Impact Assessment, The Home Office

Title: Scheduling of a cannabis-based product for medicinal use, Epidyolex, under the Misuse of Drugs Regulations 2001 **IA No:** HO0368 **RPC Reference No:** N/A **Other departments or agencies:** Department of Health and Social Care (DHSC)	**Date:** May 2020 **Stage:** FINAL **Intervention:** Domestic **Measure:** Secondary legislation **Enquiries:** Emma Nichols (emma.nichols5@homeoffice.gov.uk)
RPC Opinion: Not Applicable	**Business Impact Target:** Non qualifying provision

Cost of Preferred (or more likely) Option (in 2019 prices)

Net Present Social Value NPSV (£m)	3.5	Business Net Present Value BNPV (£m)	0.2	Net cost to business per year EANDCB (£m)	-0.02

What is the problem under consideration? Why is government intervention necessary?

Epidyolex falls under Schedule 2 of the Misuse of Drugs Regulations 2001 ('2001 Regulations'). The Home Office is required, under the Misuse of Drugs Act 1971 to ensure that drugs are under the appropriate level of control. Following the marketing authorisation of Epidyolex, the Advisory Council on the Misuse of Drugs has recommended placing Epidyolex into Schedule 5 of the 2001 Regulations based on the low risk of misuse and diversion of the controlled drug content. Schedule 5 will place fewer restrictions on use of Epidyolex for legitimate purposes. Government legislation is required to amend the scheduling of Epidyolex.

What are the policy objectives and the intended effects?

Ensure that a drug with a marketing authorisation is subject to the appropriate level of control. Moving Epidyolex to Schedule 5 will reduce restrictions around import / export removing administrative burdens for companies wanting to supply Epidyolex to patients with severe epilepsy. The length of time a prescription is valid for will also be extended and Epidyolex will no longer be subject to the DHSC recommendation of a maximum 30-days supply. These factors may reduce the number of healthcare appointments needed, saving time and reducing costs.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: No change. Home Office licences are required for import / export of Epidyolex. Epidyolex remains under an 'inappropriate' schedule based on the ACMD's consideration.

Option 2 (**the Government's preferred option**): Scheduling of Epidyolex in Schedule 5 to the 2001 Regulations. This option brings Epidyolex into the appropriate schedule based on the ACMD assessment of the risks associated with the controlled drug content, which will allow longer prescription periods and reduced administrative burdens on the NHS.

Main assumptions/sensitivities and economic/analytical risks	**Discount rate (%)**	3.5

1. One treatment plan for all Epidyolex patients is assumed. It is likely patients have different treatment plans due to their complex healthcare needs, outlined in Annex A. There is an analytical risk in this assumption as the true costs and benefits of this policy may differ.

2. There is a risk of over-estimating the total reduction in appointments between patients and consultants after rescheduling, based on assumptions surrounding frequency and type of appointments and amount of Epidyolex dispensed by pharmacies. There is an analytical risk in this assumption of overestimating the costs and benefits of this policy.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** Month/Year

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Kit Malthouse Date: 1st June 2020

Summary: Analysis & Evidence

Policy Option 1

Description: Scheduling of a cannabis-based product for medicinal use, Epidyolex, the Misuse of Drugs Regulations 2001

FULL ECONOMIC ASSESSMENT

Year(s):	Price Base	2020	PV Base	2020	Appraisal	10	Transition	1

Estimate of Net Present Social Value NPSV (£m)						Estimate of BNPV (£m)	
Low:	2.7	**High:**	4.4	**Best:**	3.5	**Best BNPV**	**0.2**

COSTS, £m	Transition Constant Price	Ongoing Present Value	Total Present Value	Average/year Constant Price	To Business Present Value
Low	0.0	0.2	0.2	0.02	0.0
High	0.0	0.2	0.2	0.02	0.0
Best Estimate	0.0	0.2	0.2	0.02	0.0

Description and scale of key monetised costs by 'main affected groups'

1. Licensing authorities may lose a total of £0.2 million (PV = £0.2 million) in revenues across a 10-year period due to the rescheduling, as a licence is no longer needed to export Epidyolex.

2. Specialist consultants will need to familiarise themselves with this changes, however this cost is extremely small.

Other key non-monetised costs by 'main affected groups'

There are no non-monetised costs of this legislation.

BENEFITS, £m	Transition Constant Price	Ongoing Present Value	Total Present Value	Average/year Constant Price	To Business Present Value
Low	0.0	2.9	2.9	0.4	0.2
High	0.0	4.6	4.6	0.6	0.2
Best Estimate	0.0	3.7	3.7	0.5	0.2

Description and scale of key monetised benefits by 'main affected groups'

1. The number of appointments with specialist consultants to receive Epidyolex is expected to reduce, which is estimated to create a total benefit of £3.3 million (PV) across a 10-year period.

2. Businesses no longer have to submit applications to export Epidyolex, creating a total benefit to businesses and licensing authorities of £0.4 million (PV) across a 10-year period.

Other key non-monetised benefits by 'main affected groups'

1. The reduction in the costs associated with the reduction in requirements on handling and storage of Epidyolex due to rescheduling have not been monetised.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:					
Cost, £m	0.0	**Benefit, £m**	0.02	**Net, £m**	-0.02
Score for Business Impact Target (qualifying provisions only) £m:					N/A
Does implementation go beyond minimum EU requirements?					Yes
Is this measure likely to impact on trade and investment?					No

Are any of these organisations in scope?	Micro	N	Small	Y	Medium	Y	Large	Y

What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)	Traded:	N/A	Non-Traded:	N/A

PEOPLE AND SPECIFIC IMPACTS ASSESSMENT (Option 2)

Are all relevant Specific Impacts included?	Y	Are there any impacts on particular groups?	N

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

1. Epidyolex is a cannabis-based product for medicinal use (CBPM) manufactured by the pharmaceutical company GW Pharmaceutical and is licensed as an adjunctive treatment of two rare forms of epilepsy known as Dravets Syndrome and Lennox-Gastaut Syndrome ('LGS'). Epidyolex oral solution mostly consists of the active ingredient; cannabidiol 'CBD' (a non-controlled cannabinoid), with a small amount of tetrahydrocannabinol ('THC', a controlled cannabinoid under Class B of the 1971 Act) per container; the THC content will be no more than 0.1 milligram per millilitre.

