

Mark Drakeford AC / AM
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref: LF/MD/0688/15

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

4 September 2015

Dear David,

Public Health (Wales) Bill

I would like to thank you and the Committee for the opportunity to discuss the Public Health (Wales) Bill on 1 July 2015.

I am pleased to provide the Committee with further information on the following issues, which were raised during the session:

- a) the Welsh Government's view of the legislative competence of the National Assembly for Wales to impose restrictions on the sale of high sugar products and alcohol, and to ban the sale of conventional cigarettes in Wales;
- b) details of medical assistance sought as a consequence of undergoing any of the special procedures covered in the Bill, including the cost of providing treatment;
- c) details of the evidence I referred to that most users of e-cigarettes also use conventional tobacco cigarettes;
- d) information on the success rate of using e-cigarettes as a smoking cessation method in comparison to other options; and
- e) further information on the human rights issues associated with the Bill in relation to smoking and the use of e-cigarettes in private dwellings which are also workplaces, and on the powers of entry provisions included in the Bill.

This information is presented below.

Legislative competence of the National Assembly for Wales to impose restrictions on the sale of high sugar products and alcohol, and to ban the sale of conventional cigarettes in Wales

The Welsh Government continues to keep under review the potential public health benefits to be derived from the imposition of restrictions on the sale of high sugar products or on how alcohol is displayed by retailers. It is not Welsh Government policy to introduce a ban on the sale of conventional cigarettes in Wales. As such, detailed policy proposals have not been developed or consulted upon, nor have legislative provisions been drafted. The Committee will appreciate that any assessment of competence pursuant to section 108 of the Government of Wales Act 2006 is concerned with actual provisions of Assembly Acts, not general policies, and that in the absence of draft provisions, it is not possible to express a concluded view on competence. Nevertheless, in order to assist the Committee, set out below is a list of factors that would likely be considered during any competence analysis of draft provisions.

Section 108 of the Government of Wales Act 2006 sets out the extent of the Assembly's competence. Section 108(4) provides that a provision is within competence if it relates to one or more subjects listed under the headings in Part 1 of Schedule 7 to the Act, and does not fall within any of the exceptions in that Part. Consideration would therefore need to be given to whether the provisions would relate to Schedule 7 subjects, having regard to the purpose and effect of the provisions. The Schedule 7 subjects which may be relevant to both topics include the 'promotion of health', 'prevention, treatment and alleviation of disease, illness, injury, disability and mental disorder', and 'protection and well-being of children'. 'Food and food products' may also be relevant to restrictions on high sugar products and alcohol.

However, consideration would also need to be given to whether the provisions would fall within Schedule 7 exceptions. In relation to imposing restrictions on the sale of high sugar products and alcohol, a number of exceptions may be relevant, including the 'consumer protection' exception under heading 4 and the 'licensing' exception under heading 12. In relation to banning tobacco, consideration would need to be given to whether the provisions would fall within the 'products standards and safety' exception or the 'intellectual property' exceptions under heading 4.

Section 108(6)(c) of the Government of Wales Act 2006 further provides that, even where a provision falls within section 108(4), it will be outside the Assembly's competence if it is incompatible with Convention rights or with EU law. It is highly likely that any provisions which seek to reduce the consumption of high sugar products and alcohol would constitute an interference with possessions, falling within the scope of Article 1 of the First Protocol, and potentially an interference with the right to freedom of expression provided for by Article 10 of the Convention. Without further detail relating to the specific proposals, it is difficult to assess whether they would be within competence. In relation to banning the sale of tobacco, careful consideration would need to be given to whether any provisions would contravene the principle of the free movement of goods, specifically the prohibition

of quantitative restrictions and measures having equivalent effect to such restrictions at Article 34 of the Treaty on the Functioning of the European Union.

Notwithstanding issues of competence, any amendments tabled to the Public Health (Wales) Bill would need to comply with Standing Order 26.61.

Details of medical assistance sought as a consequence of undergoing any of the special procedures covered in the Bill, including the cost of providing treatment

Available evidence suggests that most of the complications associated with special procedures are skin infections, although there are a range of complications of varying severity which can arise. Current NHS data collection systems do not provide information on the number of people requiring medical assistance from such complications, and so the Welsh Government is not in a position to provide the requested data.

