National Assembly for Wales

Health and Social Care Committee

Access to medical technologies in Wales

Evidence from Dr Molly Price-Jones (Tybio Ltd)– MT 16

Access to Medical Technologies in Wales

Evidence submitted to the inquiry

Dr Molly Price-Jones, Director, Tybio Ltd

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1. Background information

Tybio Ltd is a consultancy company offering expertise and support to companies in the *in vitro* diagnostic (IVD) and life science industries. As such, we work with companies who are developing and launching new diagnostic devices and tests and understand the challenges they face in trying to get these adopted in Wales. In addition, I have previously been the managing director of a Welsh based subsidiary of a US IVD company.

(I have assumed that the term 'medical technologies' used in the terms of reference for this inquiry is used in the same context as 'medical devices' is used in the EU Directive 98/79/EU i.e.to describe instruments, test kits and reagents.)

2. Access to Medical Technologies in Wales

Wales is fortunate in having a thriving medical technology community with many highly innovative SMEs. However, as in all areas of the UK, there are significant barriers to getting a new technology adopted and enabling patients to get access to improved diagnostic techniques.

These barriers are

- Access to patients or patient samples
- Complexity of legal agreements
- Protection of intellectual property
- Evidence required for adoption
- Competition with 'in house' developed technology

2.1 Access to patients or patient samples

During the development of a new medical technology, it is necessary to validate the performance of the new technique using patients or patient samples. In order to do this, companies have to find the right hospital or clinic, and then negotiate with them to get access to the patients or patient samples. This relies heavily on companies making the right contacts and there is not a clear path to do this. The Wales Cancer Bank is a huge step forward and enables researchers and companies to get access to samples for testing in a structured and properly controlled way. Understandably, this only covers cancer samples and a similar means of accessing samples taken from patients with infectious diseases, for example, would be significantly enabling.

2.2 Complexity of legal agreements

It is important that the appropriate legal agreements are in place to allow collaborative work between hospitals, universities and companies to flourish. From a company perspective, this seems to be a complex web where there is no uniform set of requirements for legal documentation. It is very common for there to be no clarity about who the agreement should be between – the company and the individual researcher? the company and the university? the company and the health board? the company and Public Health Wales? In addition, a researcher in one hospital will consider an ethics approval is required for a piece of work, whereas in another hospital the researcher will deem it unnecessary. It is impractical for everyone who gets involved in collaborations to have a full understanding of what is required so a central repository of templates for the appropriate agreements, together with guidance on how, and when, the templates should be used would be a very valuable tool. This type of information is common as an intranet application within large companies where the relevant information is added to a template and then sent for legal approval before issue.

2.3 Intellectual property

This is another area where confusion can be introduced. In most cases, companies will take out patents for their technology before they start discussions about testing it in a clinical setting, and there is no ambiguity about who owns the intellectual property (IP). However, this is not always the case, and universities and hospitals are understandably very keen to try and generate as much IP as possible. This often leads to conflict as universities and hospitals try and claim rights to IP to which they are not entitled. A prior understanding, with an appropriate agreement in place (as in 2.2) would prevent this sort of misunderstanding. It would also enable new technologies to be tested and adopted earlier as the work to begin testing could start sooner, while a patent application is in progress.

2.4 Evidence required for adoption

In order for a new technology to be adopted, a body of scientific and clinical evidence needs to be compiled to demonstrate its utility, and it is entirely appropriate for the relevant people within the Health Board to be deciding what that evidence should be. Unfortunately, the evidence required is different for each Health Board. If the requirements could be harmonised across all of the Boards, it would be less time-consuming and costly to get a new technology adopted. Sadly, it is common to hear representatives from Health Boards at consultative meetings announcing that companies need to understand what their specific Board requires, independent of any other. The other aspect of the evidence required is the development of a cost-benefit analysis for the new versus the existing technology. To do this properly an in depth knowledge of costs within the NHS in Wales is required and it cannot be done by companies without support. In England, this support will now be provided by the Diagnostic Evidence Co-operatives and a similar body is needed for Wales.

2.5 Development of ‘in house’ technologies

Medical technologies developed ‘in house’ within hospitals, and used on those premises, are exempt from the Medical Devices Regulations 2002, and do not require a CE mark, but can only be used within the specific hospital where they were developed. When a company is seeking to introduce a new technology to a hospital, they often find themselves in direct competition with an ‘in house’ developed technology. The company will have to obtain a CE mark for their product, at considerable expense, and so this does not provide a level playing field on which to compete. If the hospital with the ‘in house’ technology is a large player, like the University Hospital of Wales, this takes away a very large chunk of potential business. The situation can arise where it is not cost-effective to offer a new technology if only the smaller hospitals will be able to utilise it. It also means that larger hospitals, with more medical laboratory scientists, will be able to offer technology which is not available to the smaller hospitals. The revision of the Medical Device Directives by the European Commission may remove this ‘in house’ loophole. However, if this does not happen then a

way needs to be devised of evaluating ‘in house’ versus external technologies in a genuinely fair and objective way.

3. Conclusion

There are many ways in which access to new medical technologies can be improved to allow patients in Wales to benefit. Many of these can be brought about by putting a more uniform and streamlined process in place to encourage companies to start engaging with hospitals at an earlier stage of their technology development process. The Wales Cancer Bank is an excellent resource for access to patient samples and this model could be developed in to other disease areas. The current situation is too *ad hoc,* costing companies a great deal of time and money, and often for SMEs this is prohibitive. Although there would be a cost involved in setting up a formal process, it is clear that in the longer term it would save money for all involved and reduce the barriers to adoption. It could help to make Wales a leader in the use of new medical technologies to improve the outcome for patients.