

## Y Pwyllgor Iechyd a Gofal Cymdeithasol

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Lleoliad:  
Ystafell Bwyllgora 1 – Y Senedd

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Dyddiad:  
Dydd Mercher, 22 Ionawr 2014

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Amser:  
09:20

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Cynulliad  
Cenedlaethol  
Cymru

National  
Assembly for  
Wales



I gael rhagor o wybodaeth, cysylltwch â:

Llinos Madeley  
Clerc y Pwyllgor  
029 2089 8403  
[PwyllgorIGC@cymru.gov.uk](mailto:PwyllgorIGC@cymru.gov.uk)

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### Agenda

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Rhag-gyfarfod (09.20 – 09.30)

#### 1 Cyflwyniad, ymddiheuriadau a dirprwyon

#### 2 Ymchwiliad i'r mynediad at dechnolegau meddygol yng Nghymru: Sesiwn dystiolaeth 1 – Grŵp Strategaeth Feddyginiaethau Cymru Gyfan (09:30 – 10:30) (Tudalennau 1 - 19)

Karen Samuels, Pennaeth Arfarnu Technoleg Iechyd a Rheoli Meddyginiaethau,  
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan.

Egwyl (10.30 – 10.45)

#### 3 Ymchwiliad i'r mynediad at dechnolegau meddygol yng Nghymru: Sesiwn dystiolaeth 2 – Cymdeithas Diwydiant Fferyllol Prydain (10:45 – 11:45) (Tudalennau 20 - 23)

Dr Richard Greville, Cyfarwyddwr

Joanne Ferris, Swyddog Gweithredol Polisi a Phrosiect

#### 4 Papurau i'w nodi (Tudalennau 24 - 48)

**5 Cynnig o dan Reol Sefydlog 17.42 (vi) i benderfynu gwahardd y cyhoedd ar gyfer eitem 6 ar agenda heddiw ac o'r cyfarfod fore 30 Ionawr 2014 (11:45)**

**6 Ystyried cynllun gwaith y Pwyllgor o ran yr ymchwiliad i argaeledd gwasanaethau bariatrig (11:45 - 12:00) (Tudalennau 49 - 54)**

# Eitem 2

Mae cyfyngiadau ar y ddogfen hon

## **Response of the All Wales Medicines Strategy Group to the National Assembly for Wales' Health and Social Care Committee enquiry into access to Medical Technologies**

### **About The All Wales Medicines Strategy Group**

Established in 2002, the All Wales Medicines Strategy Group (AWMSG) provides advice on both new and existing medicines, medicines management and prescribing to the Welsh Government's Minister for Health and Social Services in an effective, efficient, and transparent manner.

AWMSG brings together an expert panel of NHS clinicians, pharmacists, academics, health economists, industry representatives, patient advocates and lay representatives to reach a consensus on the use of new medicines and on policies that promote the best use of medicines for patients in Wales. All involved work together to ensure equity of access to the most clinically appropriate and cost-effective medicines. The Group's main priorities are:

- Appraisals: To develop timely, independent and authoritative advice on new medicines.
- Medicines management: To develop resources to support prescribers and thereby maximise health gain through the safe and cost-effective use of medicines.

AWMSG works closely (via a memorandum of understanding) with NICE to complement the NICE appraisal programme and thus ensure appraisal of new medicines not on the NICE work-programme.

The following response draws on the experience gained by AWMSG in Wales since 2002, and its possible application to the area of medical technologies.

### **Comments in relation to the terms of Reference of the Review.**

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

In addition to its work on the appraisal of new medicines, NICE publishes health technology appraisals (HTA's) of selected new medical technologies (including devices and diagnostics) through its Medical Technologies Evaluation Programme (MTEP). Just as NICE technology appraisals of medicines are relevant and valuable to NHS Wales, we believe that the NICE technology guidance is produced to a high standard and is likely to be highly relevant to the needs of patients in Wales. The programme is supported by a Medical Technologies Advisory Committee (MTAC) with a member (the Vice-Chair) who works in NHS Wales. Since December 2010, NICE's MTAC has approved 15 pieces of guidance on medical technologies and a further 8-9 are in preparation. The Cedar Evaluation Centre based in Wales is an active External Assessment Centre for medical technologies for NICE and has a strong track record of delivery in this area.

The difficulty with the NICE guidance on medical technologies is that unlike corresponding guidance on new medicines, it is not mandatory and so it is up to commissioners in Health Boards in NHS Wales and related organisations to make decisions on the uptake of the guidance. This can result in variation of access to clinically-effective and cost-effective technologies across Wales, or in delays in decision-making, particularly when the initial outlay may be significant, and the cost benefit to be made occur sometime into the future. In

addition, only selected medical technologies (around 5 per year to date) are assessed by NICE. A proactive approach to HTA of new medical technologies in Wales will help to inform central strategic planning and support existing or future prioritisation frameworks

We note that detailed information about clinical effectiveness and cost effectiveness of medical technologies is also more difficult to obtain than for medicines, so there are significant differences in the processes for HTA of medical technologies. Nevertheless, it is important that appraisals of such technologies adhere to the same key principles that have been identified in relation to appraisals of medicines. The ideal appraisal process should be transparent, timely, relevant, in-depth and usable (*Garrido et al.* 2008) [http://www.euro.who.int/data/assets/pdf\\_file/0003/90426/E91922.pdf](http://www.euro.who.int/data/assets/pdf_file/0003/90426/E91922.pdf)

**Transparency** of the HTA process is important to ensure that all stakeholders' involvement is clear to each other, and to ensure that process issues around technology appraisal do not cloud the vitally important scientific issues. Transparency also engenders greater trust among stakeholders, since it also involves full declaration of relevant interests by decision makers

**Timeliness** of the HTA process ensures that clinically-effective and cost-effective health (including medical) technologies can be made available as soon as possible.

**Relevance** is important in ensuring that the advice produced is appropriate and applicable to the needs of the user and therefore **usable** by the service. This requires close communication with all stakeholders (particularly clinicians) throughout the HTA process.

**In-depth** appraisals, using all the available evidence on clinical and cost effectiveness and the expertise of health technology assessors and health economists are vital to give stakeholders confidence in the guidance produced.

**Efficiency** of the appraisal process for all health technologies is essential if the NHS Wales is to obtain optimum value for money and an avoidance of duplication work.

**Independence** of the organisation conducting the HTA process from policy-makers and government is vital ensuring that the guidance produced can be trusted, and has sufficient credibility among those working in NHS Wales.

A process for appraisal of medicines not on the NICE work programme has been available in Wales for over 10 years via the All Wales Medicines Strategy Group. AWMSG has conducted over 183 appraisals of medicines since 2002. In October 2010 the high standard of the AWMSG appraisal process was acknowledged by the award of accreditation by NICE's Accreditation Programme, NHS Evidence. This allows AWMSG to carry the Accreditation Mark on any new clinical guidance produced under the accredited process, assuring health and social care professionals that they are accessing some of the best information available online to make informed decisions about patient care. This same rigour should be applied to any future processes developed in Wales for the appraisal of medical technologies.

Several new developments in the assessment of health technologies may also be relevant. NICE are developing a process for the appraisal of **Highly Specialised Technologies (HST's)** and AWMSG has proposed that their guidance on medicines should be adopted in Wales. If medical technologies other than medicines are added to the HST work

programme, the implications to NHS Wales of this guidance in relation to medical technologies will need to be considered.