Each of the four procedures covered by the Bill involve the piercing of the skin, and as such pose a potential risk to health if they are carried out in an unhygienic fashion. I am therefore satisfied that the proportionate regulation of these procedures is appropriate, in order effectively to protect the public from potential harm.

To illustrate the type of harms that can result and their impact on the NHS, a study in England found that complications were reported with 27.5% of body piercings, with problems serious enough to seek further help in 12.9% of cases. Among 16-24 year olds, 5.1% of piercings resulted in help being sought from a pharmacist, 3% from a GP, and 0.6% from an A&E department, with 0.9% requiring a hospital admission. While we have not identified similar data for the other special procedures, evidence from the USA, for example, suggests a complication rate with tattoos of 2-3%. Further information is provided in the Bill's Explanatory Memorandum at paragraphs 541-556.

As the Committee is aware, we have also become aware of recent specific instances of harm being caused in Wales from poor practice. Nine individuals were hospitalised and required surgery in relation to pseudomonas infection following piercings conducted at one establishment in Newport. As Dr Gill Richardson explained in her evidence to the Committee on 9 July 2015, this incident will have cost Aneurin Bevan University Health Board, Public Health Wales and the local authority around £0.25 million.

Evidence that most users of e-cigarettes also use conventional tobacco cigarettes

The majority of e-cigarette users are "dual users" who continue to smoke conventional tobacco products. Varying suggestions have been made about the likely proportion of dual users, ranging from three fifths of all adult users in 2015 according to an ASH UK survey,¹ to approximately 85% of all users according to the Smoking Toolkit Study². Further details of these studies are given below:

¹ ASH factsheet 33: Use of electronic cigarettes in Great Britain. May 2015

<http://www.ash.org.uk/information/facts-and-stats/fact-sheets>

² Smoking Toolkit Study. Trends in electronic cigarette use in England.

<http://www.smokinginengland.info/latest-statistics/> (accessed 27th August 2015. Please note this slide is updated quarterly)

ASH factsheet 33: Use of electronic cigarettes in Great Britain. April 2014 and 20 October 2014, accessed at [http://www.ash.org.uk/information/facts-and-stats/fact-sheets in February 2015](http://www.ash.org.uk/information/facts-and-stats/fact-sheets-in-February-2015). This factsheet has been updated to feature 2015 data since use in the RIA. Findings included:-

- An estimated 2.1 million adults in Great Britain currently use electronic cigarettes; and
- About one third of users are ex-smokers and two-thirds are current smokers.

The total sample size was 12,269 and fieldwork was undertaken between 5 and 14 March 2014. All surveys were carried out online. This is the source which was used in the Regulatory Impact Assessment (RIA) for the Public Health (Wales) Bill, proportioned to Wales.

ASH factsheet 33: Use of electronic cigarettes (vapourisers) among adults in Great Britain. May 2015 – available at <http://www.ash.org.uk/information/facts-and-stats/fact-sheets>.

Findings included:

- An estimated 2.6 million adults in Great Britain currently use electronic cigarettes; and
- Nearly two out of five users are ex-smokers and three out of five are current smokers.

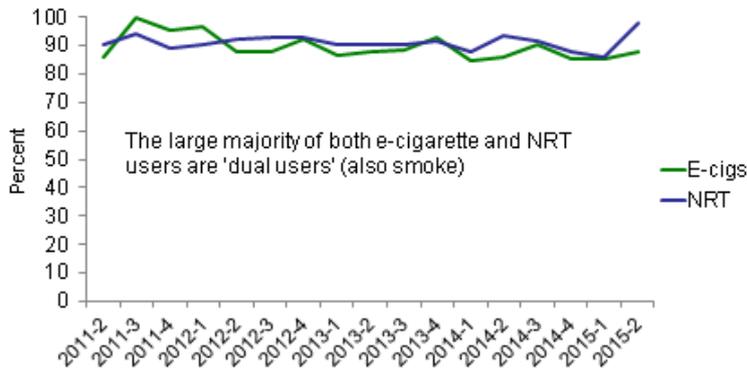
The total sample size for this study was 12,055 and fieldwork was undertaken between 26 February and 12 March 2015. All surveys were carried out online.