2. Prior to receiving a marketing authorisation on 19 September 2019, Epidyolex was considered an 'unlicensed' or 'special' CBPM. This meant that only specialist clinicians on the General Medical Council's specialist register, or doctors acting under their direction, were able to prescribe this medicine. Additionally, this product could only be obtained via GW Pharmaceutical's early access programmes delivered through NHS epilepsy specialist centres, usually specialist children's hospitals.

3. On 19 September 2019, Epidyolex received marketing authorisation from the European Commission which now means that Epidyolex is a 'licensed' Schedule 2 CBPM in the UK and EU. Following this, in December 2019, Epidyolex received a recommendation from the National Institute for Health and Care Excellence (NICE) for use, in combination with clobazam, as an option for treating seizures associated with Dravet syndrome and LGS in people aged two years and older, which means that this product may be prescribed on the NHS and has been funded since January 2020.

4. As Epidyolex received marketing authorisation on 19 September 2019 and is considered a licensed medicine distinct from other unlicensed CBPMs, the ACMD have considered whether the controls on Epidyolex, under Schedule 2 of the 2001 Regulations are appropriate.

5. The ACMD have recommended that Epidyolex be moved from Schedule 2 and be placed in Schedule 5 of the 2001 Regulations. A move from Schedule 2 to Schedule 5 will result in fewer controls surrounding its import, export, prescribing, storage and distribution.

A.2 Groups Affected

6. Moving Epidyolex into Schedule 5 will allow greater quantities of Epidyolex to be supplied under one prescription and will allow more flexible prescribing models, such as repeat prescriptions, to be issued if clinically appropriate. Both of these will have the advantage of reducing the need for frequent patient appointments saving time (and costs) for healthcare professionals. Reduced appointments will also benefit patients. Additionally, for businesses and the Home Office Drugs and Firearms Licensing Unit, it will reduce the need for administration around import and export licences, enhancing capacity within the Licensing Team.

7. Scheduling a CBPM which has received marketing authorisation under the 2001 Regulations distinguishes it from those unlicensed CBPM products, whose quality, safety and efficacy cannot be guaranteed. This is predicted to increase prescribing of Epidyolex by healthcare professionals and so GW Pharmaceutical may require increased manufacturing of Epidyolex products.

A.3 Consultation

Within Government

8. The ACMD have recommended that Epidyolex be moved from Schedule 2 and be placed in Schedule 5 of the 2001 Regulations. DHSC have agreed with this recommendation. The Medicines and Healthcare products Regulatory Agency (MHRA)and NHS England have also been consulted on this decision and the devolved administrations have been made aware of the recommendation and proposed amendment.

Public Consultation

9. GW Pharmaceutical, the manufacturer of Epidyolex were in discussion with government and the ACMD on the definition of Epidyolex to ensure it accurately reflected product characteristics.

10. The Government have engaged with the relevant clinical and regulatory bodies on the proposed Scheduling decision for Epidyolex. Those contacted include; the Care Quality Commission, British Paediatric Neurology Association, Association of British Neurologists, Royal College of General Practitioners, British Medical Association, Royal Pharmaceutical Society, and the Pharmaceutical Services Negotiating Committee.

11. The views from the Royal Pharmaceutical Society, Care Quality Commission, Pharmaceutical Services Negotiating Committee, Association of British Neurologists and British Medical Association were supportive. Those bodies agree that the proposed amendment will be beneficial to patients and will provide more flexibility in prescribing and dispensing of Epidyolex.

B. Rationale for intervention.

12. The 2001 Regulations provide access to controlled drugs for legitimate medicinal or exceptionally for industrial purposes. Drugs which are controlled under the Misuse of Drugs Act 1971 ('the 1971 Act') are listed in one of five Schedules to the 2001 Regulations, based on an assessment of their medicinal or therapeutic usefulness, the need for legitimate access and their potential harms when misused. The Schedule into which a drug is placed primarily dictates the extent to which it is lawful to import, export, produce, possess, supply and administer. It imposes requirements around prescribing, record keeping, labelling, destruction, disposal and safe custody. Schedule 1 controlled drugs are subject to the greatest restrictions and Schedule 5 to the lowest.

13. As of 1 November 2018, cannabis-based product for medicinal use (CBPMs) were placed in Schedule 2 to the 2001 Regulations and removed from Part 1 of the Misuse of Drugs Designation Order 2015 ('the 2015 Order') meaning that CBPMs may be prescribed for medicinal use in the UK. Epidyolex satisfies the definition of a CBPM in the 2001 Regulations and is affected by restrictions imposed by Schedule 2 such as licensing requirements for import / export, Safe Custody 1973 requirements (for storage in specific containers) and prescription requirements. As with other CBPMs, Epidyolex is also classified as a Class B drug under the 1971 Act.

14. Prior to receiving a marketing authorisation on 19 September 2019, Epidyolex was considered an 'unlicensed' or 'special' CBPM. This meant that only specialist clinicians on the General Medical Council's specialist register, or doctors acting under their direction, were able to prescribe this medicine. Additionally, this product could only be obtained via GW Pharmaceutical's early access programmes delivered through NHS epilepsy specialist centres.

15. On 19 September 2019, Epidyolex received marketing authorisation from the European Commission which now means that Epidyolex is a 'licensed' Schedule 2 CBPM in the UK. Following this, in December 2019, Epidyolex received a recommendation from the National Institute for Health and Care Excellence (NICE) for use, in combination with clobazam, as an

option for treating seizures associated with Lennox–Gastaut syndrome and Dravet sydrome in people aged two years and older, which means that this product may now be prescribed on the NHS.