It is also anticipated that two major amendments to the current NICE methodology appraisal of medicines will be made to address **Value Based Assessment (VBA)** of medicines from September 2014. Firstly, the wider societal benefits of health technologies will be expanded beyond those falling on the NHS, e.g. costs to carers and employers. Secondly, a measure of “Burden of illness” will be considered by NICE in order to reflect the severity of the illness. Burden of illness takes into account both the quality of life as well as the length of life. AWMSG has aligned its appraisal process closely with that of NICE’s Technology Appraisals and so AWMSG has proposed that it will adopt these measures of value in future appraisals when appropriate. The potential implications of this approach to possible future HTA of medical technologies other than medicines in NHS Wales will also need to be considered.

Finally, an important review of the processes in Wales for appraisal of Orphan and ultra-orphan medicines has been published very recently and the possible implications of its recommendations to the appraisal of medical technologies other than medicines will require careful consideration. <http://wales.gov.uk/topics/health/publications/health/reports/?lang=en>

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

Over the thirteen years of AWMSG’s development, it has become more common (as personalised medicine starts to fulfil its potential) for certain new medicines to be linked with “companion” technology products, including companion diagnostics. In addition, the mode of delivery of some medicines is becoming increasingly sophisticated, necessitating technological developments in association with the pharmaceutical product. NICE has demonstrated by its appraisal of medical technologies that “therapeutics” in the 21<sup>st</sup> century is about much more than just medicines and it has produced critical appraisals of evidence across the whole range of therapeutic modalities. Thus there are 7 items of NICE guidance on diagnostic technologies in preparation. For these reasons we believe that certain medicines and related medical technologies need to be considered alongside each other, indicating the need for a more joined approach to assessment, appraisal and commissioning in this area. It is therefore also vital that the processes that are developed are closely aligned with the Welsh Health Specialised Services Committee, which is tasked with ensuring that the population of Wales has fair and equitable access to the full range of specialised services.

The **horizon scanning** process for new medicines in Wales has developed rapidly over recent years, linked up with other UK centres and helping to inform AWMSG’s appraisal work plan. This affords NHS Wales more information to plan its future budgeting priorities in the prevailing tight economic climate. A similar coordinated approach should also be applied to new medical technologies, since some will have a major immediate impact on costs to the service.

**Surveillance systems** are vital in ensuring safety for patients. Wales is fortunate in that its relatively small size and well-developed communications networks can potentially ensure better rates of safety reporting. Thus in 2010, and thanks to the work of the Yellow Card Centre Wales (part of the AWMSG support network) the reporting of suspected adverse

reactions to medicines by health professionals and patients in Wales was 50% higher than in the UK overall (*Data from Yellow Card Centre Wales*). A more joined up approach to the central safety reporting of issues associated with medical technologies would provide stronger safety signal generation and thus help to inform NHS Wales of concerns at an early stage. Strong safety systems are also important in informing future commissioning priorities.

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

AWMSG has developed a responsive HTA process for medicines that ensures strong engagement with manufacturers before, during and after appraisal. Thus AWMSG was the first HTA body to welcome manufacturers to give evidence at the appraisal process, which takes place in public. NICE, having observed this approach, have since adopted it, and now meet in public with the manufacturers present and able to contribute.

It is recognised that some small manufacturers may have relatively limited health expertise (some health technology manufacturers fall into this category) so opportunity is given for advice from AWMSG network health economists. In addition the HTA process itself is scrutinised by a dedicated user-group which advises the AWMSG steering group about possible enhancements to the HTA process. This transparent approach, if applied to possible future medical technology HTA processes, would ensure that those developing and manufacturing medical technologies would be fully engaged and have a voice in future developments.

**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.**

It has become clear over the last decade that a positive recommendation by NICE or AWMSG for a medicine does not automatically result in timely adoption of the medicine by NHS Wales. This can occur despite clear mechanisms for the uptake of advice on all recommended (including high-cost) medicines. Thus the barriers to implementation of guidance are not just financial. They are also sometimes related to the slow dissemination of evidence-based advice to local decision makers and prescribers on what treatments are most effective and cost-effective. It should be noted that the majority of medicines appraised by AWMSG are recommended as an 'option for use', and a decision is made by clinicians within the health board as to how best to treat the patient. A positive recommendation does not, by default, mean that it is 'better' than other medicines already available.

The Welsh Analytical Support Unit (WAPSU, part of the AWMSG Support Network) was established in 2010 to monitor implementation of NICE and AWMSG guidance. By monitoring uptake of new medicines, it supports Health Boards in ensuring patients can rapidly access effective and cost-effective treatments in an equitable manner. It also supports Welsh Government in its central strategic planning role and it advises the procurement process in Wales. Its work has also been associated with rationalisation of medicines use and saving of significant financial resources.

We believe it is essential that any new processes for the managed introduction of medical technologies into NHS Wales are supported by robust monitoring mechanisms to ensure timely and equitable adoption of guidance.

## **Conclusions**

We have made specific proposals on how the NHS in Wales might assess the potential benefits of new or alternative medical technologies. We believe that the processes should be more joined up, and feel that this goal is feasible. Not all the barriers to adoption are financial and we have made some suggestions on how these might be addressed. We would be pleased to provide any further details in relation to this submission, and thank the Committee for the opportunity to contribute to the enquiry.

**All Wales Medicines Strategy Group, November 2013**



# Eitem 3

Association of the British Pharmaceutical Industry  
Floor 4, 2 Caspian Point, Pierhead Street, Cardiff CF10 4DQ  
t +44 (0)870 890 4333 (ext 1312) f +44 (0)29 2045 4298 wales@abpi.org.uk



Committee Clerk,  
Health and Social Care Committee,  
National Assembly for Wales,  
Cardiff Bay, CF99 1NA

14<sup>th</sup> October 2013

Dear Llinos

## **Access to medical technologies in Wales: Call for Evidence**

Thank you for the opportunity to submit a response to your call for evidence around access to medical technologies in Wales. Our response is appended to this letter.

I would be very happy to further discuss any aspect of our response with the Committee and provide any supplementary evidence, as required.

If I can provide any further information, please don't hesitate to contact me.

Regards

A handwritten signature in blue ink, appearing to read 'Richard Greville', written over a horizontal line.

**Dr Richard Greville**  
**Director – ABPI Cymru Wales**



## 1. Access to Medical Technologies in Wales

1.1 Thank you for the opportunity to respond to your inquiry into *Access to Medical Technologies in Wales*.

1.2 It is clear that access to medicines falls outside the scope and remit of this inquiry. We appreciate that the intention of doing so is to maintain focus during the inquiry. However, it is also critically important to recognise that many of the new technologies, as defined by the inquiry, which are now coming to market or will be available in the coming years, are “companion” products to new medicines.

## 2. Stratified Medicines

2.1 Stratified medicines (sometimes known as “personalised medicines” or “genomic medicines”) enable the pharmaceutical industry to target treatments specifically to the patient sub-populations most likely to respond. This is not creating medicines unique to a patient, but rather, about the ability to classify individuals into sub-populations, who differ in their susceptibility to a particular disease or their response to a specific treatment. Preventive or therapeutic interventions can then be concentrated on those identified sub-populations who will benefit, sparing expense and side effects for those who will not. Critically for this inquiry, this new way of treating people also involves the development and use of companion diagnostics to identify the appropriate patient sub-populations and thereby achieve the best outcomes in the management of a patient’s disease.

2.2 We believe that the development and implementation of an integrated stakeholder approach to stratified medicine will bring benefits to patients. It will also benefit prescribers, payers, and regulators and will improve the efficiency and productivity of developing new treatments, and enhance UK competitiveness and attractiveness for pharmaceutical, diagnostic and devices research and development (R&D). Welsh Government needs to ensure that it is well connected and recognised as a partner in the UK stakeholder map, whilst being supportive of ensuring connectivity for and between Wales based stakeholders.

