(DRU0024)

Written evidence submitted by Tonia Antoniazzi, Co-Chair of The All-Party Parliamentary Group on Access to Medical Cannabis Under Prescription (DRU0024)

Executive Summary

- The Medical Cannabis under Prescription APPG was formed in 2018 with a statement of purpose 'to help secure appropriate access to medical cannabis on the NHS in its various forms including full plant extract containing both CBD and THC in formulations produced to a consistent high quality pharmaceutical grade and manufactured to GMP standard.' The APPG is currently co-chaired by Tonia Antoniazzi MP and Alberto Costa MP.
- Since the landmark rescheduling of cannabis-based products for medical use by the Home Office on the 1st November 2018, the APPG is aware of only a handful of NHS prescriptions that have been written for patients in the UK on the NHS. Other patients continue to be denied access and struggle to financially afford private prescriptions of up to £2,000 per month.
- There is also growing concern within the medical cannabis community that this failure to widen patient access following the 2018 law change has contributed to the shocking statistics which show that 1.4 million people in the UK are treating their illnesses with illegal recreational cannabis.
- It is now the view of the APPG that Government policy on medical cannabis has reached crisis point. The Home Office took the bold and decisive decision to reschedule medical cannabis which offered hope to the most vulnerable patients in the UK for whom medical cannabis could offer some relief to their symptoms. However, the reality is that over three years since legalisation on 1st November 2018, access to medical cannabis is extremely limited with only a few thousand prescriptions almost all within the private sector. Indeed, even in the cohort of paediatric epilepsy, members of which led the campaigns widely acknowledged to have resulted in the law change, there have been only 3 NHS prescriptions. This has resulted in the families of the majority of patients in this cohort being at financial and emotional breaking point.
- The APPG has prepared answers to the terms of reference to the inquiry. The answers are listed below and are focused on the current drug policy framework and international comparisons, which are of most relevance to the medical cannabis situation in the UK.

Background

About the All-Party Parliamentary Group on Access to Medical Cannabis Under Prescription

1. The Medical Cannabis under Prescription APPG was formed in 2018 with a statement of purpose 'to help secure appropriate access to medical cannabis on the NHS in its various forms including full plant extract containing both CBD and THC in formulations produced to a consistent high quality pharmaceutical grade and manufactured to GMP standard.' The APPG is currently co-chaired by Tonia Antoniazzi MP and Alberto Costa MP.

2. Since the Group's formation in 2018, the APPG and its membership has campaigned tirelessly to tackle the ongoing access issues regarding NHS prescriptions, with a particular emphasis on the paediatric epilepsy cohort. Yet despite countless parliamentary debates, parliamentary questions and correspondence with NHS leaders and officials, ministers, Health Secretaries and the Home Secretary, patients have continued to be denied NHS access. In April 2021, the APPG wrote to the Prime Minister to call for his intervention in this crisis and to grant access to some form of

compassionate funding until the wider issues can be resolved. This letter received over 100 cross-party parliamentary signatures in support and received significant coverage across the BBC.[1]

About End Our Pain

3. End Our Pain acts as the Secretariat for the APPG on Access to Medical Cannabis Under Prescription. The End Our Pain Campaign was founded in 2016 and originally focused on the MS adult cohort. In 2018 the campaign worked with the family of the then 6-year-old Alfie Dingley, who suffers from a rare form of severe intractable epilepsy, to help him secure access to an NHS prescription. In June 2018, Alfie was granted the first ever long-term licence issued to an individual to use medical cannabis by the then Home Secretary Rt Hon Sajid Javid MP. Medical cannabis was then formally legalised in November 2018.

4. Following the law change, End Our Pain has continued to campaign on behalf of patients, with particular emphasis on other children and their families suffering from severe forms of intractable epilepsy to also secure access to NHS prescriptions. This Campaign has gained significant political and media coverage and has mobilised a support base of over 500,000 supporters throughout the UK.

Background to the current medical cannabis crisis and challenges

5. Access to medical cannabis under prescription was legalised after a great deal of very high-profile campaigning by two families each with a child affected by severe intractable epilepsy, one of whom was the then 6-year-old Alfie Dingley. A number of members of the APPG worked closely with the Dingley family to secure his long-term Home Office licence and the subsequent law change on 1st November 2018. Yet to the best of the APPG's knowledge, since the law change, just 3 NHS prescriptions for the type of medical cannabis that is life transforming for Alfie Dingley have been issued. This almost total block on NHS prescriptions for paediatric epilepsy has left patients and their families forced to pay up to £2,000 a month to access private prescriptions or simply go without access to a legal medicine due to these high costs. Patients feel completely let down by the current system, especially as the UK remains the world's largest producer of medical cannabis.[2]

6. It is crucial to note that the law change offered hope to patients with a whole range of other conditions from cancer to chronic pain. These patients are also suffering an almost total block on NHS prescriptions too.