Smoking Toolkit Study. Trends in electronic cigarette use in England. Updated 23 April 2015 – available at <http://www.smokinginengland.info/latest-statistics/>

This study involved monthly household surveys, with each month involving a new representative sample of approximately 1,800 respondents, of whom approximately 450 are smokers.

The findings are illustrated in the graph below.

Proportion of e-cigarette and NRT users who are smokers



N=2355 e-cigarette users and N=2302 NRT users of adults who smoke or stopped in past year

www.smokinginengland.info/files/STS%20STS

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The 2015 ASH data were not available at the time of preparing the Bill's RIA. The 2014 ASH data were therefore applied in the RIA, in order to enable us to make our best current assessment of costs and benefits, as they provide an estimate of the current number of adult e-cigarette users in Great Britain as well as the proportion of e-cigarette users who still currently smoke (the so called 'dual users'). The RIA will be reviewed during Stage 2 of the Bill process and consideration will be given to revising the costs and benefits on the basis of new evidence and data available at the time of the review.

Applying the 2014 ASH data, it is estimated that there are around 100,800 e-cigarette users in Wales and that two thirds of e-cigarette users use them alongside tobacco products. Such "dual users" are still exposing themselves to the health harms from tobacco smoking³, which may have negative implications for individuals and public health. Continuing to smoke any conventional cigarettes confers essentially the full cardiovascular risk, and cancer risk may only be modestly affected, because smoking duration is more important than intensity.⁴ NICE indicates there may be some harm reduction benefits from reduced tobacco consumption if cessation is not an option⁵.

Based on these same sources, Public Health England stated in its 2015 report that around two-thirds of e-cigarette users also smoke. Given this figure, it suggests that data are needed on the natural trajectory of 'dual use', ie whether dual use is more likely to lead to smoking cessation later or to sustain smoking.⁶

³ <http://www.nhs.uk/chq/Pages/2344.aspx?CategoryID=53>

⁴ Background Paper on E-cigarettes (Electronic Nicotine Delivery Systems). Rachel Grana, PhD MPH; Neal Benowitz, MD; Stanton A. Glantz, PhD. Center for Tobacco Control Research and Education University of California, San Francisco WHO Collaborating Center on Tobacco Control. Prepared for World Health Organization Tobacco Free Initiative December 2013.

⁵ <https://www.nice.org.uk/guidance/ph45>

⁶ E-cigarettes: an evidence update: A report commissioned by Public Health England. Public Health England. August 2015

The use of e-cigarettes as a smoking cessation method in comparison to other options

While many smokers quit without recourse to smoking cessation services and products, it is recognised that nicotine products can play an important role in helping smokers to quit altogether, or to reduce their consumption of tobacco products. Nicotine products include traditional forms of licensed nicotine replacement therapy (NRT), such as nicotine patches, gums and lozenges. There is evidence to suggest that long-term use of NRT concurrent with smoking is not associated with an increased incidence of harm, including cardiovascular events or cancer, with the latest analysis of outcome at 12.5 years from study outset⁷.

At present, the health effects of long-term e-cigarette use have not been established⁸. The most robust evidence comes from a Cochrane Review⁹ of 13 completed studies on smoking cessation, published in December 2014. This reported there is some evidence from two trials that nicotine-containing e-cigarettes help smokers to stop smoking long-term, or reduce the amount smoked, compared with non-nicotine e-cigarettes. However the Cochrane reviewers concluded that the quality of the evidence overall is low because it is based on a small number of studies. The one study¹⁰ that compared e-cigarettes to nicotine patches found no significant difference in six-month abstinence rates. However, the authors noted that there was insufficient statistical power in the study, therefore a clinically important difference cannot be ruled out.

The Bill's Explanatory Memorandum provides details of some relevant studies, and we are continuing to monitor the literature. We are aware of more recent studies and analyses, for example a study which shows daily use of e-cigarettes while smoking appears to be linked to an increase in attempts to stop smoking and reducing the amount smoked, but not with cessation. However, the same study found that non-daily use of e-cigarettes while smoking does not appear to increase attempts to stop smoking, nor reduce the amount smoked¹¹. Another recent paper, which looked at 11 published studies, suggested that smokers who use e-cigarettes are about 30% less likely to quit smoking than smokers who do not use e-cigarettes¹².