2.3 The Academy of Medical Sciences recently published their report ‘Realising the potential of stratified medicine’<sup>1</sup>. ABPI welcomed this report and were delighted to co-sponsor and work with colleagues at the Academy of Medical Sciences on it.

2.4 The ABPI has been intensively engaged on the development of an integrated approach to stratified medicine over an extended period, working closely with a range of partners such as:

- The diagnostics sector
- Research funders
- Regulators
- Healthcare providers and policymakers
- Health informatics programmes
- Health economists

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<sup>1</sup> <http://www.acmedsci.ac.uk/index.php?pid=118&pressid=113>



2.5 As part of this engagement, ABPI recently hosted the second pharma-diagnostics stratified medicine networking event, where it was agreed that biomarker testing in order to 'stratify medicines' has an expanding role in clinical decision-making. A number of recommendations emerged from the event, these included:

- The new commissioning and innovation bodies (CCGs and AHSNs) in England should be engaged and shaped to ensure optimal and sustainable adoption of stratified medicine, and learn from barriers to adoption
- Biomarker test results should be adequately used to inform patient treatment
- A framework for molecular pathology that incorporates test laboratory service standards, patient pathway analysis to include tests, appropriate and evidence-based commissioning of services and education of healthcare professionals should be created
- Innovative alternatives to traditional business models should be developed within the pharmaceutical and diagnostics industries and healthcare sector to incorporate a stratified approach

2.6 These recommendations should be considered to be as relevant and pertinent to Wales and we would be happy to share further learns' gained from this engagement if the Committee would find it useful.

### **3. Appraisal Processes**

3.1 The Committee has specifically asked for comments on the current appraisal processes for innovative medical technologies and the decision-making process of NHS Wales for funding new medical technologies and treatments.

3.2 The Committee will be aware that all new medicines have to receive a positive recommendation from either the National Institute for Health and Clinical Excellence (NICE) or All Wales Medicines Strategy Group (AWMSG) to receive routine funding in NHS Wales.

3.3 NICE has a Medical Technologies Evaluation Programme, which was established in 2009. The independent Medical Technology Advisory Committee at NICE has two core remits:

- Selecting medical technologies for evaluation by NICE guidance programmes, and
- Developing medical technologies guidance

3.4 Its work programme focuses specifically on the evaluation of innovative medical technologies, including devices and diagnostics. Products evaluated include:

- Medical devices that deliver treatment, such as those implanted during surgical procedures,
- Technologies that give greater independence to patients, and
- Diagnostic devices or tests used to detect or monitor medical conditions

3.5 The Committee may wish to raise the role of the Medical Technologies Evaluation Programme in Wales with Welsh Government officials as part of the inquiry. Routine funding of all innovative medical technologies should be assessed with the same rigour for evidence of clinical and cost effectiveness as demanded for medicines.



3.6 It may also be useful for the Committee to consider speaking with CEDAR<sup>2</sup>, an NHS evaluation centre and part of the Cardiff and Vale University Health Board, who have been commissioned to provide external assessments for NICE in this area.

#### 4. Links to Economic Development

4.1 There is growing recognition of the importance of innovation and its adoption to both the health of the population and economic development. The Welsh Government is committed to providing 'world class' healthcare for its population as well as investing in life sciences as one of the 3 grand challenges in its Science Strategy and as one of the 7 priority sectors for economic development. Co-ordination and inter-linkages between organisations and Government departments involved in these ambitions is essential to ensure a successful, holistic and joined-up overarching strategy. The recently published Chief Medical Officer for Wales Annual Report dedicates a chapter to looking at the relationship between health and wealth and recommends that "NHS Wales and the Welsh Government should continue to drive economic development by supporting and sustaining a strong life science sector..."<sup>3</sup>

4.2 The Minister for Economy, Science and Transport and the Minister for Health and Social Services have jointly asked their officials to prepare a capital bid to build and support an infrastructure able to capture, store and analyse genomic information to meet clinical, research and economic development needs, which may lead to a Joint Ministerial statement of intent for genomic medicine in Wales.<sup>4</sup> Such an initiative could be very supportive of both the delivery of "world-class" healthcare and the broader medical technologies industry.

4.3 The development of an infrastructure for using e-health and genomics in research, alongside routine patient care, will enable more effective biomedical research across the entire R&D system – from the feasibility, recruitment and management of trials to observing patient outcomes over time. The quality and adoption of this new "Big Data" technology across Wales will be fundamental to its utility and usefulness.

4.4 This could provide the starting point for "Laboratory Wales" and further develop the country's potential to become a fast-breeder for life sciences. However, capital funding needs to be linked to comparable investment in recurring revenue to support associated services, including the adoption of innovative practices.

Organisation: ABPI Cymru Wales

Contact (completed by): Dr. Richard Greville

Email: rgreville@abpi.org.uk

Telephone: 029 20 454297

We are happy for all information contained herein to be shared, as appropriate.

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<sup>2</sup> <http://www.wales.nhs.uk/sites3/home.cfm?orgid=443>

<sup>3</sup> <http://wales.gov.uk/docs/phhs/publications/131009reporten.pdf>

<sup>4</sup> <http://wales.gov.uk/about/cabinet/decisions/dr2013/aprjun/health/7384635/?lang=en>

# Eitem 4

Yr Adran Iechyd, Gwasanaethau Cymdeithasol  
Department for Health and Social Services  
(DHSS - CDO Dental Division)  
Y Gyfarwyddiaeth dros Iechyd y Cyhoedd/Directorate for  
Public Health



Llywodraeth Cymru  
Welsh Government

David Rees AM  
Committee Chair  
Health and Social Care Committee  
National Assembly for Wales  
Cardiff Bay  
Cardiff  
CF99 1NA

Our ref: SF/MD/3802/13

18 December 2013

Dear Chair

Following my appearance before the Committee on 21 November as part of a possible inquiry in to NHS dentistry you requested some additional information on a number of issues. The questions raised are highlighted in bold and the response follows:

- **Additional information on the evaluations undertaken in relation to the quality and outcome and the children and young people dental pilots**

The published qualitative evaluation reports produced by Miller Research Ltd can be accessed at:

<http://wales.gov.uk/topics/health/cmo/professionals/dental/publication/information/dental-pilots/?lang=en>

The quantitative evaluation carried out by Public Health Wales is considered developing policy in confidence and is not in the public domain. However, the latest update is attached at Annex 1 for the Committee's information.

- **Additional information on the reasons why details on funding allocations to individual dental practices are no longer published**

A previous Minister for Health and Social Services wished to publish the value of NHS contracts for General Dental Services Contracts (GDS) and Personal Dental Services Agreements (PDS). The data did not include discretionary payments made by Local Health Boards to those dentists eligible for additional payments which are outside those

made for the direct delivery of units of dental activity (the contract currency) i.e. maternity pay, seniority pay and business rates.

While there were no objections to the exercise from the British Dental Association there was the recognition that it is difficult to compare like with like due to contracts delivering varying courses of treatment to very different patient client groups based on clinical need.

Dentists operate their practices as small independent businesses which also raised the risk of issues considered commercial in confidence. To anonymise the raw data required a manual process which was onerous and labour intensive. Following a change of Minister the publication of the data on the website of the Shared Service Partnership ceased.

- **A copy of Public Health Wales' revised guidance on dealing with missed appointments, when available**

A revised copy of the guidance is attached at Annex 2.

- **A note on the additional orthodontic services commissioned recently by Hywel Dda Local Health Board, and a copy of the additional data on orthodontic activity in Wales to which he referred during the meeting**

I understand Hywel Dda LHB has recently undertaken a competitive procurement process to secure additional orthodontic treatment capacity and outreach services across the area at Aberystwyth; Llanelli; Lampeter; Cross Hands; Haverfordwest and Cardigan. This is designed to improve access and ensure orthodontic planning and expenditure is needs based rather than reactive to demand.