16. The Home Office are required, under the 1971 Act to ensure that drugs are under the appropriate level of control. As Epidyolex has now received marketing authorisation and is considered a licensed medicine distinct from other unlicensed CBPMs, the ACMD have considered whether the controls on Epidyolex, under Schedule 2 of the 2001 Regulations are appropriate.

17. As stated by the ACMD, the risk of illicit possession or diversion is low. Most importantly, the THC content in Epidyolex is low and much lower than a similar cannabis-based medicine 'Sativex' which is in Schedule 4 Part 1 under the 2001 Regulations. A container of Epidyolex will contain no more than 0.1 milligram per millilitre of THC and therefore will not be an attractive product for illicit supply.

18. Based on this assessment, the ACMD have recommended that Epidyolex be moved from Schedule 2 and be placed in Schedule 5 of the 2001 Regulations and DHSC has signalled its assent to this recommendation.

C. Policy objective

19. A move of a drug from Schedule 2 to Schedule 5 of the 2001 Regulations will result in fewer controls surrounding its import, export, storage, distribution and prescription requirements. The Misuse of Drugs (Safe Custody) Regulations 1973 ('the 1973 Regulations') provide for the safe custody of controlled drugs, specifically those drugs placed under Schedule 2 of the 2001 Regulations and some Schedule 3 substances. These substances must generally to be kept either in a locked safe, cabinet or room or in a locked receptacle. As a Schedule 5 medicine under the 2001 Regulations, Epidyolex will no longer be subject to the strictest "Safe Custody" requirements, which will save time for healthcare professionals in relation to both record keeping requirements under the 2001 Regulations, and need for compliance with the 1973 Regulations.

20. Prescribing and supply of Epidyolex will face fewer restrictions due to the move from Schedule 2 to Schedule 5.

21. Prescriptions are valid for, and must be dispensed within 6 months for Schedule 5 drugs, as opposed to 28 days under Schedule 2. Patients will have more flexibility on when to submit their prescriptions.

22. General Practitioners (GPs) may also employ more flexible prescribing models such as repeatable prescription where it is safe to do so if acting under the direction of a consultant in line with a shared care arrangement. Pharmacists can then supply patients at intervals set by the prescriber under this arrangement, which reduces the need for repeat appointments between a patient and prescriber, saving time and costs for GP practices and consultants. This also saves time for patients required to attend appointments, and patients would have to attend a community pharmacy of their choosing to collect their prescription items.

23. Additionally, DHSC has issued strong recommendations that the maximum quantity of Schedule 2, 3 or 4 controlled drugs prescribed should not exceed 30 day's supply. This is not a legal restriction but prescribers should be able to justify the quantity requested (on a clinical basis) if more than 30 days' supply is prescribed. This recommendation does not apply to Schedule 5 controlled drugs, giving freedom to supply the patient with greater quantity of medicinal product, again, reducing the need for healthcare appointments.

24. Schedule 5 drugs are not subject to licensing requirements for import and export. The Home Office Drugs and Firearms Licensing Unit has received almost 1,500 import or export requests for Epidyolex as a Schedule 2 drug since it received marketing authorisation. Each request is urgent as it represents a patient need to treat a serious condition. This has placed heavy pressures on the Licensing Team within the Home Office which is not justifiable if the risk of diversion or misuse is not proportionate with its current scheduling as a Schedule 2 controlled drug. Removing restrictions around import and export by placing Epidyolex in Schedule 5, will help meet patient needs through an accessible supply route without the requirement for companies to apply for Home Office licences. Additionally, individual patients will not require import licences when travelling to or from the UK with Epidyolex reducing administrative burdens for these patients.

D. Options considered and implementation.

The options considered in this Impact Assessment are:

25. **Option 1:** Do nothing

26. **Option 2:** Reschedule "Epidyolex" from a Schedule 2 CBPM to a Schedule 5 drug, defined by an individual definition under the 2001 Regulations. This option brings Epidyolex into the appropriate schedule based on the ACMD assessment of the risk of misuse and diversion of the controlled drug content.

Preferred option and implementation plan

The preferred option will be achieved through secondary legislation.

- By giving Epidyolex its own definition under Schedule 5 of the 2001 Regulations, it will no longer be caught under the generic definition of a CBPM under Schedule 2, meaning that all regulatory requirements surrounding Schedule 2 controlled drugs will no longer apply. This will remove restrictions around the the distribution, supply, prescribing and storage of Epidyolex, currently imposed on this substance as a Schedule 2 CBPM. This will benefit businesses, healthcare professioanls and patients who all require access to Epidyolex.
- The policy will be implemented from the date that the legislative amendment comes into force. The intended laying date is 3 June 2020. As such, the effects of this legislation will come into force 21 days later, on the 24 June 2020.
- Businesses and healthcare professionals who handle Epidyolex will be responsible for the operational response for handling drug under the requirements of Schedule 5 of the 2001 Regulations. For England, NHS Business Services Authority (NHSBSA) will record the number of items which have been prescribed, dispensed in the community and submitted to the NHSBSA for reimbursement in England. This is part of their standard monitoring of prescriptions. Enforcement of the proposed legislation will be undertaken by the Police Service, Health Regulatory Bodies, Accountable Officers and other relevant agencies within the health sector.
- Although the approach for implementing this policy does not enable experimentation/trialling of the Scheduling decision, the Government is required to ensure drugs remain under the appropriate level of control. Should evidence airse which suggests inappropriate control of a drug, the ACMD can assess/re-assess Scheduling decisions and recommend any changes where appropriate. To ensure Epidyolex was placed under the appropriate level of control, the Scheduling decision was based on a scientific assessment taking into consideration the controlled drug content of Epidyolex against the risk of misuse and diversion by independent experts (the ACMD).