A great deal has been learnt across the UK in providing effective smoking cessation support since the introduction of specialist services in 2000. A study of data from English

⁷ <https://www.nice.org.uk/guidance/PH45/chapter/9-The-evidence>

⁸ Pisinger Charlotta, Døssing Martin, A systematic review of health effects of electronic cigarettes, *Preventive Medicine* (2014), doi:10.1016/j.ypmed.2014.10.009

⁹ Electronic cigarettes for smoking cessation and reduction (Review). 2014. The Cochrane Collaboration. Published by John Wiley & Sons, Ltd. Available at: <http://www.cochrane.org/features/new-cochrane-evidence-shows-electronic-cigarettes-facilitate-smoking-cessation>

¹⁰ Bullen C, Howe C, Laugesen M, McRobbie H, Parag V, Williman J, et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet* 2013;382(9905):1629–37.

¹¹ Is the use of electronic cigarettes while smoking associated with smoking cessation attempts, cessation and reduced cigarette consumption? A survey with a 1-year follow-up. Leonie S. Brose, Sara C. Hitchman, Jamie Brown, Robert West and Ann McNeill. *Addiction* Volume 110, Issue 7, pages 1160–1168, July 2015

¹² <https://tobacco.ucsf.edu/meta-analysis-all-available-population-studies-continues-show-smokers-who-use-e-cigs-less-likely-quit-smoking> March 2015

specialist stop smoking services¹³ looked at 126,890 treatment episodes in 24 stop smoking services in 2009/10 to assess the association between intervention characteristics and success rates. There was substantial variation in success rates across intervention characteristics after adjusting for smoker characteristics:

- NRT used on its own was associated with higher success rates than no treatment at all;
- NRT combined with Varenicline (a prescription medicine used to treat nicotine addiction) was more successful than NRT used on its own;
- Group support was linked to higher success rates than one-to-one support;
- Primary care settings (such as in GP surgeries and hospitals) were less successful than specialist clinics.

It is often stated that smokers are up to four times more likely to successfully quit with support from cessation services. Evidence to support this statement comes from studies which found that:

- When comparing like-for-like types of smokers, the success rate of those who quit with no support is typically three to four per cent¹⁴;
- One large study in England found that breath-test validated quit rates at 12 months were 15 per cent for smoking cessation services and 20 per cent for specialist services¹⁵.

In Wales, smokers are supported to quit by a range of services including the Stop Smoking Wales service and an increasing provision of smoking cessation services in community pharmacies. Dr Julie Bishop, director of health improvement for Public Health Wales recently commented that Stop Smoking Wales had “already started work to ensure that smokers who choose to use e-cigarettes to help them quit also have access to specialist behavioural support”¹⁶.

Human rights issues in relation to smoking and the use of e-cigarettes in private dwellings which are also workplaces

The current law on smoking in private dwellings which are also work-places

The current smoke-free policy is implemented by the Health Act 2006 and the Smoke-free Premises etc. (Wales) Regulations 2007 (“2007 Regulations”). Regulation 3 of the 2007 Regulations contains a number of exceptions to the smoke-free requirements of the Health Act 2006 in relation to dwellings which are also used as workplaces. The policy rationale underpinning these exceptions was that a person’s private dwelling should never be

¹³ Brose, West, McDermott, Fidler, & McEwan (2011). What makes for an effective stop-smoking service

¹⁴ Hughes JR, Keely J, Naud S (2004). Shape of the relapse curve and long-term abstinence among untreated smokers. *Addiction*. 2004;99:29-38

¹⁵ Ferguson J, Bauld L, Chesterman J, Judge K. (2005) The English smoking treatment services: one-year outcomes. *Addiction*. 100 Suppl 2:59-69.

¹⁶ Page 4, The I newspaper 19 August 2015

required to be smoke-free solely by virtue of the fact that a person attends the dwelling to provide specific services (“the excepted services”).