The LHB is also implementing an Orthodontic Assessment Service which I believe commenced last month. The LHB estimates this increase in resources will facilitate a reduction in waiting times for an initial assessment down to 6 months within the next 18 months. This service will be provided within each county throughout the LHB area.

LHBs are now using Managed Clinical Networks (MCNs) to identify patients who have been referred to more than one orthodontist or referred ahead of need to free up capacity; both of which have contributed to the length of waiting lists. The development of MCNs will also help create a more efficient referral management process to reduce early, multiple and inappropriate referrals.

We intend to move towards a position where all primary care orthodontics is provided by specialists and/or Dentists with Enhanced Skills (DES). We need to develop an orthodontic workforce led by specialist orthodontists and supported by orthodontic therapists, DES, orthodontic nurses and orthodontic technicians. As the skill mix and services change there will be a need to review the funding of such services and the specialist orthodontic training numbers.

Together for Health: A National Oral Health Plan requires all LHBs to produce a Local Oral Health Plan by 31 December 2013. This will address the oral health needs (including orthodontics) of their residents and highlight the services to be provided.

Waiting lists for orthodontic primary care service provision do indeed vary across Wales and can be affected by the following factors:

- i) Referrals made too early by the referring dentist;
- ii) Referrals of children who do not meet the eligibility criteria;
- iii) Multiple referrals to service providers;
- iv) Poor assessment to treatment ratios (under contract there is no limit on the number of times patients can be assessed without progressing to treatment).
- v) Orthodontic providers not declining early referrals and;
- vi) Capacity – historically, insufficient Units of Orthodontic Activity (UOA) capacity has been commissioned by Hywel Dda LHB.

The orthodontic statistical data I referred to during the evidence session is available within the report by the independent expert group following a review of orthodontic services in Wales. The report can be found at:

<http://wales.gov.uk/topics/health/cmo/professionals/dental/publication/information/report/sep10/?lang=en>

- **A note on the action being undertaken by Cardiff and Vale University Health Board in relation to tooth whitening and the illegal practice of dentistry**

A briefing on the action being taken by Cardiff Council's Trading Standards Service in conjunction with Cardiff and Vale LHB is at Annex 3. A flyer issued to dentists in the Cardiff and Vale LHB area is at Annex 4. A position statement on tooth whitening by the General Dental Council (GDC) is at Annex 5.

- **Information regarding the number of domiciliary dental visits undertaken in Wales during the last year**

The table below shows the number of domiciliary visits undertaken in Wales during 2012/13 under GDS and PDS arrangements.

Contract Health Body Name	Contract Type Name	Number of Domiciliary Visits
Betsi Cadwaladr University Health Board	GDS Contract	9
Betsi Cadwaladr University Health Board	PDS Contract	285
		<b>294</b>
Hywel Dda Health Board	GDS Contract	0
Hywel Dda Health Board	PDS Contract	3
		<b>3</b>
Abertawe Bro Morgannwg University Health Board	GDS Contract	176
Abertawe Bro Morgannwg University Health Board	PDS Contract	1,220
		<b>1,396</b>
Cardiff and Vale University Health Board	GDS Contract	12
Cardiff and Vale University Health Board	PDS Contract	0
		<b>12</b>
Cwm Taf Health Board	GDS Contract	314
Cwm Taf Health Board	PDS Contract	0
		<b>314</b>

Aneurin Bevan Health Board	GDS Contract	791
Aneurin Bevan Health Board	PDS Contract	20
		<b>811</b>
Powys Health Board	GDS Contract	11
Powys Health Board	PDS Contract	4
		<b>15</b>
	<b>Total</b>	<b>2,845</b>

Source: NHS Dental Services, Business Services Authority

The table below shows how the total contacts are distributed by treatment location for each age group and Community Dental Service (CDS).

In 2012-13 the majority (89.0 per cent) of contacts took place within a health centre/clinic, which is the same as in 2011-12. In most age groups the majority were treated in the health centre/clinic; however in the 65 or over age group 50 per cent were seen in a health centre/clinic and 48.5 per cent were seen by means of a domiciliary visit. The 5-15 year age group accounted for the highest percentage of total health centre/clinic and mobile surgery contacts, 57.9 per cent and 71.6 per cent respectively. 80.4 per cent of the total domiciliary contacts were with patients aged 65 or over.

**Table 9: Location of treatment by age group and CDS, 2012-13**

CDS	<i>Number of Contacts</i>				
	0-4	5-15	16-64	65 or over	Total
<b>Health centre/clinic</b>					
Betsi Cadwaladr	2,761	21,472	17,589	4,561	46,383
Powys Teaching	729	3,847	2,167	727	7,470
Hywel Dda <sup>(a)</sup>	1,128	7,990	3,399	475	13,105
Abertawe Bro Morgannwg <sup>(b)</sup>	2,358	9,886	3,358	463	16,185
Aneurin Bevan	2,200	8,953	4,348	1,369	16,870
Cardiff and Vale	2,604	31,990	9,166	1,515	45,275
<b>Wales</b>	<b>11,780</b>	<b>84,138</b>	<b>40,027</b>	<b>9,110</b>	<b>145,288</b>
<b>Mobile surgery</b>					
Betsi Cadwaladr	79	600	291	34	1,004
Powys Teaching	1	8	4	6	19
Hywel Dda	0	0	0	0	0
Abertawe Bro Morgannwg	83	917	82	0	1,082
Aneurin Bevan	26	662	802	56	1,546
Cardiff and Vale	112	2,756	358	26	3,252
<b>Wales</b>	<b>301</b>	<b>4,943</b>	<b>1,537</b>	<b>122</b>	<b>6,903</b>
<b>Domiciliary</b>					
Betsi Cadwaladr	0	0	130	1,744	1,874
Powys Teaching	1	1	13	103	118
Hywel Dda	1	29	61	150	241
Abertawe Bro Morgannwg	10	1	104	681	796
Aneurin Bevan	64	301	795	2,995	4,155
Cardiff and Vale	4	226	410	3,153	3,793
<b>Wales</b>	<b>80</b>	<b>558</b>	<b>1,513</b>	<b>8,826</b>	<b>10,977</b>

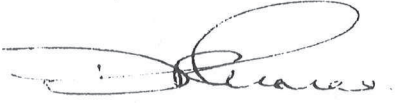
Source: Welsh Government

(a) Total for Health centre/clinic in Hywel Dda includes 113 cases where age was not specified.

(b) Total for Health centre/clinic in Abertawe Bro Morgannwg includes 120 day centre contacts where age was not specified.



Yours sincerely

A handwritten signature in black ink, appearing to read 'D. Thomas', with a large, stylized loop at the beginning.

David Thomas  
Chief Dental Officer



## Welsh Dental Pilot Programme

The pilots were developed to test alternative systems of payment to dentists and new approaches to the delivery of NHS dental services in Wales. Central to the pilots is a move away from UDAs towards a system which focuses on tailored patient care, based on risk assessment and quality.

