Health and Social Care Committee

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From Dr Sarah Wollaston MP, Chair

Rt hon Matt Hancock MP
Secretary of State for Health and Social Care

Letter by email to: mb-sofs@dhsc.gov.uk

31 October 2019

Dear Matt,

On behalf of the Health and Social Care Committee, I would like to thank you for your response to our report on *drugs policy: medicinal cannabis*.

It is encouraging to see that the Government has shown a clear commitment to implementing a number of our recommendations. These include providing clear information on the availability of CBPMs to patients and the public, improving the evidence base supporting the prescription of medical cannabis, examining how medicinal cannabis is prescribed in other EU countries and providing improved guidance to practitioners and pharmacists on supplying cannabis-based products.

However, there are a number of areas in our report which the Government response has either ignored or not answered directly. These concern in particular recommendations 5, 6 and 10, the content of which is reflected throughout the Committee's report.

I have provided further details on the issues below. I look forward to hearing from you further with the Government's response to those issues.

Yours sincerely,

Dr Sarah Wollaston MP
Chair of the Committee

Areas unaddressed by the Government's response to the Committee's report on drugs policy: medicinal cannabis.

1) Focusing on addressing intractable epilepsy – (Recommendation 5 of the Committee's Report)

In November 2018 medicinal cannabis was changed from Schedule 1 to Schedule 2 of the Misuse of Drugs Regulation 2001. This was largely due to the efforts of those suffering with intractable epilepsy and their families, and was the impetus for the Committee launching an inquiry into medicinal cannabis. The importance of improving access to medicinal cannabis for individuals (especially children) with intractable epilepsy is reflected throughout the Committee's report.

In recommendation 5 of our Report, we recommended that the National Institute of Health Research (NIHR) should make resources immediately available for a programme of clinical trials for the treatment of intractable epilepsy. This will allow many more patients to access treatments in specialist centres. These trials should be facilitated as a matter of urgency. This is because it is clear that we will fail patients if we do not establish the evidence base for the place of medicinal cannabis in treatment.

However, the Government's response falls short of providing a clear commitment to taking direct and focussed action on the area intractable epilepsy. In particular, although intractable epilepsy is listed as a priority area for NIHR in the Government's response, it remains one of five priorities and consequently it is possible for future research proposals to focus more on the other four priorities. This could marginalise research and trials into treating intractable epilepsy. This could potentially be a significant problem as NIHR's funding is not ring-fenced. It is therefore unclear what provisions are in place to prevent research into intractable epilepsy taking a back seat, and what specific action is being undertaken to support the treatment of intractable epilepsy as an issue in its own right. What action is the Government taking to ensure that its own work and the work of the NIHR is sufficiently addressing the issue of intractable epilepsy?

2) Providing a stronger commitment that collaboration on research with the EU will continue in all Brexit scenarios - (Recommendation 6 of the Committee's Report)

A key concern highlighted in the Committee's report, emphasised in recommendation 6, is the impact of Brexit on the prescribing and researching of medicinal cannabis products in the UK.

In recommendation 6, the Committee said that the Department of Health and Social Care should set out in its response to the Committee's report how it will work with research organisations here in the UK and internationally to ensure that research is being co-ordinated and encouraged in the most appropriate areas. We also asked for the Government to set out how it will ensure that the future of European multi-centre clinical trials and the post marketing surveillance that protects patient safety are not put at risk by Brexit.

However, the Government's response failed to address this recommendation directly, using vague and uninformative language to describe its current work. What specific work is the Government and the Department for Health and Social currently doing to ensure that the

future of European multi-centre clinical trials and post marketing surveillance are not jeopardised post-Brexit, to avoid undermining patient safety?

3) Long-term deals to secure the supply of CBPMs in the UK - (Recommendation 10 of the Committee's Report)

In recommendation 10 of our report, we urged the Department of Health and Social Care to take steps to secure long-term international deals in order to ensure a consistent supply of CBPMs in the UK. This is vital in ensuring that patients are not delayed in receiving their prescriptions and the cost of the medicinal cannabis products are kept as low as possible. The Committee also stated that it expects the Department for Health and Social Care to work with other governments, devolved and abroad, to make a more collaborative and attractive deal for industry. The Committee said that it expects to hear from the Department what success it has had in this area by the beginning of 2020.

However, the Government's response to this recommendation is vague and unspecific in terms of its work to establish supply of CBPMs in the UK, and how it plans to keep costs low and ensure there is no delay in the supply of such products. Can you clarify the specific steps that the Government is currently taking and planning to take in this area?

In accordance with our original recommendation, the Committee will expect to receive a further update by 28th February 2020, but we look forward in the meantime to hearing what steps you are taking now.