These “excepted services” are:

- (i) to provide personal or health care for a person living in the dwelling;
- (ii) to assist the domestic work of the household in the dwelling;
- (iii) to maintain the structure or fabric of the dwelling; and
- (iv) to install, inspect, maintain or remove any service provided to the dwelling for the benefit of a person living in it.

The 2007 Regulations achieved this general policy objective through a combination of two provisions:

- (i) Regulation 3(1)(b), which provides that part of a private dwelling can only ever be smoke-free if used *solely* for work purposes (or is shared with another private dwelling – Regulation 3(1)(a)); and
- (ii) Regulation 3(3), which provides that even if there are parts of a private dwelling that are used solely for the purposes of work, those parts are not required to be smoke-free if the work consists solely of the excepted services.

The majority of the parts of dwellings that are used to provide excepted services will only be used *partly* for those purposes. Regulation 3(1)(b) provides that those parts are not required to be smoke-free. Regulation 3(3) ensures that any parts of the dwelling that are used *solely* for the purposes of the excepted services are not inadvertently caught by the requirement to be smoke-free (for example a room that is used only as a place where physiotherapists attend to provide physiotherapy to the householder, or a room in a house that is only used by domestic attendants to keep cleaning equipment etc.).

The rationale for the policy of never requiring a part of a private dwelling to be smoke-free only because excepted services are provided there is linked to the requirement for smoke-free premises to be smoke-free all of the time (i.e. 24 hours a day)¹⁷, and not just when being used as a place of work. The nature of the excepted services is such that, ordinarily, they are provided only intermittently (for example, weekly, monthly or annually). As such, it is considered that it would be disproportionate to criminalise the occupant should he or she happen to be smoking when passing through the relevant part of the house, despite the fact that that part of the dwelling may not be used for work purposes for, for example, six months.

A distinction may be drawn in this respect between the excepted services, where the dwelling’s occupant has not chosen to run a business from the home and is merely receiving particular types of service intermittently, and where the occupant has opted to run a business from the home, and is using a part of the home solely for that purpose. In the latter, a conscious decision has been made to make part of the home a workplace, and generally, that workplace would be used more regularly than the excepted services would be provided. As such, it is considered proportionate to require parts of dwellings that are used solely as workplaces (i.e. places from which business are carried on) to be smoke-free all of the time.

E-cigarettes and private dwellings

¹⁷ Section 2(2) provides that smoke-free premises are required to be smoke-free all of the time.

The current position outlined above will be considered further in the context of the Public Health (Wales) Bill, particularly in light of the fact that the Bill will require any parts of dwellings that are used partly or solely as workplaces to be smoke-free, but only when being used as a workplace. In the absence of any relevant exemptions in regulations made under section 10 of the Bill, section 6 will require parts of private dwellings that are workplaces to be smoke-free when used as a place of work. In this context, being 'smoke-free' means that smoking and the use of nicotine inhaling devices ("NIDs") will be prohibited.

In developing our policy in relation to NIDs in dwellings that are used as workplaces, three options were considered:

- (i) to allow the use of NIDs at all times;
- (ii) to prohibit the use of NIDs (and smoking) at all times; and,
- (iii) to prohibit smoking and the use of NIDs when the relevant part of the dwelling is being used as a workplace (i.e. the approach taken in the Bill).

In determining the approach to be taken in the Bill, full consideration was given to Article 8 of the European Convention on Human Rights. I am content that the Bill strikes the right balance between occupiers' rights to use NIDs in their own homes, and the health benefits that arise as a result of restricting their use.

The evidential basis for prohibiting the use of NIDs in parts of dwellings that are workplaces is the same as for restricting the use of NIDs more generally. It is considered that the use of NIDs normalises smoking behaviour. NIDs such as e-cigarettes mimic the sensation and appearance of smoking a cigarette¹⁸ and provide some of the additional behavioural cues that are known to be important in tobacco dependence, including the 'hand to mouth' action. In this context, it is considered that there are significant public health benefits from prohibiting the use of NIDs in dwellings that are workplaces, particularly where children may be present. Examples of such workplace scenarios include:

- child minding services offered from a person's private dwelling;
- hairdressing services offered from a private dwelling (i.e. where people, including children, attend the dwelling to have their hair cut);
- music or language lessons or other private tuition offered from a private dwelling (i.e. where people, particularly children, attend the private dwelling for the lesson / tuition);
- physiotherapy services provided in a private dwelling (i.e. where people, including children, attend the private dwelling for physiotherapy treatment); and
- cupcake decorating party services for children provided from the kitchen of a private dwelling (i.e. the child and their friends attend the private dwelling for a birthday party).