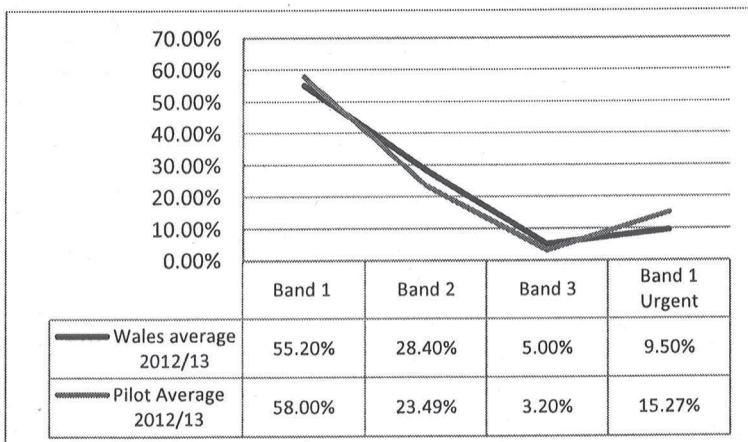
The pilots started on 1 April 2011 in 8 practices across Wales and have now entered into their third year. This has introduced a simple care pathway, helping to outline the needs of patients by using a high, medium and low risk scale.

Qualitative findings continue to show practice staff and patients value the changes that the pilots have brought about. Dentists comment they are able to treat patients without the worry of the UDA target, giving patients additional time and oral health education. Practice staff report better service delivery, where education is prioritised. Communications with patients ensure they fully understand what is expected in terms of personal responsibility and improved oral health, and what they can expect from their dentist. Whilst this is encouraging, the number of new patients has fallen and over the last year there has been an 18% reduction in the number of Courses of Treatment (CoT):

- Band one decrease of 12%
- Band two decrease of 34%
- Band three decrease of 60%
- Band one urgent increase of 9%

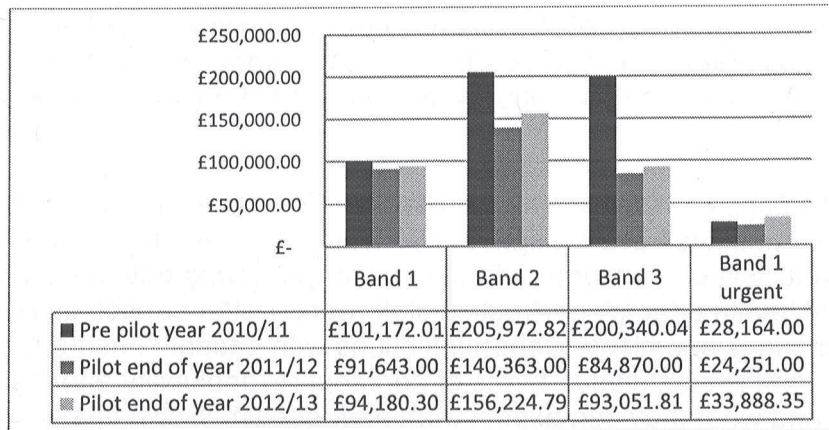
In looking at the pilot average compared to the Welsh average of CoT submitted to dental services, there is a marked difference:

**Figure 1**



There has also been a reduction in the level of Patient Charge Revenue (PCR):

**Figure 2**



It is important to note that the pilots focus on the use of a dental care assessment; oral health education; and appropriate NICE recall guidance. A period of adjustment is required and as more time is spent with each patient a reduction in patient numbers and PCR is to be expected. Further data and testing will clarify the full effect of the pilots and will be used to evaluate and inform the future development of the dental contract. The pilots will run until March 2015.

December 2013



## **GUIDELINES FOR DENTISTS, DENTAL TEAMS AND LOCAL HEALTH BOARDS REGARDING REFUSAL TO TREAT PATIENTS**

### **Background**

1. The General Dental Services Contract and Personal Dental Services Agreement Regulations 2006 specify a number of areas where practitioners have an absolute right to refuse treatment to current patients or those requesting treatment. These include:

### **Specific Groups \***

2. The Contractor may refuse to provide mandatory services or additional services in relation to a person falling outside a specified group of persons only where the contract provides for the Contractor to provide such services to a specified group. For example: fee paying patients where contract specifies child and exempt adults.

*\*This applies only to Local Health Boards (LHBs) who have contracted with General Dental Practitioners (GDPs) for specific groups i.e. child only or child and exempt contract.*

### **Patients who ask to be seen by a particular practitioner (“patient preference of practitioner”)**

3. The Contractor should endeavour to comply with a reasonable preference expressed under the Regulations but need not do so if the preferred performer has reasonable grounds for refusing to provide services to the patient. ‘Reasonable grounds’ may include the following:

- Preferred dentist does not usually work on the day/time specified by the patient;
- Preferred dentist is at full capacity with patients who that dentist feels cannot be transferred to the care of another dentist within the practice;
- Preferred dentist has a period of leave pending (e.g. maternity) and does not believe the patient’s treatment can be completed before that leave commences; and
- Preferred dentist does not routinely perform the services in the practice required by the patient.

### **Violent patients**

4. Where:

- A patient of the Contractor has committed an act of violence against, or behaved in such a way against any of the persons as described in the Regulations (for

example practice staff, other patients or those visiting the premises); a consequence of which that person has feared for their safety; and

- The Contractor has reported the incident to the police.

5. The Contractor may notify the LHB that it will no longer provide services to that patient under the Contract. Notification may be given by any means including telephone, email, fax or letter. If not given in a letter it must subsequently be confirmed in writing within seven days (for this purpose a faxed or email notification is not a written one).

6. It is understood by the LHB that situations in which violent behaviour occur will differ greatly and their effect is difficult to predict. Although each situation should be considered on its individual circumstance, the LHB considers it reasonable that a person might possibly 'fear for his/her safety' if faced with the following:

- Verbal abuse, including: swearing, threats, inappropriate or offensive use of language;
- Threatening behaviour, including: invading reception areas or personal space of other patients/staff, suggestion of physical abuse by wielding items at hand;
- Non-verbal threats or inappropriate sentiments including letters or e-mails; and
- Threatening or inappropriate comments on social media such as Twitter or Facebook.

#### **Patients who refuse to pay NHS charges prior to the commencement of, or during, treatment**

7. The Contractor may:

- Refuse to begin a course of treatment or an orthodontic course of treatment; or
- Terminate a course of treatment or orthodontic course of treatment prior to its completion.

8. If the Contractor has, in accordance with the NHS Charges Regulations, requested that the patient pay a charge in respect of that course of treatment or orthodontic course of treatment, and that patient has failed to pay that charge.

9. Failure to attend appointments; the existing Regulations do not allow charging for missed appointments where no dental services/treatment have been provided, nor do they allow dentists to request a non-refundable deposit. There is no clear power for imposing a charge on NHS patients where they have not received relevant dental services.

#### **Irrevocable breakdown in relationship between Contractor and patient**

10. Where:

- In the reasonable opinion of the Contractor, there has been an irrevocable breakdown in the relationship between patient and the Contractor; and
- Notice of such a breakdown has been given to the patient by the Contractor.

11. The Contractor may notify the LHB that it will no longer provide services to that patient under the contract.

12. As with instances of violent behaviour, it is difficult to predict scenarios in which it is reasonable to suggest an irrevocable breakdown in relationship has occurred. In instances where the contractor believes there is a possible breakdown in relationship the contractor is recommended to liaise with the LHB prior to terminating their service provision to that patient.

### **REFUSAL TO TREAT PATIENT: GUIDELINES**

13. A patient's repeated failure to attend (FTA) or refusal to pay NHS charges could be considered a cause for irrevocable breakdown in relationship between Contractor and patient. The LHB appreciates that patients who fail to attend may present in 3 main categories:

- Failure to attend consecutive appointments;
- Repeated failure to attend but not consecutive; and
- More than one last minute cancellation (that is a cancellation at such short notice the practice could not reasonably be expected to fill the appointment).

**The LHB will endorse the following non-attendance behaviour as an 'irrevocable breakdown':**

1. Either two consecutive appointments are missed or;
2. The Contractor can demonstrate consistent but not necessarily consecutive FTAs.

