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National Assembly for Wales

Health and Social Care Committee

Access to medical technologies in Wales

Evidence from Public Health Wales – MT 35

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Committee Clerk
Health and Social Care Committee
National Assembly for Wales
Cardiff Bay

15 November 2013

Dear Sir,

**RE: Inquiry into Access to Medical Technologies in Wales**

Thank you for the opportunity to provide evidence to the committee on the inquiry into access to medical technologies in Wales. Comments have been provided below in relation to the different sections of the terms of reference of the committee.

**1. To examine how the NHS assesses the potential benefits of new or alternative medical technologies**

There are clear processes for assessing new medicines via NICE and All Wales Medicines Strategy Group (AWMSG) but no comparable process to manage the introduction of new technologies.

The different departments purchasing equipment in Wales could strengthen their joint assessment of new equipment. The Shared Services Partnership Procurement Services has internal procurements processes. Similarly, individual Health Boards and Trusts have local procedures for procurement and purchasing. There is scope for adding clinical and health economic advice to these purchasing decisions.

Some requests for new technologies currently come via Individual Patient Funding Requests. The seven Health Boards and the Welsh Health Specialised Services Committee (WHSSC) have Individual Patient Funding Request panels, which often receive requests to fund the use of a new technology for an individual patient. Where a large number of requests are received a policy may be developed for a group of patients.

All new technologies have to have the CE Kite mark. CE marking indicates a product's compliance with EU legislation and allows the sale of products anywhere within Europe. All member states have to have a competent authority. The competent authority in the UK is the Medicines and Healthcare products Regulatory Agency (MHRA). It is widely accepted within the medical community that the requirements for licensing medicines are much more demanding than those for devices. From a public health

perspective that is a matter for concern. Further information can be found in a recent British Medical Journal article (Wilmshurst P. The regulation of medical devices. *BMJ*. 2011 May 13;342:d2822.)

**2. To examine the need for, and feasibility of, a more joined up approach to commissioning in this area**

There is a very strong case for a more joined up approach so as to:

- Prevent the introduction of unproven technologies that may do harm
- Prevent the introduction of new technologies that are not cost effective or value for money
- Ensure rapid access to new technologies that improve the quality or efficiency of care
- Support the business community in Wales in developing new innovative products

It is imperative that all patients where new technology is used should be entered into a relevant register and followed up for at least 10 years. There are examples where the introduction of new technology has had unintended long term adverse effects, for example, the early silicone breast implants had long-term unexpected adverse effects, new radiological dyes injected into the spine have caused chronic back pain despite initially having been thought to be safer, carbon fibre replacements for ligaments have caused inflammation etc.

**3. To examine the ways in which NHS Wales engages with those involved in the development/ manufacture of new medical technologies**

The Health and Wellbeing Best Practice and Innovation Board have undertaken work in this area and recommend that healthcare research funding priorities maximise the potential for translation and impact, support e-health data to a whole population level, and improve the quality of service and performance data reporting and management. Other proposals included considering a dedicated technology adoption gateway service, including promoting digital technology and healthcare innovation. This approach is supported.

**4. To examine the financial barriers that may prevent the timely adoption of effective new medical technologies, and innovative mechanisms by which these might be overcome.**

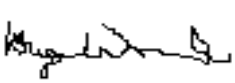
Judicious use of innovation funds and start up grants can act as a catalyst for transition from early prototype to early successful businesses.

There is an opportunity to foster joint working between industry and NHS staff to provide better research access to NHS patients. However, it is also important that systems are set up that ensure tight governance mechanisms so as to reduce the risk of potential conflicts of interest resulting in NHS staff promoting products in the NHS because they will gain financially from their commercial interests. There is some academic research indicating that this is a significant risk.

An appendix is attached which proposes the setting up of a Welsh Health Technology Assessment Board.

Should further clarification be needed by the Committee on the comments in this response, Public Health Wales would welcome the opportunity to do so.