It is also considered that prohibiting the use of NIDs in parts of dwellings that are workplaces will preserve the improved air environment that has resulted from the Health

¹⁸ Public Health England. Electronic Cigarettes: A report commissioned by Public Health England. Professor John Britton and Dr Ilze Bogdanovica. UK Centre for Tobacco and Alcohol Studies Division of Epidemiology and Public Health, University of Nottingham. 2014

Act 2006. NIDs contain various chemicals that are vaporised and emitted into the air, and studies have suggested that e-cigarette aerosol can contain some of the toxicants present in tobacco smoke, albeit at levels which are much lower.^{19 20} Again, my view is the approach taken in the Bill has particular health benefits in relation to workplaces generally, especially those that are likely to be attended by children and young people.

In developing the policy, consideration was also given to the fact that, in practice, the effect of the restriction will be very minimal. The prohibition will only apply during working hours and, even then, the occupant will be free to use a NID in an adjoining room. To cite the example given in Annex A to your letter, the partial restriction on the right to use a NID would not prevent Mr A from leaving the living room to go to, for example, the kitchen, to use his NID.

I would also note that the powers provided at section 10 of the Bill will allow the Welsh Ministers to make regulations to exempt premises, or specified areas within premises, from the requirement to be smoke-free. Any such exemptions may be in respect of both smoking and the use of NIDs, smoking only, or the use of NIDs only. Consideration will be given to whether these powers should be exercised to provide an exemption, in relation to NIDs, for private dwellings that are particular types of workplaces and where children are never present.

Powers of entry

The powers of entry in the Bill relate to local authorities and other enforcement authorities. It is not envisaged that any non-public authorities will be designated as enforcement authorities. Public authorities and the Courts are subject to the European Convention on Human Rights pursuant to section 6 of the Human Rights Act 1998.

The provisions in the Bill relating to powers of entry provide safeguards that the powers may only be exercised following consideration and approval of a warrant by a Justice of the Peace. In view of this, I am content that the powers of entry to private dwellings with a warrant are proportionate, and the safeguards presented by consideration and approval of the warrant by a Justice of the Peace are sufficient to ensure there is no unjustified interference with a person's protected human rights.

A Justice of the Peace should not sign a warrant authorising an Authorised Officer to act in a way which would constitute an unjustified interference with a person's protected human rights. Should the Justice of the Peace consider it necessary to do so in the individual circumstance, he/she can also attach conditions to a warrant, such as timings or other restrictions.

In relation to giving notice of entry, in many circumstances, this would defeat the purpose of entering the premises. If notice of entry were to be served, a person could simply hide

¹⁹ Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Hajek et al. 2014. *Addiction*, 109, 1801-1810 doi:10.1111/add.12659

²⁰ Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. Farsalinos and Polosa. *Therapeutic Advances in Drug Safety*. Apr 2014; 5(2): 67-86. doi: 10.1177/2042098614524430 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110871/>

or dispose of any evidence or documents that were in the dwelling before the Authorised Officer attended on the specified date.

I am aware that the UK Government Department of Health published a report in December 2014 following a review of the health and care powers of entry, to ensure they achieve the right balance between the need to respect the rights of individuals and the need to enforce the law to protect public health. Fifty four powers of entry in primary and secondary legislation were identified in the context of health and care. The review found that the majority of these are vital and proportionate. Accordingly, forty one powers of entry were retained. Where powers of entry were retained, the Department of Health worked with the Home Office to ensure the appropriate safeguards were in place, which included a 'long-stop' option for bodies to seek a warrant. The Welsh Government has not carried out a separate review of powers of entry.

I hope that the information provided in this letter answers the questions raised by Committee members, and I look forward to answering any further questions from members in due course.

Best wishes

A handwritten signature in black ink, reading "Mark Drakeford", enclosed in a thin black rectangular border.

Mark Drakeford AC / AM

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol

Minister for Health and Social Services