14. It is suggested that dentists make patients aware of this policy (either by displaying it or including information in their practice leaflet or website). We suggest that patients receive a standard communication letter following a first missed appointment warning them of the consequences. Appendix 1 includes two letters – (i) **suggested** wording which can be used to warn patients of the Contractor's refusal to treat, and (ii) **suggested** wording to tell patients that the practice will no longer treat them.

15 Dental teams are aware it is good practice to record all FTAs and last minute cancellations in the patient's record. It may also be helpful to note any attempt to contact the patient to ensure they attend appointments. This information will be helpful in the event of any dispute. It is also good practice to:-

- Have a written fail to attend (FTA) Management policy and procedure in place which is in line with NHS regulations and is accessible to patients;
- Ensure FTA management procedures are applied fairly and consistently; and
- Ensure any action taken by the practice to exclude a patient is not a surprise to that patient.

**David Thomas  
Chief Dental Officer  
December 2013**

## Appendix 1

### (i) SAMPLE WARNING LETTER

Dear

I am writing to remind you that you missed a dental appointment on ..././.... If you would like another appointment please contact the practice as soon as possible.

The practice has a policy on missed appointments which is supported by the Local Health Board.

**If you miss any more appointments or you miss two appointments running without letting the practice know, we may no longer be able to offer you treatment in this practice.**

Thank you

Yours sincerely

### (ii) SAMPLE FINAL LETTER

Dear

You have failed to attend your dental appointments on (*dates*), and/or have missed two appointments running. We tried to contact you by (*text / phone etc*) to remind you of the appointments.

In line with NHS Regulations and the practice policy as supported by xxxx Local Health Board, we will no longer provide you with treatment at this practice.

A list of other dental practices can be obtained by telephoning the Local Health Board on XXXXX. If you are in pain and need urgent dental treatment, please telephone XXXXXX.

Failed appointments are a serious problem to the National Health Service. They prevent other patients from being seen, and waste money and staff time.

Yours sincerely



## Tooth whitening – Cosmetic Products Regulation

### **1.0 Background**

- 1.1 This document has been produced by Cardiff Council's Trading Standards Service with support from Welsh Government dental branch and other organisations including the British Dental Association and Welsh Dental Committee and has been shared with the General Dental Council.
- 1.2 The document outlines the legal framework relating to the supply and use of tooth whitening products in the course of a business and the concerns surrounding the supply and use of such products, particularly by people who are not registered with the General Dental Council and who are therefore involved in the illegal practice of dentistry.
- 1.3 It highlights that there are a number of supply chain scenarios that Cardiff Trading Standards Service has encountered and, as such, proposes that a graduated approach to enforcement is adopted in order to provide effective enforcement of the laws surrounding the supply and use of tooth whitening products and procedures.

### **2.0 Consumer Safety and the Current Situation**

- 2.1 There is concern over the dangers relating to the supply of illegal tooth whitening products both for use at home and the use of such products by people who are not registered with the General Dental Council (lay people)
- 2.2 The GDC has indicated that it will seek to prosecute those who provide tooth whitening and are not registered with the GDC. This provision of tooth whitening by lay people is the illegal practice of dentistry. It has also indicated that it is currently of the view that tooth whitening should only be carried out by GDC registrants who are trained and competent to do so. This is generally taken to be referring to dentists although the current GDC Scope of Practice document indicates that hygienists and therapists may also carry out tooth whitening provided they have obtained the appropriate training and competency and only then under the prescription of a dentist.
- 2.3 Tooth whitening is also used by dental professionals as a therapeutic treatment for patients who want to change the appearance of their teeth, where the alternative treatments available would involve destructive techniques. Dentists have advised that there should however, be some recognition that in certain controlled and legal situations whitening may be required for persons under the age of 18.
- 2.4 Tooth whitening products contain bleach and are to be used with caution. The current legal limit for the supply of tooth whitening products containing the active ingredient, hydrogen peroxide, is 0.1%.

- 2.5 There have been reported cases of tooth whitening kits containing 30% hydrogen peroxide. The use of products containing bleaching ingredients at such high levels poses a real threat of permanent damage to a person's health; tooth enamel may be damaged, and people can suffer prolonged and increased tooth sensitivity.
- 2.6 In addition, dental colleagues have advised that other "bleaching" products such as sodium perborate and chlorine dioxide are being used by some lay people. These products are unsafe, and often very acidic. Perborate is covered by regulations, but carbon dioxide is not covered by any regulations. Their use should be strongly discouraged.
- 2.7 Provision by lay people will not be done in the controlled surroundings of a dental surgery. Occasionally it is done in beauty "parlours", open areas in shopping centres or even in peoples own homes. This poses the following potential risks to customers:
- Risk of injury which may not have been explained to customers, including: chemical injury to lips and mouth, for example ulceration; serious injury to eyes if chemicals accidentally splash, and ingestion of products leading to nausea / sickness.
  - Inadequate hygiene measures and inadequate cross infection control which means that infections can be passed to and from staff and customers.
  - Little or no staff training in using potentially harmful materials.
  - In many cases there will be no quality or safety checks on the business premises, the procedures used and the staff working there. (although laser clinics offering tooth whitening will be registered with HIW).
  - Lack of confidentiality and privacy.
  - No system of complaints or redress if the customer is harmed.

### **3.0 Legal Framework**

- 3.1 A House of Lords Judgement in 2001 confirmed that tooth whitening agents are covered by the EU Cosmetics Directive. The Cosmetic Products (Safety) Regulations 2008 which implement the Directive in the UK presently allow the supply of tooth whitening products which contain no more than 0.1% hydrogen peroxide, present or released. Other products namely, carbamide peroxide and sodium perborate are hydrogen peroxide 'releasing' and would also fall under the controls.
- 3.2 Supply is defined as per section 46 of Consumer Protection Act 1987.

3.3 The EU Scientific Committee for Consumer Products issued an opinion in 2005 that tooth whitening products containing up to 6% hydrogen peroxide would be safe for consumer use. The Cosmetics Directive has now been amended to take into account the above, on the condition that such products must first be administered by a dentist, with the cycle of use then being completed by a consumer at home (who is not younger than 18). This change is due to be implemented in UK law by September 2012.

#### 4.0 Supply Chain Scenarios

A number of supply chain scenarios have been highlighted to Cardiff Trading Standards, some by concerned members of the public who have made complaints to the department. These include:

- Supply to consumers for home use
- Use by lay people of whitening product on consumers
- Use by dentists of whitening product on patients
- Wholesale of whitening products to dental professionals
- Wholesale of whitening products to non dentists
- The provision of tooth whitening training for lay people

Cardiff Council has successfully prosecuted one company for the supply of tooth whitening products to consumers for home use. However, the Trading Standards Department has received a number of complaints about tooth whitening carried out by lay people, which have not been investigated due to the remit of the 'supply' falling outside consumer protection legislation.

One such company was found to be using products containing over 30% hydrogen peroxide. Cardiff Trading Standards referred the details of the business to the GDC, who successfully prosecuted the company for the practice of tooth whitening by a person who was not registered with the GDC. Therefore an enforcement regime exists and can be deployed through effective collaboration.

Due to current wide scope of supply of tooth-whitening products and services, there is no consistent approach to regulating sales and services at all stages in the supply chain. We would seek to achieve a common approach to a number of scenarios, which are outlined below, together with a proposal for appropriate and proportionate regulation.

## **4.1 Tooth whitening by GDC registrants**

### **4.1.1 Tooth whitening by GDC registrants in surgery**

Cardiff Trading Standards believes that the administration of peroxide-based whitening products in the course of treatment provided by dentists or registered hygienists and therapists does not constitute a supply of a cosmetic product within the meaning of CPA.