Department of Health & Social Care

From the Rt Hon Matt Hancock MP
Secretary of State for Health and Social Care

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The Rt Hon Jeremy Hunt MP
Chair of the Health and Social Care Committee
House of Commons
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28 February 2020

Dear Jeremy,

Firstly, may I again congratulate you on your appointment as chair of the Health and Social Care Select Committee, and I look forward to working with you and the rest of the Committee.

I am writing in response to your predecessor, Dr Sarah Wollaston's letter of 31 October 2019, inviting me to provide further detail to the Government's response to the Health and Social Care Committee inquiry on medicinal cannabis.

I am writing to clarify the points requested:

Recommendation 5. The National Institute of Health Research should make resources immediately available for a programme of clinical trials for the treatment of intractable epilepsy. This will allow many more patients to access treatments in specialist centres. These trials should be facilitated as a matter of urgency. Families of children suffering from these distressing and life-threatening conditions should not have to travel abroad to seek treatment, but we will fail future patients if we do not establish the evidence base for the place of medicinal cannabis in treatment. (Paragraph 69)

The Committee asked, "*what action is the Government taking to ensure that its own work and the work of the NIHR is sufficiently addressing the issue of intractable epilepsy?*"

There is a clear need for more evidence to support prescribing and funding decisions and we are working hard with the health system, industry and researchers to improve the knowledge base available. As part of this work the Department is working closely with NHS England-NHS Improvement (NHSE-I) and the National Institute for Health Research (NIHR) to establish clinical trials.

In November 2019 the NIHR held a workshop with research applicants, NHSE-I, the DHSC and other research experts. The aim was to design a safe and scientifically robust trial for adults and children with severe epilepsy, including those patients and families

currently using these products. This process is expected to halve the time usually required to design and gain funding agreement for a safe and high quality clinical trial which could then be commissioned by the NIHR.

Patients agreeing to be part of this trial will have their medication supplied and funded. Clinicians have already had discussions with patients and patient organisations to help inform the proposed study as part of the usual process of study design. NHSE-I will be meeting with families, including those represented by End Our Pain, shortly to update them on progress.

Since my response to the Committee's recommendations the National Institute for Health and Care Excellence (NICE) has published two technology appraisals for Epidyolex (a licensed CBD product) in combination with clobazam for the treatment of seizures associated with Dravet syndrome (https://www.nice.org.uk/guidance/ta614) and Lennox-Gastaut syndrome (https://www.nice.org.uk/guidance/ta615) (two rare forms of intractable epilepsy). Funding has been fast-tracked by NHSE-I and has been available since 6 January 2020 for patients who fulfil the criteria in the technology appraisals. This will improve access to licensed cannabis-based products for appropriate patients.

In addition:

- A new Refractory Epilepsy Specialist Clinical Advisory Network has now launched. This will make a positive addition to the current well-established clinical networks; and
- A patient registry is being developed with input from specialist clinicians and other advisory bodies to capture patient outcomes across all indications, including intractable epilepsy, when cannabis-based medicines are prescribed.

Recommendation 6. The Department of Health and Social Care should set out in its response to this report how it will work with research organisations here in the UK and internationally to ensure that research is being co-ordinated and encouraged in the most appropriate areas. Government should also set out how it will ensure that the future of European multi-centre clinical trials and the post marketing surveillance that protects patient safety are not put at risk by Brexit. (Paragraph 70)

The Committee asked, "*What specific work is the Government and the Department for Health and Social [Care] currently doing to ensure that the future of European multi-centre clinical trials and post marketing surveillance are not jeopardised post-Brexit, to avoid undermining patient safety?*"

The UK Government is committed to making the UK a global science superpower that attracts brilliant people and businesses from across the world.

We value the strong collaborative partnerships that we have across Europe in the areas of science, research and innovation, recognising their importance to all parts of the UK and we want to continue to support these opportunities.

The ability of sponsors (organisations that run clinical trials, such as pharmaceutical companies and academic institutions) to run multinational trials involving the UK, will not change following EU exit. However, at the end of the transition period in the absence of

an EU/UK future relationship agreement, UK sponsors would require a legal representative in the EU.

In order to maintain and enhance the UK attractiveness for clinical research and promote our inclusion as a site for multi-site trials, the Medicines and Healthcare products Regulatory Agency (MHRA) is taking forward a number of commitments made as part of the second Life Sciences Sector Deal. For example, developing a strengthened UK environment for clinical research that provides support for innovative trial design, enabling industry and the wider research community to access advice and support for innovative trial designs. Further, the MHRA is providing support for a streamlined precision medicine-diagnostic pathway, permitting accelerated access to novel therapeutics for UK patients, while simultaneously encouraging drug and device development in the UK.

