Technical Regulation

Medical Technology Industry in Ireland

IMDA Submission to the Business Regulatory Forum

25 May 2006

Irish Medical Devices Association (IMDA)
Telephone (01) 6051564
Sharon.higgins@ibec.ie
www.ibec.ie/imda

Table of Contents

1 Medical Technology Sector

1.1 The sector in Ireland

Med Tech in Ireland is constantly re-inventing itself, driving innovation, developing new competencies and delivering on growth. There are 140 medical device companies in Ireland, directly employing almost 26,000 people or 11% of the manufacturing workforce. Well in excess of 50% of these companies are engaged in R&D. Exports of Irish manufactured medical technologies amounts to some €6 billion each year, representing 7% of Ireland's exports.

1.2 Medical Technology products and Innovation

Medical technology extends and improves life and alleviates pain, injury and handicap. Millions of patients in Europe depend on medical technology, at home, at the doctor's, at hospital and in nursing homes. Wheelchairs, orthopaedic shoes, artificial heart valves, contact lenses, insulin pens, hip prostheses, condoms, oxygen masks, scanners, pregnancy tests, surgical instruments, bandages, syringes, life-support machines, demineralised bone filling for bone defects: all these products and many more fall under the definition of medical device. The uniqueness of the medical devices sector resides in its enormous diversity and innovativeness. There are more than 10.000 different categories of products.

Increasing technological convergence over recent years means that the medical devices and diagnostics sector is on the cusp of a revolution that will yield exciting breakthroughs against many of the costliest and most harmful diseases we face. Advances in technology will continue to detect diseases earlier and offer new, more effective treatment options for diseases like cancer and heart failure. The world medical devices market is worth €180 billion annually and is growing at a rate of 6% per annum, with even higher growth in some areas.
Products have an average lifecycle of only 18 months before an improved product becomes available.

1.3 Safe, Efficient and Effective Regulation is key to innovation

Patients, doctors, academia and industry benefit from a regulatory environment that enables innovative products to reach the market place ahead of competition while at all times safeguarding the patient.

2 Technical Regulatory Issues

2.1 Innovation requires a well resourced Competent Authority

The introduction of new medical technologies onto the market place relies heavily on the support of a well resourced responsive Competent Authority. Being first to market with a safe, effective product is key to future success.

The Irish Competent Authority, the Irish Medicines Board (IMB) has provided a very high level of service to consumers and the industry sector in Ireland. However, the rapid move to more complex, convergent technologies means that the resources that they have are no longer sufficient to enable products to be reviewed and authorized in time to be first onto the market.

A particular issue arises because the IMB does not have resources to review products comprising of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined produced as a single entity.

The Irish Medical Devices Association (IMDA) has raised the inability of the Irish Medicines Board (IMB) to provide the resources required to service the review of drug/ device combination product on numerous occasions at the highest levels within the Department of Health and Children, the Department of Enterprise Trade and Employment and the Department of Finance over the past four years.

The impact for the Irish industry is severe – increased company costs for going overseas to register new products, the extra time and resources involved, and fundamentally a missed opportunity for a country which so strongly stakes its future on innovation and R&D.

Immediate action and appropriate resourcing of IMB is required.

2.2 Parallel review by Competent Authority and Ethics Committee needed to make Clinical Trials more efficient

Clinical Trials are important because:

- Supports access to quality healthcare.
- Attracts smart people to smart jobs.
- Improves the efficiency of the healthcare.
- Increases clinical competence.
- Promotes the economic development of the state.

In the medical device industry, where product lifecycles are short and hence months are crucial, it is important that the timelines for clinical trials are as short as possible in order to reduce the overall time to market. Irish regulations around clinical trials put Ireland at a competitive disadvantage when comparing the speed with which a clinical trial can be approved to start and hence potentially take to execute.

Ireland has seen relatively low levels of activity in the area of medical device clinical investigations when compared to other European countries. Lately, the level of interest from both manufactures and clinicians in conducting clinical investigations in Ireland which involve medical devices appears to have increased. The Irish Medicines Board is also receiving increasing numbers of queries from the variety of stakeholders in the device investigation sector e.g. device manufacturers, clinicians/clinical investigators, hospital ethics committees, academic researchers etc.

In response to industry pressure and dwindling clinical investigation applications the UK changed its legislation a number of years ago to allow parallel review of clinical trial applications by Research Ethics Committees and the Competent Authority for Medical Devices - the MHRA. This equates to a saving of at least 4 weeks in the clinical trial project. In such a time, small high recruiting trials can be started and finished.

In Ireland the review must still be performed serially with all affected ethics committees needing to meet, consult and approve before submission to the IMB can proceed.

IMDA is asking the IMB and the European Commission for an opinion on the proposal to have a parallel review in place in Ireland similarly to the UK.

2.3 FDA Fees: Small Business Qualification not Currently Available to Non US companies under US FDA Medical Device User Fee and Modernization (MDUFMA) Act of 2002

If you qualify as a MDUFMA small business, you will be eligible to pay reduced fees for your medical device applications that are subject to a user fee. You will also be able to obtain FDA review of your first premarket application (PMA, PDP, BLA, or PMR) without paying any fee.

Qualification: Gross receipts or sales of no more than $30 million on your Federal income tax return for the most recent tax year.

Sections 738(d)(2)(B) and 738(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act specifically state than an applicant must support its claim that it qualifies as a small business by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, partners, and parent firms . . . . If you have not filed a Federal (U.S.) income tax return, you cannot qualify as a small business under MDUFMA.

FY 2005 Medical Device Review User Fees

Application	Standard Fee	Small Business
Premarket application (PMA, PDP, BLA)	$239,237	$90,910
Premarket report (PMR) for a reprocessed single-use device	$239,237	$90,910
First premarket application (PMA, PDP, BLA, or PMR) *by a small business*	(Not applicable)	Fee is waived
Panel-track PMA supplement	$239,237	$90,910
BLA efficacy supplement	$239,237	$90,910
180-day PMA supplement	$51,436	$19,546
Real-time PMA supplement	$17,225	$6,546
510(k) premarket notification	$3,502	$2,802

The US Congress will be reviewing the Act in 2006 and a decision could be made by 01 October 2007. There is an opportunity to propose alternative qualification methods via EU, Irish Government and small business forums.

2.4 Clarification on scope of Draft Advanced Therapy Products Legislation required

The draft Regulation on Advanced Therapy Products published by the European Commission in November 2005 will establish harmonized rules for marketing human tissue engineering products as well as gene therapy products and somatic cell therapy products in the European Union.

The aim is to close the current regulatory gap. Whereas gene therapy and somatic cell therapy products are classified as 'medicinal products' and already regulated under the Medicinal Products Directive (2003/63/EC), there is at the moment no harmonized EU regulatory framework for human tissue engineering products.

IMDA understands that the current scope of the Advanced Therapy Medicinal Products regulation would exclude products which do not meet the definition of a "medicinal product".

If this is confirmed, then a number of human tissue engineered products would not be covered by any European legislation: those whose primary intended purpose/mechanism is not pharmaceutical, immunological or metabolic.

These products may be made of or contain non-viable human cells and tissues (e.g. demineralised bone and collagen) or even viable human cells or tissues (e.g. autologous engineered skin or cartilage).

IMDA believes that, at least for the non-viable products, the Medical Devices Directive (MDD) is an appropriate EU legal framework. However, the scope of the MDD would need to be amended by removing the current exclusion for human tissue and cell products or their derivatives.

Clarification of the scope of the Advanced Therapy Medicinal Products regulation and an amendment to the scope of the Medical Devices Directive necessary.