Therefore such in-surgery use of whitening products containing >0.1% hydrogen peroxide is outside the remit of Trading Standards. Control at this level would fall to the dental regulator, the GDC, who can take action against a dentist should a patient suffer harm as a result of a dentist's negligence.

Registrant with the GDC must understand the details of provision of tooth whitening. Further details are available on GDC website.

### **4.1.2 Dentists – supply to consumers**

The Cosmetics Directive has been amended to take account of the Scientific Committee on Consumer Products' opinion that up to 6% hydrogen peroxide tooth whiteners are likely to be safe when used under specific conditions.

The Directive has been amended to state that a dentist may administer tooth whitener up to 6% hydrogen peroxide. Thereafter the dentist may supply such products to consumers (18 or over) for home use, for completion of the cycle of use. This amendment must be implemented in UK law by September 2012, so this should be considered before providing advice to businesses.

It is proposed that advice can be given to dental professionals by the GDC indicating that: an initial supply of tooth whitening product would still attract a legal limit of 0.1%; the supply of product following a treatment would have a legal limit up to 6%.

### **4.1.3 Wholesale of tooth whitening products to dentists**

This would constitute a supply under CPA and the Cosmetic Products Regulations and therefore it would be an offence to supply >0.1% whiteners to dentists.

However, since the ultimate use for the product will be by a dental professional, regulated by the GDC who can control any professional negligence in this regard, it is felt that there is no public interest concern to enforce the provisions of the legislation in this situation.

A dental professional is responsible for understanding current standards that affect their work and adhering to relevant guidelines.

As such wholesalers should be advised of the law, stipulating that tooth whitening products may only be supplied to dental professionals. Adequate steps should be taken by wholesalers to ensure sales are made only to dental professionals, e.g. the purchaser must provide a valid GDC registration number before purchase is authorised. Trading standards would undertake a monitoring role in this sector of trade.

#### **4.2 Provision of tooth whitening by people who are NOT registered with GDC**

##### **4.2.1 Tooth whitening carried out by people who are not registered with GDC**

Similar to GDC registrants outlined in 4.1.1 above, Cardiff Trading Standards believes that the administration of peroxide-based whitening products in the course of treatment provided by people who are not registered with the GDC does not constitute a supply of a cosmetic product within the meaning of CPA.

The GDC is of the opinion that tooth whitening is a form of dentistry and as such, should only be carried out by a GDC registered professional. Anyone who is not registered with the GDC and who carries out tooth whitening is therefore committing an offence under the Dentists Act 1984.

The GDC has brought at least 2 successful prosecutions in relation to this, with further cases pending. Cases of this nature should be referred to the GDC

##### **4.2.2 Wholesale of tooth whitener to people who are not registered with the GDC, e.g. beautician**

This again would constitute a supply, and an offence to supply if >0.1% hydrogen peroxide. Given the above position of the GDC, such businesses should be advised that they are committing an offence, in addition to the possibility of the purchaser also committing an offence with further use or sale. We would propose that business advice be given and further enforcement undertaken by Trading Standards to ensure compliance.

### **4.3 Retail supply to consumers for at home use**

4.3.1 It is legal to supply tooth whiteners <0.1% hydrogen peroxide and anything supplied which contains >0.1% would therefore be considered to be illegal.

Enforcement action for products found at levels above 0.1% may have to consider the view of the Scientific Committee and whether prosecution for cases 0.1% - 6% may not be in the public interest.

4.3.2 It is proposed that advice is given to businesses where breaches of the Regulations are found >0.1% <6% with proportionate enforcement action to ensure no further breach/supply of product. Cases of supply over 6% should be put forward for prosecution by Trading Standards.

### **5.0 Conclusion**

5.1 It is evident that the different possible permutations of supply do not lend themselves easily to a simple enforcement policy.

5.2 It is proposed that Local Authority regulators, together with central government, health professionals, industry professionals and trade associations work together to tackle the key areas of concern within the supply chain as proposed above.

### **6.0 Recommendations**

6.1 Working with dental colleagues, Cardiff Trading Standards recommend the proactive identification, follow up visits and provision of advice to businesses engaged in the supply and use of tooth whitening products within Cardiff and also provide advisory information to the public.

6.2 This document will be shared with other Trading Standards services in Wales to explore whether it can be adopted as an all Wales approach

May 2012

## ***Tooth-whitening by people who are not registered with the General Dental Council - advice from Cardiff Trading Standards***

Many dental teams are concerned about the provision of tooth – whitening services by people who are not registered with the GDC – for example, beauticians and hairdressers.

The GDC considers this to be the illegal practice of dentistry, and has brought at least two successful prosecutions, with others pending.

Cardiff Trading Standards has worked with dentists to develop a process to deal with illegal tooth – whitening. This includes advising providers about the legal position, followed by enforcement action (which may include prosecution) and / or notifying the GDC if appropriate. Trading Standards will also work with suppliers of tooth whitening products to ensure they stay within the law.

At present this is only in Cardiff, but Cardiff Trading Standards will share their work with other Local Authorities.

Risks of illegal practice may not have been explained to customers, and they include :-

*Injury to lips and mouth, and serious injury to eyes if chemicals accidentally splash.  
Ingestion of products leading to nausea / sickness.*

*Inadequate hygiene measures and inadequate cross infection control*

*Little or no staff training in using potentially harmful materials.*

*In many cases there will be no quality or safety checks on the business premises, the procedures used and the staff working there. (although laser clinics offering tooth whitening will be registered with HIW).*

*Lack of confidentiality and privacy.*

*No system of complaints or redress.*

If you have any concerns about illegal tooth –whitening services in the Cardiff area, please e-mail [fairtrading@cardiff.gov.uk](mailto:fairtrading@cardiff.gov.uk) to alert Trading Standards. Please provide information on the location and service you are concerned about, as well as your name and contact details. This information will be treated in confidence.

See the GDC website for further information- [www.gdc-uk.org/](http://www.gdc-uk.org/)

BDA members can also access BDA website -[www.bda.org/](http://www.bda.org/)

Sarah Smith, Cardiff Trading Standards

1. The first part of the document is a list of names and addresses of the members of the committee. The names are listed in alphabetical order, and the addresses are given in full. The list includes names such as Mr. J. H. Smith, Mr. W. B. Jones, and Mr. C. D. Brown, along with their respective street addresses and cities.

2. The second part of the document is a list of the names and addresses of the members of the committee who were present at the meeting. This list is also in alphabetical order and includes names such as Mr. J. H. Smith, Mr. W. B. Jones, and Mr. C. D. Brown, along with their respective street addresses and cities.

3. The third part of the document is a list of the names and addresses of the members of the committee who were absent from the meeting. This list is also in alphabetical order and includes names such as Mr. J. H. Smith, Mr. W. B. Jones, and Mr. C. D. Brown, along with their respective street addresses and cities.

4. The fourth part of the document is a list of the names and addresses of the members of the committee who were present at the meeting and who were also present at the previous meeting. This list is also in alphabetical order and includes names such as Mr. J. H. Smith, Mr. W. B. Jones, and Mr. C. D. Brown, along with their respective street addresses and cities.

