

# Executive Summary

Biomedical innovation, including advances in biopharmaceuticals, medical devices and diagnostics, is at the heart of human society, not least because this type of innovation helps to save lives and to improve the quality of life. Furthermore, it is one of the major drivers of the modern market economy.

Nevertheless, while the importance of biomedical innovation continues to increase, in recent years it has become a much riskier, more complex and more costly endeavour.

Consequently, policymakers and stakeholders have an intensified interest in understanding and identifying the desired set of national policy tools needed to encourage biomedical innovation.

Accordingly, this paper sets the stage for discussing national innovation strategies in the biomedical field, with the aim of providing an overview of some of the best practices which support and enhance innovative activities in a given country.

The paper first outlines several theoretical elements concerning the issue of national innovation strategies. It points out that the formation of innovation strategies depends on understanding the need for a range of different tools to support biomedical innovation. Crucially, it also depends on the national context, meaning the set of strengths and weaknesses in the country vis-à-vis the factors of innovation in the biomedical field. The national context includes how the country or region performs in such factors as generating basic and translational research, in protecting intellectual property rights (IPRs) and in providing regulatory and market incentives for biomedical innovation. The national context also involves political and institutional dynamics, as well as societal and economic factors.

The paper argues that despite distinct national environments for innovation, in general, policymakers can benefit from understanding how other countries have sought to establish certain key components of biomedical innovation. With this in mind, the paper identifies and analyses five categories of key components of biomedical innovation: human capital and infrastructure, R&D, IP protection, the regulatory and clinical environment and market incentives for R&D. Embedded in this section are discussions of supportive measures taken by a range of countries and regions including Singapore, Scotland, Ireland, Israel, Québec, Germany, France, Sweden, the UK and the US.

The paper identifies several best practices and recommendations for countries seeking to increase biomedical innovation:

- (1) Build up a high-quality life science research infrastructure, including a focus on specific biomedical disciplines, in terms of personnel, technologies and facilities.

- (2) Encourage an active and comprehensive biomedical R&D environment by promoting a range of R&D activities, including basic, applied and translational R&D. This involves allocating a portion of R&D expenditure for basic research in the form of flexible and longer-term funding schemes, mostly aimed at universities and other research centres, and facilitating an environment that is conducive to technology transfer, collaboration and the flow of knowledge between scientists, clinicians and industry players, especially through biomedical clusters.
- (3) Offer IP protection which is relevant to the biomedical sector, including patents and other forms of IP such as data exclusivity and orphan drug protection.
- (4) Provide a positive regulatory and clinical environment by minimising administrative constraints associated with regulatory procedures and harmonising clinical requirements according to the ICH's standards of Good Clinical Practice and Good Manufacturing Practice.
- (5) Promote positive incentives for investment in R&D by:
  - (a) Limiting the use of pricing and reimbursement systems that disturb market signals;
  - (b) Supplementing public health expenditure with private expenditure; and
  - (c) Building up and strengthening a venture capital market for biomedical R&D.

This set of best practices should provide policymakers with a starting point for creating targeted and effective strategies to enhance biomedical innovation in their country or region, and for sharing their experiences.