E. Appraisal.

General assumptions and data

27. All costs and benefits have been calculated against Option 1 (the do-nothing option).

28. A discount rate of 3.5 per cent has been used in this analysis.

Healthcare professionals

29. Healthcare professionals involved in the care of patients with rare forms of epilepsy are likely to be consultants with high levels of experience. As such, it is assumed healthcare professionals prescribing Epidyolex are consultants on the highest pay band. Therefore, it is estimated that the average annual salary of a prescriber of Epidyolex is £107,668[1], equating to an hourly salary of £55.21 assuming a 37.5-hour[2] working week.

30. After uplifting for staff on-costs[3], the gross hourly labour cost of a specialist consultant prescribing Epidyolex is estimated at £64.66.

31. There are an estimated 776 consultants in directly affected specialities needed to familiarise themselves with guidance this guidance.

32. NHS Improvement will be issuing online guidance about these changes to consultants in directly affected specialities. It is assumed this online guidance will contain 2,000 words. It is also assumed consultants have an excellent reading ability, with a best estimated reading speed of 850 words per minute (wpm), with high and low reading speeds of 700 and 1,000 wpm respectively[4]. The high and low reading speeds represent an individual with an excellent reading ability reading from an email and paper respectively, with the best estimate set at the midpoint.

Patient appointments

33. Epidyolex prescriptions are typically given to patients during appointments with specialist consultants. As data is not available on how long it takes to assess a patient and write a prescription for epidyolex, it is assumed to take as long as a standard appointment with a General Practitioner (GP). NHS England report a GP appointment lasts 12 minutes on average[5]. It is assumed that attending an appointment to prescribe Epidyolex takes 45 minutes for the average patient, after accounting for travel time.

34. In a recent survey of patients, 35 per cent of patients reported they were not satisfied with their GP's appointment times[6]. Assuming patients were unsatisfied with appointment times because they were during working hours, it is assumed that 35 per cent of GP appointments take place during working hours. It is assumed that this proportion also holds for appointments to prescribe Epidyolex.

Number of Epidyolex patients

35. Data on the current number of patients receiving Epidyolex was provided by DHSC[7]. This data indicates that there are 209 patients currently receiving Epidyolex in England. Projections of the number of patients to receive Epidyolex from 2020/21 to 2024/25 come from a recent report by the National Institute for Health and Care Excellence (NICE)[8]. These estimates are split by patients from the prevalent population and the newly diagnosed population under the current system. These two datasets are combined in this analysis.

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[1] BMA. *Consultant Band 8:* https://www.bma.org.uk/pay-and-contracts/pay/consultants-pay-scales/pay-scales-for-consultants-in-england

[2] NHS. *Terms of Contract:* https://www.nhsemployers.org/pay-pensions-and-reward/medical-staff/salaried-gps

[3] Eurostat. *Hourly Labour Costs (staff on-costs estimated at 17.1%. https://ec.europa.eu/eurostat/statistics-explained/index.php/Hourly_labour_costs*

[4] http://www.readingsoft.com/

[5] BBC News Article. https://www.bbc.co.uk/news/health-24959626

[6] The GP Patient Survey. CCG Results Weighted. 'YOUR LOCAL GP' tab. http://www.gp-patient.co.uk/surveysandreports

[7] DHSC. Provided by private correspondence

[8] Table 1. https://www.nice.org.uk/guidance/ta615/resources/resource-impact-report-pdf-7019305741

36. As data is not available on when patients began or finished their Epidyolex treatment inter-year, it is assumed for both the prevalent and newly diagnosed population; 'people in first year of treatment' received treatment for 6 months of the year; 'people continuing treatment from the previous year' received treatment for 12 months of the year; 'people not adhering to treatment' did not receive treatment at all; and 'people discontinuing treatment in year' received treatment for 6 months of the year'.

37. Data is not available on the estimated number of Epidyolex patients beyond 2024/25. It is therefore assumed that the growth rate in patient numbers from year 4 to year 5 (1.3 per cent) will continue year-on-year through to year 10. This could be an overestimate since the growth in patient numbers over the first five years reflects early take-up within the NHS and could level off after that.

38. A funding decision has not yet been made in Scotland at the time of writing. It has been assumed funding in Scotland will be finalised by the date of implementation.

39. As data is not available on future patient numbers in Scotland or Wales, it is assumed Epidyolex patient rates in Scotland and Wales are the same as England. Patient numbers in England are therefore scaled up to represent all Epidyolex patients in England, Wales and Scotland (factor of 1.15) using ONS mid-year population estimates[9].

40. Total patient numbers can be seen in Annex Table A.1.

Epidyolex prescriptions

41. No data is available on the number of Epidyolex prescriptions each patient receives per year. It has therefore been assumed that under the current system Epidyolex patients receive one prescription per month in treatment. It is also assumed that an appointment with a consultant is required to receive an Epidyolex prescription.

42. As no data is available on the level of supply of Epidyolex a patient receives when collecting their prescription, it is assumed the supply of Epidyolex dispensed by a pharmacy is equal to the time length of the prescription. Therefore, a three month supply will be dispensed at one time, for a three month prescription[10].

43. Therefore, it is estimated that under the current system there would be a best estimate of 8,000 Epidyolex prescriptions in year 1, rising to 30,500 in year 10 (Annex Table A.2).

44. This change will reduce the need for patients to visit their consultant to receive prescriptions for Epidyolex. However, as patients prescribed with Epidyolex have complex healthcare needs, they will still require some appointments with their consultant regardless of the scheduling of Epidyolex. No data is available on how appointments will change as a result of this policy.

45. It is therefore assumed that as a result of this change, patient visits to their consultants to receive an Epidyolex prescription will reduce from once every month to a best estimate of once every three months, with high and low estimates of once every two and six months respectively.

46. This change is therefore assumed to lead to a reduction of a best estimated 5,300 prescription appointments with consultants in year 1, rising to 20,400 in year 10. The estimated total reduction in the number of prescription appointments after this change can be seen in Annex Table A.3. The estimated total number of prescription appointments that will take place after this change can be seen in Annex Table A.4.

