advanced Therapy Treatment Centres will act as a pilot for this model of healthcare delivery for ATMPs.

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