Response to NHS Chief Executive’s Open Call for Evidence and Ideas

Respondent ID: 67

Organisation name: Exmoor Plastics Ltd

Type of response: Document
NHS Chief Executive Innovation Report
Survey for ideas to increase the spread of innovation

Introduction

The survey below is taken from the Department of Health call for ideas and evidence on how the adoption and spread of innovation can be accelerated throughout the NHS (see attached introduction letter). The responses to this survey will shape a report to the NHS Chief Executive on innovation in the NHS to be published in November 2011.

This initiative was announced in the Plan for Growth and is being led by Sir Ian Carruthers, Chair of the NHS Life Sciences Innovation Delivery Board and Chief Executive of NHS South West.

ABHI has been invited to input to this report. We would like to hear your views, your ideas and your recommendations. This could include actions for government, the Department of Health, industry, the National Commissioning Board, the NHS, and other sectors.
The survey

1. Contact and organisation details

<table>
<thead>
<tr>
<th>Name of Organisation:</th>
<th>Exmoor Plastics Ltd</th>
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<tbody>
<tr>
<td>Name of Chief contact:</td>
<td>Brian East</td>
</tr>
<tr>
<td>Contact details (email &amp; phone):</td>
<td>Email: <a href="mailto:brian.east@exmoorltd.com">brian.east@exmoorltd.com</a>   Tel: 01823 351040</td>
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2. Learning from elsewhere about adoption and spread

Recent, personal experience makes clear that it is easier in Japan than in the UK to obtain, for innovative, British medical devices, clinical trials, relevant published scientific data and regular users.

Refs. Shinshu and Sapporo papers – see attached.

3. Actions at a local level in the NHS

Enterprises that develop innovative medical devices are characteristically small. Large corporations eschew risky investment in the development of medical devices and purchase successful products or companies in this field.

Small medical device companies generally have very limited resources from which, inter alia, to fund:

1. market research, proof of concept, acceptability
2. the employment of a dedicated, expensive development team
3. the expenses of regulatory burdens
4. premises, plant, tooling, jigs, fixtures
5. the creation – and maintenance – of Technical Files
6. bioburden and sterilisation validation exercises and subsequent audits (e.g. gamma irradiation)
7. global patent protection
8. participation in exhibitions at home and abroad
9. production training in house
10. product and sales training of distributors around the world, entailing high travel, accommodation and subsistence expenses
11. consultancy services.

The foregoing amount to a huge financial burden for a small enterprise – but they are not incurred in isolation. The development team cannot wait for a given project to make its way from concept to completion, sitting idly until profits are reaped from it. A number of projects, at different phases of their development, must be managed concurrently, which means that this investment is replicated, multiplying the financial burden and stretching resources to the limit – and, alarmingly at times! – beyond the limit.

Have you discerned, however, what is missing from the list of expenses?
Clinical trialling and scientific publications are missing.

This is a final stumbling block for the innovators. Clinicians talk blithely about £50,000, £100,000 being required to fund a clinical research fellow, who would obtain patients’ consent to their clinical data being included anonymously in a research paper and collate the results of the trial. This is a serious obstacle to the innovative enterprise, which is already sustaining all of the heavy financial benefits described above. N.B. If the NHS is earnestly seeking innovative medical devices, that will afford benefits, including savings, the most sure way of encouraging investment in them is to guarantee to appraise them: initially modestly (a handful of trialists only), progressively extending those appraisals, on the basis of benefit, until a full scale trial be undertaken.

If the NHS were to make this self-interested commitment, it would, at the same time, be using its publicly funded resources to promote growth in production, create jobs – and to supply essential evidence to exporters of the value of their devices.

Of course, the Dept of Health has provided routes via which medical devices may make their way into use by the NHS, e.g. NICE and NTAC. However, since they depend upon clinical evidence to support their recommendation that the NHS should adopt a given device – which evidence does not exist, since no trials have been performed – there is clearly a serious impediment to the discharging of their rôles as facilitators.

It has been made clear that it is the policy of the Dept of Health that commercial enterprises should pay for clinical trials. It does not need to be iterated; it needs to be reversed.

4. Actions by NHS Partners

5. Any other comments

It would be efficacious to change completely the rôle of NTAC, making it the gateway to product adoption by the NHS. Instead of considering a handful of devices annually, give NTAC the authority to impose on NHS hospitals the task of appraising innovative medical devices and let them manage a progressive system in which new devices should be trialed by, say, three discrete hospitals initially. On the basis of a favourable report by those trialists, a slightly wider trial should be imposed on, say, three discrete groups of hospitals. If found to be likely to render desired – and economical – benefits, only then should the device be submitted to a full-scale trial, of a size adequate to allow a decision about adoption to be taken.