[9] ONS mid-year estimates https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates

[10] There is no direct financial costs or savings to patients from changes in numbers of prescriptions (due to changes in length of prescribing). This is because patients with epilepsy who need continuous anticonvulsive therapy are exempt from prescription charges on medical grounds.

Epidyolex Licence applications

47. Companies involved in the manufacture and sale of Epidyolex will need to maintain their existing Home Office licences for controlled drugs to continue their operations in the UK.

48. However, as a result of this legislation change, companies involved in the manufacture and sale of Epidyolex will no longer need to apply for licences to export Epidyolex outside of the UK.

49. Data on export licences were only available over the past five-month period. From November 2019 to March 2020 the Home Office received 183 licence applications for the export of Epidyolex. Scaling this up to an annual basis, it is estimated the Home Office will receive 439 export licence applications in year 1 for Epidyolex[11].

50. No data is available on the estimated number of exports of Epidyolex prescriptions from year 1 onwards. It is therefore assumed the number of exports will change in line with the growth rate in Epidyolex patient numbers in England, Wales and Scotland.

51. It is therefore estimated that by year 10 there will be 1,088 exports of Epidyolex prescriptions (Annex Table A.5).

52. The application fee for a licence to export Epidyolex is £24[12]. It is assumed the licence fee is set so as to recover the cost to licensing authorities of processing an application.

Patients/carers

53. The value of non-working time is estimated at £8.10 an hour, which is the mid-point between the value of non-working time for commuting and other[13].

54. The average value of working time is estimated at £21.52[14] an hour. After accounting for staff on-costs[15], the gross value of working time is estimated at £25.20 an hour.

COSTS

Set-up costs

Cost 1 - Familiarisation Costs

NHS

55. It is assumed consultants in directly affected specialities will receive online guidance containing 2,000 words informing them of the legislation changes. With the online guidance containing 2,000 words and assuming consultants read at a best estimated rate of 850 wpm, with high and low estimates of 700 and 1,000 wpm respectively, it will take consultants a best estimated 2 minutes 21 seconds, with high and low estimates of 2 minutes and 51 seconds and 2 minutes, to familiarise themselves with the changes.

56. Using the gross hourly labour cost of £64.66, it is estimated the best estimted cost per specialist consultant of familiarising themselves with these changes is £2.54, with high and low estimates of £3.08 and £2.16 respectively.

57. There is assumed to be 776 consultants in specialities directly affected by these changes. Therefore, the best estimated total familiarisation costs to the NHS of this policy are £2,000, with high and low estimates of £2,400 and £1,700 respectively.

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[11] (183 / 5) * 12

[12] https://www.gov.uk/guidance/controlled-drugs-licence-fees

[13] Values of time (DfT) *TAG Data Book – Table A 1.3.2 Forecast values of time per person*: https://www.gov.uk/government/publications/tag-data-book

[14] Values of time (DfT) *TAG Data Book – Table A 1.3.2 Forecast values of time per person*: *https://www.gov.uk/government/publications/tag-data-book*

[15] Eurostat. *Hourly Labour Costs (staff on-costs estimated at 17.1%. https://ec.europa.eu/eurostat/statistics-explained/index.php/Hourly_labour_costs*

Businesses

58. GW Pharmaceutical and other companies involved in the manufacture and sale of Epidyolex will need to familiarise themselves with these changes. However, as they have already been made aware of these changes the familiarisation costs will likely be negligible and have not been monetised.

Table 1 - Total set up costs

Stakeholder		Set-up costs
NHS	Best	£2,000
	High	£2,400
	Low	£1,700
Businesses	Best	-
	High	-
	Low	-

Note figures are rounded

Ongoing costs

Licensing authorities

Cost 2 – Loss in revenues to licensing authorities

59. As a result of this change, companies involved in the manufacture and sale of Epidyolex will no longer need a licence to export Epidyolex outside of the UK. This will result in a reduction in the revenues licensing authorities receive from Epidyolex export applications.

60. In year 1 there will be an estimated 439 licence applications to export Epidyolex. Assuming the number of exports of Epidyolex change in line with patient numbers in England, Wales and Scotland, by year 10 there will be a total of 1,088 Epidyolex exports. The annual estimated number of Epidyolex exports can be seen in Annex Table A.5.

61. It is assumed the cost of an export licence application (£24) is set so as to recover the cost to licensing authorities of processing an application.

62. In year 1 there will be an estimated cost of £10,500, rising to £26,100 in year 10. The estimated annual cost to licensing authorities can be seen in Table 2.

Table 2, Estimated cost to licensing authorities of foregone Epidyolex export applications (£m)

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Total Cost[16]	0.01	0.02	0.02	0.02	0.02	0.02	0.03	0.03	0.03	0.03

63. This is equivalent to an estimated total cost to licensing authorities across a 10-year period of £0.2 million (PV = £0.2 million)

[16] The same figures have been used for best, high and low calculations

Total Costs

Table 3 – Total costs

Stakeholder	Costs	PV Costs
NHS	-	-
Patients/carers	-	-
Businesses	-	-
Licensing authorities	0.2	0.2
Total costs	0.2	0.2

64. The estimated total cost of this policy is £0.2 million (PV = £0.2 million).

BENEFITS

Set-up benefits

65. There are no set up benefits of this policy.

Ongoing benefits

NHS

Benefit 1 - Saved time issuing prescriptions

66. Currently patients are likely to receive a 30 day supply of Epidyolex due to the DHSC recommendation regarding the supply of Schedule 2, 3 and 4 controlled drugs[17]. Rescheduling Epidyolex from a schedule 2 to a schedule 5 drug under the Misuse of Drugs Regulation 2001 will allow patients to receive greater supplies if clinically appropriate. Therefore, there are potential savings to healthcare professionals from the foregone time spent having appointments with patients to issue monthly prescriptions.

67. It is reasonable to assume that as a result of this policy, the number of appointments to receive Epidyolex prescriptions may reduce from once every month to a best estimate of once every three months, with high and low estimates of once every two and six months respectively.