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## GDC POSITION STATEMENT ON TOOTHWHITENING

The Cosmetic Products (Safety) Amendment) Regulations 2012 (implementing Directive 2011/84 EU which amends Directive 76/768/EEC) come into force on 31 October 2012. The General Dental Council (GDC) would like to remind its registrants:

- Products containing or releasing between 0.1% and 6% hydrogen peroxide cannot be used on any person under 18 years of age.
- Products containing or releasing less than 0.1% of hydrogen peroxide, including mouth rinse, tooth paste and tooth whitening or bleaching products are safe and will continue to be freely available on the market.
- Tooth whitening or bleaching products containing or releasing between 0.1%-6% of hydrogen peroxide should be used as follows:
  - an appropriate clinical examination is to be carried out in order to ensure that there are no risk factors or any other oral pathology concerns;
  - exposure to these products should be limited to ensure that the products are only used as intended in terms of frequency and duration of application;
  - the products should not be directly available to the consumer, only through a dentist, dental hygienist or dental therapist.

Toothwhitening products containing or releasing between 0.1% and 6% hydrogen peroxide can ONLY be sold to dental practitioners;

For each cycle of use, the first use can ONLY be carried out by dental practitioners or under their direct supervision if an equivalent level of safety is ensured.

After the first cycle of use, the product may be provided by the dental practitioner to the consumer to complete the cycle of use.

- Concentrations exceeding 6% of hydrogen peroxide present or released in oral products, including tooth whitening or bleaching products, remain prohibited unless wholly for the purpose of the treatment or prevention of disease.
- It is a criminal offence to act in breach of the Regulations.
- GDC registrants need indemnity for any treatment which they provide.
- The GDC does not bring criminal prosecutions of breaches of the regulations as this role is undertaken by Trading Standards. However the GDC is concerned with the fitness to practise of its members. It takes the view that if a practitioner has committed a criminal offence, that must be relevant to any assessment of that practitioner's fitness to practise irrespective of whether there has been a prosecution. Therefore, if we receive information or a complaint that a registrant is using a product for cosmetic purposes in excess of the 6% they may face fitness to practise proceedings and can expect to have the matter referred to the relevant Trading Standards department..

- The GDC's position remains unchanged in relation to non-registrants providing tooth whitening. Where an individual is not registered with the GDC they are not entitled to provide tooth whitening as tooth whitening falls within the definitions of practice of dentistry under sections 37 and 38 of the Dentists Act. The GDC will continue to prosecute individuals who carry out tooth whitening illegally under the Dentists Act 1984.

Dental professionals who need further advice interpreting the details of the Directive and how it affects them should contact their indemnity or insurance provider, or seek independent legal advice.

31 October 2012

**Y Pwyllgor Iechyd a Gofal Cymdeithasol**  
**Health and Social Care Committee**

Cynulliad  
Cenedlaethol  
Cymru  
National  
Assembly for  
Wales



**Chris Martin**  
Chair, Hywel Dda Health Board

18 December 2013

Dear Chris,

Thank you for your letter of 5 December providing an update on your discussions with the Minister for Health and Social Services regarding the work of Hywel Dda Health Board. The Committee discussed your correspondence at its meeting on 5 December.

You refer to a number of actions that you will be undertaking in light of the issues raised with you by the Minister and Assembly Members. The Committee is keen to receive regular updates on the planned work outlined in your letter to re-assure Members that necessary action is being taken to address recent concerns about the provision of services in the health board area. Furthermore, the Committee would welcome copies of any reports and / or findings that may arise from the internal reviews that you are commissioning.

Yours sincerely,

**David Rees AM**  
Chair, Health and Social Care Committee  
Cadeirydd y Pwyllgor Iechyd a Gofal Cymdeithasol

Bae Caerdydd  
Cardiff Bay  
CF99 1NA

Ffôn / Tel: 029 2089 8403

**Tudalen 46**  
E-bost / Email: [PwyllgorIGC@cymru.gov.uk](mailto:PwyllgorIGC@cymru.gov.uk) / [HSCCommittee@wales.gov.uk](mailto:HSCCommittee@wales.gov.uk)

Croesewir gohebiaeth yn y Gymraeg a'r Saesneg / We welcome correspondence in both English and Welsh



GIG  
CYMRU  
NHS  
WALES

Bwrdd Iechyd Prifysgol  
Hywel Dda  
Hywel Dda University  
Health Board

Ein cyf/Our ref:  
Gofynnwch am/Please ask for: Chris Martin  
Rhif Ffôn /Telephone: 01437 771240  
Ffacs/Facsimile: 01437 771222  
E-bost/E-mail: [Chris.martin@wales.nhs.uk](mailto:Chris.martin@wales.nhs.uk)  
Date: 20 December 2013

Pencadlys Bwrdd Iechyd Prifysgol Hywel Dda  
Llys Myrddin, Lôn Winch, Hwlfordd,  
Sir Benfro, SA61 1SB  
Rhif Ffôn: (01437) 771220

Hywel Dda University Health Board Headquarters  
Merlins Court, Winch Lane, Haverfordwest,  
Pembrokeshire, SA61 1SB  
Tel Nr: (01437) 771220

David Rees AM  
Chair, Health & Social Care Committee  
National Assembly for Wales  
Cardiff Bay  
Cardiff  
CF99 1NA

Dear David

Thank you very much for your letter of 18 December 2013.

I will ensure that you receive updates as the work progresses.

Yours Sincerely

Chris Martin  
Chairman

Pencadlys Bwrdd Iechyd Prifysgol Hywel Dda  
Llys Myrddin, Lôn Winch, Hwlfordd,  
Sir Benfro, SA61 1SB  
Rhif Ffôn: (01437) 771220  
Rhif Ffacs: (01437) 771222

Hywel Dda University Health Board Headquarters  
Merlins Court, Winch Lane, Haverfordwest,  
Pembrokeshire, SA61 1SB  
Tel Nr: (01437) 771220  
Fax Nr: (01437) 771222

Cadeirydd / Chairman  
**Mr Chris Martin**  
Prif Weithredwr /Chief Executive  
**Yr Athro/Professor Trevor Purt**

Bwrdd Iechyd Prifysgol Hywel Dda yw enw operadu'r Bwrdd Iechyd Prifysgol Lleol Hywel Dda  
Hywel Dda University Health Board is the operational name of Hywel Dda University Local Health Board

Mae Bwrdd Iechyd Prifysgol Hywel Dda yn amgylchedd di-fwg Hywel Dda University Health Board operates a smoke free environment

**Y Pwyllgor Iechyd a Gofal Cymdeithasol**  
**Health and Social Care Committee**

Cynulliad  
Cenedlaethol  
Cymru  
National  
Assembly for  
Wales



**Chris Martin**  
Chair, Hywel Dda Health Board

18 December 2013

Dear Chris,

Thank you for your letter of 5 December providing an update on your discussions with the Minister for Health and Social Services regarding the work of Hywel Dda Health Board. The Committee discussed your correspondence at its meeting on 5 December.

You refer to a number of actions that you will be undertaking in light of the issues raised with you by the Minister and Assembly Members. The Committee is keen to receive regular updates on the planned work outlined in your letter to re-assure Members that necessary action is being taken to address recent concerns about the provision of services in the health board area. Furthermore, the Committee would welcome copies of any reports and / or findings that may arise from the internal reviews that you are commissioning.

Yours sincerely,

**David Rees AM**  
Chair, Health and Social Care Committee  
Cadeirydd y Pwyllgor Iechyd a Gofal Cymdeithasol

Bae Caerdydd  
Cardiff Bay  
CF99 1NA

Ffôn / Tel: 029 2089 8403

**Tudalen 48**  
E-bost / Email: [PwyllgorIGC@cymru.gov.uk](mailto:PwyllgorIGC@cymru.gov.uk) / [HSCCommittee@wales.gov.uk](mailto:HSCCommittee@wales.gov.uk)

Croesewir gohebiaeth yn y Gymraeg a'r Saesneg / We welcome correspondence in both English and Welsh

# Eitem 6

Mae cyfyngiadau ar y ddogfen hon