7. It is important to clarify terminology. In simple terms there are two main types of medical cannabis. There is the type that is life transforming for the likes of Alfie Dingley containing both of the two main components - CBD and THC. It should be noted that there is a particular medicine relevant to the paediatric epilepsy cohort, that has been through full RCT trials and is licenced – Epidyolex – which is primarily CBD only. We believe that there have been some hundreds of prescriptions for this product. However, the APPG has been campaigning since 2018 for NHS access to the type of medical cannabis containing both CBD and THC and wider access to Epidyolex.

8. Cannabis based medical products (CBMPs) are defined by The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018 as:

[1] https://www.bbc.co.uk/news/uk-politics-56763650
[2] https://www.independent.co.uk/news/uk/home-news/cannabis-legal-uk-worlds-largest-producer-marijuana-weed-un-body-findings-a8243921.html

[A] cannabis-based product for medicinal use in humans means a preparation or other product. . . which a) is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers); (b) is produced for medicinal use in humans; and (c) is (i) a medicinal product, or (ii) a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product.

9. Unless prescribed, possession or supply of cannabis in the UK remains illegal under the Misuse of Drugs Act.

Questions posed by the Committee

10. The APPG's submission focuses on medical cannabis in context of the Committee's questions around the wider UK drug framework.

11. It has been estimated that up to 1.4 million people in the UK are treating their illnesses with illegal recreational cannabis.[3] As many as 2.8 percent of the adult population are self-medicating with street cannabis to manage the symptoms of conditions such as Huntington's disease, arthritis, cancer, multiple sclerosis, depression, anxiety and chronic pain. As a group, patients are spending more than £2.6 billion a year on black market cannabis.[4]

12. These research findings highlight that there is a fundamental problem with the current framework, as patients are essentially being criminalised as they are forced to turn to access medical cannabis via illegal means. It is the APPG's view that this is a direct result of failure to follow through following the landmark 2018 law change. While the Home Office and the Home Secretary reacted quickly to the high-profile cases that sparked such political momentum in the Houses of Parliament in 2018 and rescheduled medical cannabis, since then there has been very little progress in work to develop wider access and clear policy in practice. On this particular point, the APPG believes that the conventional pharmacological medicine route may not be appropriate for whole plant extract medical cannabis. Trying to regulate whole plant extract medical cannabis products as you would a traditional pharmaceutical product risks making the current situation a policy failure. Such a huge number of patients across the UK should not be forced to turn to the black-market in attempts to access medicines that have drastically improved their own and their family's quality of life.

13. Whilst this situation affects many thousands of people with a range of conditions it is exemplified by the particularly distressing group of families with severely epileptic children who the APPG is supporting. The APPG has been working closely with the particularly high-profile cohort of children suffering from severe and intractable paediatric epilepsy, as their transformations since using medical cannabis have been most dramatic. These children make for some of the most powerful case studies in highlighting the benefits of medical cannabis. Alfie Dingley has now gone over 500 days without a single seizure after previously suffering up to 300 a week. Furthermore, an observational study carried out by Drug Science in December 2020 of 10 patients with severe epilepsy found that there was an 97% mean reduction in monthly seizure frequency post-initiation of CBMPs.[5]

14. Despite such drastic transformations, to the best of our knowledge, just three children in this cohort have access to NHS prescriptions, two of which are the children involved in the initial campaign for legalisation. As stated above, dozens of other families, with children that have shown

[3] https://www.independent.co.uk/news/uk/home-news/cannabis-legal-uk-worlds-largest-producer-marijuana-weed-un-body-findings-a8243921.html
[4] Ibid.
[5] https://www.drugscience.org.uk/end-our-pain/

similar dramatic improvement, are having to pay up to £2,000 a month to buy the medicine privately. To make matters worse, the ability of such families to fundraise such huge sums has also been severely curtailed by Covid restrictions. The gravity of the current situation is that the APPG has been informed that these families are expected to run out of money in the coming weeks and months and some are already preparing for the worst-case scenarios for their children, whose conditions are especially life-threatening.

So why are NHS prescriptions not flowing?

15. At the same time as the law change, a number of bodies issued 'guidance' on when medical cannabis should be prescribed. These bodies included the British Paediatric Neurology Association (BPNA), the General Medical Council (GMC), National Institute for Clinical Excellence (NICE) and the Royal College of Physicians (RCP). None of this guidance says that medical cannabis cannot be prescribed but the high level of caution originally expressed in this guidance, particularly from the BPNA, is likely to have played a part in preventing wider prescribing of these products.