68. Assuming an appointment with a specialist consultant to issue an Epidyolex prescription takes 12 minutes, and with the gross hourly labour of a specialist consultant being £64.66, the benefit to the NHS of reducing one appointment to issue an Epidyolex prescription is £12.93[18].

69. Scaling this up to the total number of foregone appointments with specialist consultants to prescribe Epidyolex each year in England, Wales and Scotland (Annex Table A.3), would give a best estimated total annual saving in year 1 of £0.07 million, rising to £0.26 million in year 10. These annual savings can be seen in Table 4.

Table 4 – Estimated saving to the NHS of foregone appointments (£m)

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Best	0.07	0.15	0.21	0.23	0.25	0.25	0.25	0.26	0.26	0.26
Low	0.05	0.11	0.15	0.17	0.18	0.19	0.19	0.19	0.19	0.20
High	0.09	0.19	0.26	0.29	0.31	0.31	0.32	0.32	0.32	0.33

70. This is equivalent to a best estimated saving across a 10-year period of £2.2 million (PV = £1.8 million), with high and low estimates of £2.7 million (PV = £2.3 million) and £1.6 million (PV = £1.4 million) respectively.

[17] https://bnf.nice.org.uk/guidance/controlled-drugs-and-drug-dependence.html

[18] (£64.66 / 60) * 12 = £12.93

Benefit 2 – Reduced costs associated with storage and handling Epidyolex

71. Rescheduling Epidyolex from a schedule 2 to a schedule 5 drug under the Misuse of Drugs Regulation 2001 will reduce the requirements on the handling and storage of Epidyolex. This will likely mean reduced costs to healthcare providers associated with the storage and handling of Epidyolex.

72. However, as there is no data available on the reduction in storage costs, it has not been monetised.

Patients and carers

Benefit 3 –Time saved attending appointments to receive Epidyolex prescriptions

73. Currently patients are likely to receive a 30 day supply of Epidyolex due to the strong DHSC recommendation regarding the supply of Schedule 2, 3 and 4 controlled drugs[19]. Rescheduling Epidyolex from a schedule 2 to a schedule 5 drug under the Misuse of Drugs Regulation 2001 will allow patients to receive greater supplies if clinically appropriate. As a result of this change, patients will save time travelling to appointments with specialist consultants to receive their Epidyolex prescriptions.

74. Patients attending appointments may have a carer present. As such, there may be an additional time saving for carers, however there is no way of quantifying this, so it has not been monetised.

75. It is assumed it takes a patient 45 minutes to attend an appointment with a specialist consultant to receive an Epidyolex prescription. Therefore, it is estimated that the saving to patients for not attending one appointment is £18.90[20] and £6.07[21] during working and non-working hours respectively.

76. It is estimated that as a result of this legislation, in year 1 there will be a best estimate of 5,300 fewer appointments between Epidyolex patients and consultants, rising to 20,400 in year 10. The total number of saved appointments as a result of this legislation can be seen in Annex Table A.3.

77. It is assumed that 35 per cent of appointments between Epidyolex patients and consultants take place during working hours and 65 per cent during non-working hours. It is therefore estimated that in year 1, of the total 5,300 saved appointments, a best estimate of 1,900 would have taken place during working hours and 3,500 during non-working hours.

78. The best estimated saving in year 1 to patients of forgone prescription appointments is £0.1 million, rising to £0.2 million by year 10. These annual savings can be seen in Table 5.

Table 5 – Estimated saving to patients of foregone appointments (£m)

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Best	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Low	0.0	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2
High	0.1	0.2	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.3

79. This is equivalent to a best estimated total saving across a 10-year period of £1.8 million (PV = £1.5 million), with high and low estimates of £2.2 million (PV = £1.9 million) and £1.3 million (PV = £1.1 million) respectively.

Licensing authorities

Benefit 4 – Reduced time processing applications

80. As a result of this change, companies involved in the manufacture and sale of Epidyolex will no longer need a licence to export Epidyolex outside of the UK. This will result in a reduction in the number of applications licensing authorities must process.

[19] https://bnf.nice.org.uk/guidance/controlled-drugs-and-drug-dependence.html

[20] (£25.20 / 60) * 45

[21] (£8.10 / 60) * 45

81. In year 1 there will be an estimated 439 licence applications to export Epidyolex. Assuming the number of exports of Epidyolex change in line with patient numbers in England, Wales and Scotland, by year 10 there will be a total of 1,088 Epidyolex exports. The annual estimated number of Epidyolex exports can be seen in Annex Table A.5.

82. It is assumed the cost of an export licence application (£24) is set so as to recover the cost to licensing authorities of processing an application.

83. In year 1 there will be an estimated saving of £10,500, rising to £26,100 in year 10. The estimated annual saving to licensing authorities can be seen in Table 6.

Table 6 – Estimated saving to licensing authorities *and businesses (also benefit 5)* of forgone Epidyolex export applications (£m)

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Total Saving[22]	0.01	0.02	0.02	0.02	0.02	0.02	0.03	0.03	0.03	0.03

84. This is equivalent to an estimated total saving to licensing authorities across a 10-year period of £0.2 million (PV = £0.2 million)

Businesses

Benefit 5 – Reduced applications to export Epidyolex

85. As a result of this change, companies involved in the manufacture and sale of Epidyolex will no longer need a licence to export Epidyolex outside of the UK. This will result in a saving of the licence fee and the time spent completing the application forms. No information is available on the time it takes to complete a controlled drugs export licence application, so it has not been monetised.

86. In year 1 there will be an estimated 439 licence applications to export Epidyolex. Assuming the number of exports of Epidyolex change in line with patient numbers in England, Wales and Scotland, by year 10 there will be a total of 1,088 Epidyolex exports. The annual estimated number of Epidyolex exports can be seen in Annex Table A.5.

87. In year 1 there will be an estimated saving of £10,500, rising to £26,100 in Year 10. The estimated annual saving to businesses can be seen in Table 6.

