Irish Medtech Association
Ibec

Irish Medtech Association position on building medical device sterilisation capacity in Ireland to ensure sustainable future medtech investment

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A. Executive Summary

The Irish medical technology sector is increasingly concerned at the lack of sterilisation capacity, in particular, ethylene oxide sterilisation capacity on a national level to adequately service the volume growth within the industry in Ireland. Many manufacturers are currently unable to source sufficient capacity to meet product volumes. The lack of sterilisation capacity impacts medtech businesses across many functions, including supply chain, logistics, inventory management, validation and crucially, new product introduction and winning new business for Irish manufacturing sites. The Irish Medtech Association calls for an impact analysis of current sterilisation capacity constraints on future medtech investment with a view to developing a capacity enhancement strategy via attraction of new market entrants and/ or infrastructure supports.

B. Background and Context

The Irish medtech sector has experienced significant investment and growth over the past number of years, however, continued competitiveness of the sector is threatened by a growing lack of sterilisation capacity in Ireland. Terminal sterilisation for medical devices can be achieved through a variety of technologies. The main methods used in the medical device industry are as follows: dry heat, steam, electron beam radiation, gamma irradiation, ethylene oxide gas, formaldehyde gas and low temperature oxidative methods such as gas plasma and ozone. Traditionally, Irish manufacturing sites have had a heavier reliance ethylene oxide (EtO) sterilisation compared to other European markets.

In light of continued growth within the sector and the absence of any action, it is expected that the capacity constraint situation will become increasingly more problematic for companies. A number of contributory factors have been identified which are leading to disruptive impacts on manufacturers operations in Ireland. First and foremost among these is the lack of competition in the EtO sterilisation marketplace which is currently dominated by one major sterilisation contractor. This is the case for both EtO and gamma irradiation sterilisation services.

There is a risk to sector in only having one provider in terms of cost and competitiveness for manufacturers in Ireland. Compared with Ireland's single EtO site, there are 12 EtO sites across the EU. Given the scale of the industry in Ireland and its current heavy reliance on EtO sterilisation for products manufactured

here, this weighting is disproportionate and needs to be addressed to ensure the long term sustainability of the sector. Also, the impact of withdrawal by the sole EtO sterilisation contractor from the Irish marketplace, though unlikely, warrants analysis.

The lack of an alternate supplier has resulted in the following issues arising; manufacturers are experiencing difficulties in gaining access to new cycle slots for product and manufacturers are also struggling to secure long term sterilisation service commitments for new products. There is an increasing recognition among manufacturers that there is limited capacity in Ireland for new cycles and for future validation capacity requirements. Crucially, SME's are experiencing difficulty in accessing EtO sterilisation services.

The Irish Medtech Association is aware of a number of manufacturers nationally who have addressed this capacity issue through the costly route of development of on-site sterilisation facilities to address their volume needs. However, due to the significant capital expenditure required, this option is not feasible for most manufacturers, in particular SME's. The time to build and qualify new on-site sterilisation facilities is also very significant. Increasingly, many manufacturers based in Ireland are obliged to ship product to the UK and other EU jurisdictions for validation work and end sterilisation, incurring a very high cost burden, thus impacting upon competitiveness.

One of the most serious impacts of the lack of capacity is the impact on new product introduction to Irish manufacturing sites. The Irish Medtech Association is aware of member companies who have had corporate investment decisions for introduction of new product/ product lines being put on hold or curtailed. Irish sites will be disadvantaged at corporate level when competing for the introduction of new product unless EtO sterilisation capacity constraints are addressed in the shorter term. Winning new business is wholly dependent on the ability of the Irish site to guarantee end sterilisation services for the additional product volume introduced.

Whilst the Irish Medtech Association understands that the sole EtO sterilisation contractor has sought to address increased volume demand through the provision of additional chambers, it is generally acknowledged that this additional system capacity, whilst welcome, is not considered sufficient by industry to address potential volume growth over the coming years within the sector.

As cited above, given the lack of capacity within the system, Irish manufacturing sites are increasingly shipping product to contract sterilisation facilities abroad. Irish manufacturers ship to a number of facilities throughout the EU, however, a considerable number of manufacturers currently use UK sterilisation facilities for end sterilisation of their product. Use of such facilities post-Brexit may have significant customs implications for manufacturers based here. There are a number of possible non-tariff barriers e.g. customs delays, additional administrative work, which manufacturers will have to take into account if they are continue to use UK based sterilisation providers after the UK departs the EU. These factors will have a significant impact for SME's.

It is increasingly evident that customer demand is increasing faster than vendor capacity and that this is ultimately having a negative impact on the sector. The value creation of having additional medical device sterilisation facilities/ contractors in Ireland should be taken into account. Therefore, action to increase both EtO and gamma irradiation sterilisation capacity nationally and increase Ireland's attractiveness as a location for new providers to the market who may be struggling to justify investment in Ireland should be prioritised. The Irish Medtech Association calls for an impact analysis of current sterilisation capacity constraints on future medtech investment with a view to developing a capacity enhancement strategy via attraction of new market entrants and/ or infrastructure supports.

C. The economic contribution of Ireland's medtech sector is of increasing importance.

Ireland is well positioned to capitalise on global medtech market which is forecast to grow €435 billion by 2022, it's:

- A global medtech hub with 9 of the world's top 10 medtech companies having a base here
- The number one location for medtech foreign direct investment in Europe
- Spans 450 medtech companies, including leading contract manufacturers, designers and service providers
- As many as 60% of businesses are homegrown and 80% are either start-ups or SMEs
- Ireland is the second largest exporter of medtech products in Europe with €12.6 billion in exports
- The highest employer of medtech professionals in Europe, per capita, with many as 38,000 already working in the sector and 4,000 jobs to be added by 2020
- Ireland has the most Shingo Prizes for operational excellence of any country, per capita, in the world
- 68% of companies do R&D and spend €181 million on R&D annually

- Nearly two out of three medtech companies have commercial capabilities here and a third of FDI multinationals plan to expand or introduce new commercial operations

D. About the Irish Medtech Association

The Irish Medtech Association is the business association within Ibec representing the medtech sector. The Irish Medtech Association has more than 250 members, located throughout the island of Ireland. The Irish Medtech Association's broad focus is to promote and support an environment that ensures the sustainable development and profitable growth of our multinational and small to medium size medtech companies. Irish Medtech Association is led by a Board of Industry CEO's and Executive Leaders. Strategy implementation is coordinated through working groups and taskforces.