16. On the 27th March 2021, NICE issued clarification of their guidance relating to the use of medical cannabis for drug resistant paediatric epilepsy. They have now made it clear that "*there is no recommendation against the use of cannabis based medical products,*" which is a significant step forward.

17. Whilst this clarification offered a positive step forward for the intractable epilepsy cohort, it is important to highlight that NICE clinical guideline on cannabis-based medicinal products still does not currently recommend their use for a range of conditions such as chronic pain.

18. Further, the BPNA guidance is viewed by the epilepsy cohort in particular, and by doctors who are more willing to prescribe medical cannabis, as being excessively cautious. They appear to be of the very strong view that prescriptions in these cases should only be initiated by paediatric neurologists, even though the law allows for any specialist on the GMC specialist register to prescribe. However, their position on this matter was firmly challenged by an expert witness in a recent case heard by the GMC. The case featured in a Times article[6] in October 2021 with the GMC's expert witness stating that "*the BPNA position that only Paediatric Neurologists should initiate treatment is not supported by other national guidance, and probably not in the best interests of children, as it may impede debate and research into the appropriate use of Cannabidiols in refractory epilepsy.*"

19. The previous Secretary of State for Health & Social Care, Matt Hancock MP, also instructed the NHS to undertake a 'process review' to find out why NHS access was being blocked. This review was published on 8th August 2019 with two key recommendations.[7] It is worth noting that in this review senior NHS managers personally interviewed many of the families campaigning under the End Our Pain banner. The first recommendation was that an 'alternative' trial should be conducted as a means of getting funded access to these medicines for this cohort. The second was that an expert panel should be set up to help. The fact that the NHS recommended an 'alternative' trial was a source of hope for these families who were calling for an observational trial at the time. Such an observational study would allow patients to secure funded access to the type of medicine and for clinicians to monitor and record the benefits.

[6] https://www.thetimes.co.uk/article/cannabis-rules-deny-sick-children-safe-medicines-c2zwtzlxb
[7] https://www.england.nhs.uk/publication/barriers-to-accessing-cannabis-based-products-for-medicinal-use-on-nhs-prescription/

20. However, in June of 2020, patients were told that this 'observational' trial had morphed into a Randomised Control Trial (RCT) and was to be some years away. This was a devastating blow for patients and their families for a number of reasons. Whilst we accept RCTs as the 'gold standard' for single compound pharmaceutical products, the APPG has continuously challenged their applicability to medical cannabis. Whole plant extract medical cannabis has over 100 active ingredients and it is the entourage effect of these constituent parts that is believed to have the beneficial effect. Additionally, feedback shows that in the cases of childhood epilepsy, a degree of adjustment is required to the balance of CBD and THC to suit the particular metabolism of individual children. And most importantly, to conduct an RCT would mean that some of this cohort would have to be taken off a medicine that is working for them and be put on a placebo. This would be both unethical and potentially life threatening, which is why patients and their families have made it clear they will not take part in any RCTs. In a letter to the Health Secretary Rt Hon Sajid Javid MP in January 2022, APPG Co-Chair Tonia Antoniazzi MP highlighted the MHRA guidance, released on 16 December 2021,[8] which states the importance of collecting real world data and accepting that, in certain conditions, observational studies can act as a "viable alternative to data collection." This new guidance supports the APPG's calls for the need for the Government to fund an observational study on medical cannabis and provides further evidence that the conventional pharmalogical approach is not applicable to whole plant extract. It is the Group's firm view that observational trials are the safest and most effective means to better understand the benefits of medical cannabis.

21. In summary, it is the APPG's view that while the 2019 process review offered much hope to patients it has delivered little to no benefit. It is deeply concerning that the recommended observational trial, which was initially supported by both Government and the NHS, has since been taken off the table and that the Government, in all of their parliamentary responses, continue to state that the NHS and NIHR are continuing their focus solely on a set of randomised control trials.

International Comparisons

22. Cannabis has also been restricted in many countries across the globe, although in recent years the medical prescription / use of cannabis has been made legal in a number of countries, including 21 European countries. Beyond Europe, the medical use of the drug is permitted in the US, New Zealand and Australia, as well as Jamaica, Barbados, Bermuda, Canada, Chile, Colombia, Ecuador, Israel, Lebanon, Malawi and Mexico, Morocco, Peru, Rwanda, St Vincent, South Africa, Sri Lanka, Thailand, Uruguay, Vanuatu, Zambia and Zimbabwe.[9]

23. Significant amounts of research into the benefits of medical cannabis have been produced in the US, Canada and Israel in particular. For example, Canada legalised medicinal cannabis in July 2001 and medical cannabis is currently used by thousands of chronic pain and cancer patients. Patients have reported that this has improved their pain symptoms by more than 30%.[10] The Canadian market has been predicted to be worth up to £56 billion by 2026.[11]

24. Closer to home, in July 2021 the Irish Ministry of Health also announced a new 'Medical Cannabis Access Programme' (MCAP). Under this programme, patients obtaining medical cannabis under Ministerial approval will now have their products directly reimbursed by the Government.