88. This is equivalent to an estimated total saving to businesses across a 10-year period of £0.2 million (PV = £0.2)

Total Benefits

Table 7 - Total Benefits (£)

Stakeholder		Benefit	PV Benefit
Patients	Best	1.8	1.5
	Low	1.3	1.1
	High	2.2	1.9
NHS	Best	2.2	1.8
	Low	1.6	1.4
	High	2.7	2.3
Licensing Authorities		0.2	0.2
Businesses		0.2	0.2
Total Benefits	Best	4.4	3.7
	Low	3.4	2.9
	High	5.4	4.6

[22] The same figures have been used for best, high and low calculations

89. The best estimated total benefit of this policy is £4.4 million (PV = £3.7 million), with high and low estimates of £5.4 million (PV = £4.6 million) and £3.4 million (PV = £2.9 million) respectively.

NPSV, BNPV, EANDCB

Table 8 - Net Present Value (£m)

PV Benefits	Best	3.7
	Low	2.9
	High	4.6
PV Costs	Best	0.2
	Low	0.2
	High	0.2
NPV	Best	3.5
	Low	2.7
	High	4.4

90. The best estimate Net Present Social Value (NPSV) of this policy is £3.5 million, with high and low estimates of £2.7 million and £4.4 million respectively.

Table 9 - Business Net Present Value

BPV Benefits	Best	0.2
	Low	0.2
	High	0.2
BPV Costs	Best	0.0
	Low	0.0
	High	0.0
BNPV	Best	0.2
	Low	0.2
	High	0.2

91. The best estimated Business Net Present Value (BNPV) of this policy is £0.2 million and, is the same in the high and low scenarios.

Equivalent Annual Direct Costs to Businesses (£m)

92. In all scenarios, the equivalent annual direct cost to businesses is estimated to be -£0.02 million, because the benefit to business is £0.2 million (PV) over 10 years.

Impact on small and micro-businesses

Some individual pharmacies may see revenues decline due to the rescheduling of Epidyolex and consequent increase in lengths of precriptions reducing the frequency of disensing. This is because fees paid to pharmacies each year for dispensing prescriptions is based on the total number of prescription items they dispense, plus an additional fee for dispensing Schedule 2 drugs. Small and micro-businesses will not be excempt from this policy, however since Epidyolex prescriptions represent a tiny proportion of total prescriptions disensed by pharmacies, the loss in revenue to individual small and micro-businesses will be extremely small.

F. Proportionality.

93. Based on previous IAs on rescheduling controlled drugs under The Misuse of Drugs Regulation 2001, and the level of data available, the level of detail of the analysis in this impact assessment is sufficient.

G. Risks.

94. There is a risk in assuming one treatment plan for all Epidyolex patients, as it is likely patients have different treatment plans due to their complex healthcare needs (DHSC have outlined the possible pathways through treatment in Annex A). There is a risk this assumption may over-estimate the costs or benefits of this policy because the true costs and benefits are likely to be different.

95. It is assumed patients must have an appointment with a specialist consultant specifically to receive an Epidyolex prescription. It is also assumed, after rescheduling, patients reduce their appointments to receive prescriptions from once every month to a best estimate of once every three months, with high and low estimates of once every two and six months respectively. Due to the complex healthcare needs of patients, patients may still need to attend regular appointments with the specialist consultant regardless of whether they require Epidyolex prescription as their condition may need to be reviewed regularly especially in the early stages of prescribing Epidyolex. For some patients there may be no reduction in the number of appointments as a result of the schedule change. There is a risk these assumptions over-estimate the time saving of this schedule change to healthcare professionals and patients/carers.

96. It is assumed the supply of Epidyolex dispensed by a pharmacy is equal to the time length of the prescription. A three-month supply will be dispended at one time, for a three-month prescription. This assumption risks over-estimating the saved time to patients and healthcare consultants.

97. GP's will be involved if the patient is under a shared care arrangement treatment plan (Annex A), the costs and benefits of this have not been quantified as the likelihood of this is unknown. There is a risk the time saving to healthcare professionals of this policy could be under-estimated.

98. Using the GP standard appointment time of 12 minutes may be an under-estimate as consultant appointments likely to be longer, especially in the initial stages of prescribing Epidyolex.

99. There is a possible risk not quantifying the benefits of a reduction in patient visits to pharmacies. However, this risk is mitigated as patients prescribed Epidyolex have complex healthcare needs and would likely still be collecting other medicines on a regular basis.

H. Direct costs and benefits to business calculations

100. Business direct costs are zero and the direct benefit is estimated to be £0.2 million (PV) over 10 years, therefore **the EANDCB is estimated to be -£0.02 million**.

I. Wider impacts

101. There is likely to be no wider impacts of this policy.

J. Trade Impact.

102. As Epidyolex is exported from the UK internationally, removing the need for an export licence could increase international trade.

K. Monitoring and evaluation (PIR if necessary), enforcement principles.

103. The policy will be implemented from the date that the legislative amendment comes into force. For England, NHS Business Services Authority (NHSBSA) will record the number of items which have been prescribed, dispensed in the community and submitted to the NHSBSA for

reimbursement in England. This is part of their standard monitoring of prescriptions. Government can request this data where necessary to monitor the number of Epidyolex items prescribed, although it is not possible to obtain the number of prescriptions dispensed by hospital pharmacies in England. Devolved administrations also collect this data through their own systems.

104. Enforcement of the proposed legislation will be undertaken by the Police Service, Health Regulatory Bodies, Accountable Officers and other relevant agencies within the health sector although Epidyolex will not be associated with a possession offence under the 2001 Regulations due to the Schedule 5 classification.

L. Annexes.

a. Treatment plans for Epidyolex patients (provided by DHSC)

105. At the initial stages of any new patient to be prescribed Epidyolex, the prescription will likely be issued by a specialist consultant – this is a condition of the marketing authorisation. After the initial stages of treatment, the patient will either continue receiving prescriptions from a specialist consultant or the specialist consultant can set up a shared care plan with a GP under their direction.

