SUBJECT: Access to Notified Bodies
MEETING DATE: 14/03/2017
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For Information	**Members are asked to note the content of the paper**
~~For Discussion and Decision~~	~~Members are asked to decide on recommendations~~
~~For Approval and Action~~	~~Members are asked to agree to recommendations in paper~~

Summary: -
A number of options are presented to address the needs of medtech companies accessing notified bodies.

Background
Scottish Enterprise commissioned a research project, undertaken between July and October 2016, which sought to understand the challenges faced by Scottish companies around securing the services of notified bodies. This research investigated claims from the market of insufficient supply and barriers to access for Scottish medical technology (medtech) companies seeking these services. The report also provides a demand model for the services of notified bodies in Scotland, incorporating both current and future demand.

Methods
The methodology consisted of primary research with a range of Scottish medtech companies and interviews with four of the five notified bodies currently operating in the UK.

Findings
There are a number of challenges facing companies wanting to access notified bodies, including:

- the current pressure on the capacity of notified bodies in the UK and EU;
- the decreasing number of notified bodies available;
- the uncertainty around Brexit and whether notified bodies in the UK will be allowed to administer product certification (CE marking), or whether as a consequence, two different accreditation systems will be required; and
- the uncertainty over the new European medical device regulations.

A key finding of the interviews with medtech companies was that there can be a disjoint between the understanding of the CE marking process between operational staff and board members.

Notified bodies were also found to face a number of challenges including:

- the retention and recruitment of auditors;
- dealing with changes in membership within the EU; and
- coping with the changes and complexity of EU directives.

The demand model found that the current and future demand for notified body services does not justify investing in a new notified body to serve Scotland.

ACTIONS:

- Scottish Enterprise will support the organisation of an information sharing event for the Scottish community to make them aware of the changing EU medical device regulations.
- Scottish Enterprise will disseminate the job profile of regulatory compliance specialists to PACE and SDS to aid recruitment for companies fulfilling the requirement of the new EU medical devices directives, to retain at least one person in-house in charge of regulatory compliance.

In addition, and if necessary,

- consider auditor training to increase the number of auditors available;
- undertake more work to learn about the upcoming changes that the impact of the new directives will have on the medtech industry;
- increase awareness in the medtech community regarding how notified bodies operate and how to engage with them; and
- increase awareness of the medtech community regarding device classification and regulatory requirements.

Recommendations

- LSS – ILG help raise awareness of this report and the changes in EU medical devices directives to the life sciences community in Scotland.
- LSS to indicate whether the additional suggested actions should be undertaken.

Full report:
http://www.evaluationsonline.org.uk/evaluations/Search.do?ui=basic&action=showPromoted&id=601