Yours faithfully,



**Dr Hugo van Woerden, Director of Innovation and Development**
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**Enc**

# Appendix 1 - Proposal for the setting up of a Welsh Health Technology Assessment Board

## Background

Health Technologies are much less clearly regulated in the UK than medicines. NICE and the All Wales Medicines Strategy Group (AWMSG) play a clear role in agreeing which medicines should be made available in Wales. There is no comparable group overseeing the introduction of other health technologies.

The seven Health Boards and the Welsh Health Specialised Services Committee (WHSSC) have Individual Patient Funding Request panels, which often receive requests to fund the use of a new technology for an individual patient. Where a large number of requests are received a policy may be developed for a group of patients.

Staff in the Shared Services Partnership Procurement Services receive a constant stream of information on new technologies, some of which could increase the effectiveness or efficiency of the care of patients in Wales.

A number of new devices are developed by companies located in Wales or academic researchers located in Wales. This business and academic community needs access to testing of new equipment in the NHS and appropriate access to the NHS as a market. However, there is a balance between introducing new technologies before they are proven, leading to patient harm and increased costs and introducing new technologies too slowly, leading to avoidable mortality and morbidity and missing an opportunity to increase efficiency.

## Membership of the Assessment Group

The groups would primarily have a technical assessment remit, as opposed to any other wider function. It is therefore important that the group has a core membership that can comment on all health technologies and a co-opted membership that relates to the specific assessment of a given health technology.

The proposed membership would be:

Public Health Wales representative (Possibly as the Chair)
Welsh Health Specialised Services Representative
Representative of Welsh Health Board Medical Directors Group
Representative of Welsh Health Board Finance Directors Group
Representative of the Shared Services Partnership Procurement Services
Health Economist
Representative of the Board of Community Health Councils in Wales
CBI Wales Representative
Academic Representative

It is important the representatives nominated should have knowledge of underpinning theory behind health technology assessment or should be provided with appropriate training on joining the committee.

The Health Technology Assessment Group would meet every two months in the first instance.

The Group would be supported by a team of staff, similar to that supporting AWMSG. The staff would set up procedures to receive applications for assessment of new technologies, undertaken, with the facilities to receive applications, review the relevant literature on clinical and cost effectiveness and support a Technology Appraisal Sub-group who would undertake detailed assessment of each application and present this to the Board, in the same way as happens at AWMSG. It is proposed that

the AWMSG team would provide mentoring support to the new team during the set up of the new structures.

## Technology Appraisal Sub-group

The Technology Appraisal Sub-group would be made up of at least three members of the Board plus co-opted members with relevant knowledge. The group would always contain a minimum of health economic and clinical expertise, although these might be co-opted representatives rather than members of the Board.

## Applications for Assessment

Each technology assessment would have a standard format and would cover:

- Evidence of clinical effectiveness
- Evidence of cost effectiveness
- The epidemiology (the expected incidence of the condition requiring the treatment)
- Modelling of cost implications of agreeing such a development over at least three years

## Consultation

The draft assessments would be sent to the following bodies for comment:

- Board of Community Health Councils in Wales National Advisory Groups in Wales
- Each of the seven Health Boards
- CBI Wales

This would provide for the collation of the patients voice, clinical and managerial opinion, and the views of industry.

The draft assessment would also be placed on a website for at least two weeks for comment by any interested party.

## Advice provided

The Board would provide a decision on each application to recommend, not recommend or seek further information in relation to each application. Appropriate and sufficient resources would need to be identified to support the hosting of the proposed Assessment Board

**Options for the hosting of a Welsh Health Technology Assessment Board**

The Welsh Health Technology Assessment Board could be hosted in a number of contexts including:

1. As part of AWMSG
2. Within WHSSC
3. Within Public Health Wales
4. Within Shared Services Partnership Procurement Services

## Review of effectiveness

The Welsh Government would review the effectives of the Board after its first year of operation.