106. If the specialist consultant is satisfied that the patient is stable, the consultant may pass on the prescribing to a GP to prescribe Epidyolex on an ongoing basis. This arrangement is known as a shared care plan. If the specialist consultant wishes to set up a shared care plan, the GP will only accept ongoing prescribing if they believe they have the ability to prescribe Epidyolex and monitor the patient on an ongoing basis. The specialist consultant may continue to see the patient on a regular basis even if there is a shared care agreement in place.

107. The majority of prescriptions issued under a shared care plan are dispensed from community based pharmacies.

108. Under a shared care plan the frequency of appointment will likely be different for each patient. The GP may issue a repeatable prescription for a set time period, which can be up to one year (for example, dispensing 1 months' supply for 12 months without the need for a further prescription), however the patient will still need to attend the community pharmacy to collect medicine in line with the prescriber's instructions. Whilst GPs can issue prescriptions for more than a month to be dispensed in one go, the length of a prescription does not necessarily correspond to the amount of supply the patient will receive on first collection.

109. The specialist consultant may instead wish to keep reviewing the patient themselves, in which case the specialist consultant that initiated treatment will continue prescribing Epidyolex to the patient.

110. Specialist consultants can issue prescriptions for up to 12 months where clinically appropriate, and like under a shared care plan, there is no limit on how much supply a patient receives when collecting their prescription from a pharmacy. The majority of prescriptions issued by consultants would be collected in a hospital based pharmacy.

b. Relevant tables

Annex Table A.1 - Estimates of Epidyolex Patient Numbers in England, Wales and Scotland by year

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
People receiving 12 months of treatment	241	810	1,636	2,003	2,233	2,263	2,293	2,324	2,355	2,386
People receiving 6 months of treatment	851	1,311	701	495	299	303	307	311	315	319

Annex Table A.2 - Estimates of total prescriptions/prescription appointments[23] under current system

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Total Prescriptions	7,999	17,582	23,844	27,006	28,584	28,966	29,354	29,747	30,145	30,549

Annex Table A.3 – Estimates of total prescriptions/prescription appointments saved due to the proposed changes

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Best	5,332	11,721	15,896	18,004	19,056	19,311	19,569	19,831	20,097	20,366
Low	3,999	8,791	11,922	13,503	14,292	14,483	14,677	14,874	15,073	15,275
High	6,666	14,652	19,870	22,505	23,820	24,139	24,462	24,789	25,121	25,458

Annex Table A.4 – Estimated number of Epidyolex prescriptions/prescription appointments after this change

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Best	2,666	5,861	7,948	9,002	9,528	9,655	9,785	9,916	10,048	10,183
Low	3,999	8,791	11,922	13,503	14,292	14,483	14,677	14,874	15,073	15,275
High	1,333	2,930	3,974	4,501	4,764	4,828	4,892	4,958	5,024	5,092

Annex Table A.5 – Estimated number of Epidyolex exports

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Export Licences	439	853	940	1,005	1,018	1,032	1,045	1,059	1,074	1,088

[23] A prescription appointment is needed to issue a prescription, as per assumptions

Impact Assessment Checklist

Mandatory specific impact test - Statutory Equalities Duties	**Complete**
Statutory Equalities Duties The public sector equality duty requires public bodies to have due regard to the need to eliminate discrimination, advance equality of opportunity, and foster good relations in the course of developing policies and delivering services. [Equality Duty Toolkit] *Follow the guidance and insert a summary paragraph. Once you have done this you can delete the guidance text in this box.* Epidyolex is available through the NHS and private healthcare services to all patients with eligible conditions based on clinical need. The assessment found there would be no impacts on different groups, therefore no policy equality statement was required.	**No**

The impact assessment checklist provides a comprehensive list of specific impact tests and policy considerations (as of February 2019). Where an element of the checklist is relevant to the policy, the appropriate advice or guidance should be followed. Where an element of the checklist is not applied, consider whether the reasons for this decision should be recorded as part of the Impact Assessment and reference the relevant page number or annex in the checklist below. Any test not applied can be deleted except **the Equality Statement**, where the policy lead must provide a paragraph of summary information on this.

The checklist should be used in addition to HM Treasury's Green Book guidance on appraisal and evaluation in central government (Green Book, 2018).

The Home Office requires the **Specific Impact Test on the Equality Statement** to have a summary paragraph, stating the main points. **You cannot delete this and it MUST be completed**.

Economic Impact Tests

Does your policy option/proposal consider…?	Yes/No (page)
Business Impact Target This policy will deregulate private healthcare companies. However, this is likely to be extremely small and due to a lack of data cannot be quantified.	Yes

Small and Micro-business Assessment (SaMBA) Due to the way community pharmacies are reimbursed for dispensing they carry out on behalf of the NHS, there will be no net sector-wide effect on their funding. However, some individual pharmacies may see revenues decline slightly due to the rescheduling of Epidyolex and consequent increase in lengths of prescriptions reducing the frequency of dispensing. This is because fees paid to pharmacies each year for dispensing prescriptions is based on the total number of prescription items they dispense, plus an additional fee for dispensing Schedule 2 drugs. However, since Epidyolex prescriptions represent a tiny proportion of the total prescriptions dispensed by pharmacies, the loss in revenue will be small.	Yes

Competition Epidyolex is produced by GW Pharmaceutical. Therefore, by rescheduling Epidyolex and not all CPBMs, this policy could reduce competition in the market for CBPM treatments. However, this risk is mitigated as the Government is open to considering alternative CBPM treatments should they be brought forward with the sufficient evidence. Additionally, the ACMD assessment made clear that Epidyolex was appropriate for Schedule 5 rather than Schedule 2 based on its low controlled drug content. Other CBPMs may be made up of different level of controlled drug so this change cannot be applied to all CBPM.	Yes

Social Impact Tests

Family Test There will likely be patients of a young age with severe forms of epilepsy that will be prescribed Epidyolex. The treatment is intended to improve the patient's quality of life, which may have a positive impact on family relationships.	Yes