With regards to post-marketing surveillance, the MHRA has conducted extensive planning and systems development to ensure that we continue to have access to both UK and global safety data after 31 January 2020.

The MHRA will continue to conduct national pharmacovigilance inspections of marketing authorisation holders in order to assess compliance with UK pharmacovigilance requirements. We will continue to operate a risk-based inspection programme and product-specific risks are incorporated into the risk assessment methodology. We aim to continue cooperating with the EU so that we can tailor our inspection schedule accordingly and prioritise the highest risk pharmacovigilance systems and products.

The UK has Memorandums of Understanding with a large number of countries beyond the EU network and intends to continue to work internationally to exchange safety assessments between leading regulators for the benefit of both UK and international citizens.

Recommendation 10. We recommend that the Department of Health and Social Care should take steps to secure long-term international deals to ensure a consistent supply of CBPMs so as to ensure that patients are not delayed in receiving their prescriptions and the cost of the medicinal cannabis products are kept as low as possible. Baroness Blackwood has indicated that the Department is working with industry on establishing supply. We welcome this work and further recommend that the Department work with other governments, devolved and abroad, to make a more collaborative and attractive deal for industry. We expect to hear from the Department what success it has had in this area by the beginning of 2020. (Paragraph 93)

The Committee asked, "*Can you clarify the specific steps that the Government is currently taking and planning to take in this area?*"

Given the timing of this request for further information, the following update covers both this request and provides an update on the action the Government has taken in response to recommendation 10 of the Committee's report.

Products must obtain a marketing authorisation (licence) before a medicine may be routinely funded and existing mechanisms are in place to make decisions on whether new

licensed medicines represent value for money for the NHS and tax payer. The National Institute for Health and Care Excellence (NICE) now makes recommendations for the NHS on all new medicines and the NHS is required to fund medicines assessed by NICE as clinically and cost effective.

The vast majority of cannabis-based products are however unlicensed medicines ('Specials'). Specials are products which have been specially manufactured or imported to meet the special needs of an individual patient which cannot be met by a licensed product. NICE, having assessed the best available evidence on cannabis-based products, concludes that there is insufficient evidence to support decisions on prescribing and funding of unlicensed products.

Whereas prices of licensed, branded medicines, including for example Nabilone, Sativex and Epidyolex, are controlled by the statutory and voluntary schemes for branded medicines, the Government does not control prices of specials. Prescribers should however take into account the price of a special when deciding to prescribe a special. Unlicensed medicines, by their very nature, are generally low volume, high cost medicines. Prices are subject to market forces and may be expected to fall as the market develops and competition increases.

I have sympathy for patients and their families who are currently paying high costs for private prescriptions for unlicensed cannabis-based medicines. I have asked my officials to explore what actions, in addition to that already underway, we could take to reduce the cost of unlicensed cannabis-based medicines. I and the Department have limited powers to intervene in the price of unlicensed medicines supplied on private prescriptions and I will need to carefully consider any legal risks and unintended consequences before taking any action. I intend to meet with the industry to see what more can be done to reduce the costs of these medicines for patients in the UK. I would be happy to provide the Committee with a further update on this work.

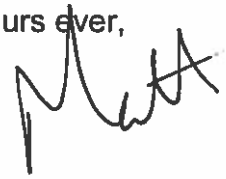
Since the Government response, the Department has also been aware that some importers of cannabis-based medicines are experiencing long lead times for receipt of export certificates from third countries. The current policy is that import is only authorised against a valid prescription. Therefore, only the amount specified on the prescription can legally be imported. This, combined with guidance issued by the Department and Scottish Government, which states that prescriptions for controlled drugs should only be issued for 30 days to guard against addiction to drugs such as opioids and ensure patients' treatment is regularly reviewed, risks a break in treatment for patients lawfully prescribed a cannabis-based product for medicinal use (CBPM). To give an example, in Canada, a primary source of CBPMs, export certificate processing is reported as taking between 4-8 weeks. This means that products cannot be imported before a prescription expires – 28 days for prescriptions for Schedule 2 & 3 controlled drugs under the Misuse of Drugs Regulations 2001.

This situation is untenable, and I and Home Office Ministers have agreed changes to the import policy to allow stocks of CBPMs, based on need anticipated by specialist prescribers, to be imported and held by licensed wholesalers, which may be drawn from on receipt of a prescription. This approach aligns CBPMs with other controlled drugs and

is also expected to reduce the cost of products for patients because of reduced import charges.

Finally, I would like to draw the Committee's attention to the planned clinical trials. NHSE-I is currently in discussion with manufacturers to supply products for these trials. Whilst these discussions are commercial in confidence, NHSE-I has a duty to ensure best value for the NHS.

Yours ever,



MATT HANCOCK