---

[8] https://www.gov.uk/government/publications/mhra-guidance-on-the-use-of-real-world-data-in-clinical-studies-to-support-regulatory-decisions

[9] https://www.theweek.co.uk/cannabis/90671/california-legalises-cannabis-is-europe-next

[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5053383/#b48-jpr-9-735

[11] https://www.medgadget.com/2019/12/medical-cannabis-market-size-worth-97-35-billion-by-2026-legal-marijuana-industry-share-trends-demand-in-canada-row-fortune-business-insights.html

25. Furthermore, Greece has looked at medical cannabis for economic opportunities, seeing the potential financial benefits of legalising marijuana as a partial solution to its economic crisis. In 2017, then prime minister Alexis Tsipras said he was bringing forward legislation allowing the drug's use for medical purposes. His successor, Kyriakos Mitsotakis, swiftly granted new licences for growing medical marijuana. The Government hope the export business will bring "around €360 million of investment and create up to 2,250 jobs", reported consultancy firm Prohibition Partners.[12]

26. Current UK policy is effectively strangling the development of a healthy domestic medical cannabis sector, particularly when compared to other countries such as the examples listed above. The APPG has met with a number of businesses who are trying to apply for a Home Office licence to grow and produce their own products and have been met with a number of issues, including significant delays and a lack of clarity regarding the complex application progress. The APPG recently met with one Welsh based business who despite their plan to create 119 local jobs in the first phase of development, have struggled with the application process and to secure a growing facility site. Meanwhile, the UK remains the largest producer of legal cannabis, producing 95 tons of marijuana in 2016 for medicinal and scientific use – 44.9 per cent of the world's total.[13]

Conclusions

27. Today, medical cannabis policy and research is developing rapidly in line with shifting public attitudes. Yet, in the UK actual patient access lags vastly behind other countries and requires urgent intervention from Government. We have now reached a point where there is an almost total blockage on access to NHS prescriptions and the vast majority of patients can no longer afford to pay privately despite the dramatic impact medical cannabis has had on improving patient's quality of life across a range of conditions. Such is the severity of the situation for the cohort of children suffering from rare forms of epilepsy in particular, that their families have informed the APPG that they believe this crisis will result in some of their loved ones ending up back in intensive care with a much lower quality of life or worse. These families do not have the luxury of time to wait another three years for access to the drug that is keeping their children well.

28. While the 2018 law change was much welcomed, the implementation of this much needed and potentially life enhancing policy is at risk of being perceived as a total failure. The existing implementation needs fundamental reform. We outline some of the APPG's calls and ideas as possible ways forward, in the hope that the Committee might feel able investigate some of these points:

1. The APPG believes a cross-departmental approach is essential to effectively tackling this policy deadlock. It is imperative that given the Home Office's landmark role in legalising medical cannabis, a decision which was taken by the now Health Secretary, that the Department works with the Department for Health and Social Care to ensure clearer regulation and guidance.

2. In view of the fact there seems to be a degree of institutionalised resistance within the medical profession, the APPG is calling for the creation of a 'compassionate access fund', similar to that in Ireland, to help patients continue to afford their medical cannabis private

[12] https://prohibitionpartners.com/2019/08/09/greece-green-lights-26-medicinal-cannabis-licences/
[13] https://inews.co.uk/news/long-reads/inside-britain-biggest-legal-cannabis-farm-explained-medicinal-marijuana-769414

prescriptions, until a long-term funding solution is established. While this is something that we have been urging the Health Secretary to consider, we hope this is a recommendation that the Home Affairs Committee might feel able to endorse.

3. The APPG continues to call for the Department for Health to re-establish or fund some kind of observational trial alongside their work on RCTs. It would be of great benefit if this was also something that the Committee might feel able to support. The APPG believes an observational trial which focused on the real-life medical benefits of medical cannabis, would be another way to shift the dialogue and attitude towards CBMPs.

4. The Government must work to continue to improve and refine its process to ensure that British medical cannabis businesses can apply for licences to grow and produce medical cannabis in the UK, as the delays and difficulties many have faced continues to prevent the development of a flourishing UK medical cannabis sector.

March 2022