Title: Legislative changes to expand independent prescribing of controlled drugs by nurses and pharmacists and enable mixing and possession of controlled drugs. **IA No:** HO0050 **Lead department or agency:** Home Office **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 24/10/2011 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Des Niimoi (020 7035 3533) Desmond.niimoi@homeoffice.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£0m	£0m	£0m	Yes	OUT

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

In 2004 the then Government committed to enhancing patient care through improved access to medicines and increased and more flexible use of non-medical prescribing. In 2006 the DH amended medicines legislation to expand nurse independent prescribing authorities and introduce pharmacist independent prescribing. Nurse and pharmacist prescribers are currently unable to prescribe controlled drugs in line with the policy objective as the regulatory framework for controlled drugs has not been amended. Government intervention - amendments to the 2001 Regulations - is necessary to enable nurse and pharmacist prescribers to prescribe all controlled drugs within their competence in line with the policy objective.

What are the policy objectives and the intended effects?

The objective is to enhance patient care by improving access to medicines through increased and more flexible use of nurse and independent prescribing by pharmacists, enable possession of controlled drugs by paramedics and enable the mixing of medicines to:

- improve the quality of service to patients without compromising patient safety;
- make it easier for patients to get the medicines they need and increase patient choice;
- free up the time of doctors to carry out other clinical work;
- introduce more flexible team working and maximise the benefits of fully utilising professional skills.

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

Option 1: Do nothing

This option is not acceptable to Government or supported by ACMD advice. The UK Government would not be acting to ensure patient's prompt access to controlled drugs within an effective regulatory framework or maximising the flexible use of healthcare skills if this option is adopted.

Option 2: Implement legislative changes to enable nurses and pharmacists to prescribe all controlled drugs within their competence, paramedics to possess drugs under a PGD and enable mixing of medicines that include controlled drugs prior to administration.

Option 2 is the preferred option.

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

Does implementation go beyond minimum EU requirements?			Yes / No / N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

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: _____ Date: 27/3/12

Summary: Analysis & Evidence

Policy Option 2

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low			40	**336**
High			82	**686**
Best Estimate			61	**505**

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

Cost estimates are based on the transfer of some prescribing duties (approximately 10-20%, 2.4-4.8hrs per week) undertaken by doctors to either pharmacists or GP practice nurses. Average wages per hour are estimated to be £14 / hr for nurses (23,162 trained) and £17.1/ hr for pharmacists (2,011 trained). Training of medical staff has already been undertaken. No costs are associated with changes to paramedics possession of medicines and the mixing of medicines.

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

Small costs may be associated with implementing new processes within local areas although it has not been possible to quantify these. Publicity costs for promoting legislative changes nationally are included in current advertising budgets.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low			102	**848**
High			204	**1696**
Best Estimate			153	**1272**

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

Time saved by GP's, by enabling some prescribing duties to be undertaken by nurses and pharmacists, may result in a cost saving of 2.4 - 4.8 hours per week per GP. Values are based on an average wage for GP's of £35.9 per hour and a volume of 25,173 GP's affected.

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

The proposed changes in legislation may improve patient care by providing better access to controlled drugs, when appropriate, for patients. It is possible that a time saving will be achieved for patients through shorter prescribing processes although it is not possible to quantify this saving (DfT estimate the average value of working time to be £26.73 per person per hour). Benefits are also expected in the improved provision of patient care by GP's, paramedics and the mixing of medicines.

Key assumptions/sensitivities/risks — **Discount rate (%)** 3.5

The assessment assumes that the saving to GP's will equate to 2.4 - 4.8 hours per week and that this time will be precisely mirrored by increased duties on GP nurses and pharmacists. However, it has not been possible to accurately quantify the total time spent by GP's on prescribing. If taken up more widely it is likely that the benefits will extend beyond those already trained, including those in the private and third sectors.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: NK	**Benefits:** NK	**Net:** NK	Yes	OUT

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

A.1 Background – Nurse and pharmacist independent prescribing
In 2000 the then Government committed to improving patients' access to NHS prescription medicines and making better use of professional skills, while freeing up time for GP appointments. This was set out in the NHS Plan July 2000 and the NHS Improvement Plan which followed in July 2004.

As a result a wide range of interested parties throughout the UK were consulted in early 2005 on a variety of proposals for the expansion of extended formulary nurse prescribing and the introduction of prescribing by pharmacists. Detailed proposals were contained in MHRA/DH consultation letters MLX 320 and MLX 321. In summary, views were sought on:

Nurses	Pharmacists
--------	**Option 1**: no change (i.e., no independent prescribing by pharmacists)
Option A: no change - maintain the NPEF for specified medical conditions	**Option 2**: prescribing for certain conditions from a limited formulary
Option B: prescribing for any medical condition from a specific Formulary	**Option 3**: prescribing for any condition from a limited formulary
Option C: prescribing for specific medical conditions from a full Formulary	**Option 4** : prescribing for specific conditions from a full formulary
Option D: prescribing for any medical condition from a full Formulary	**Option 5** : prescribing for any condition from a full formulary
Option E: advanced practice nurses with a higher level of competencies	**Option 6** : different approaches for the different clinical settings
--------	**Option 7**: a hybrid approach (between hospital, community and primary care based pharmacists)

Over 700 replies were received. Responses to the consultations closed at the end of May 2005. The results of consultation indicated that the majority of respondees, including both nurses' and pharmacists' representatives, felt that nurse prescribers and pharmacist prescribers should be able to prescribe any licensed medicine for any medical condition, where they are competent to do so. Doctors' organisations were more reticent, suggesting much more limited change. A full summary of the outcome of the consultation was placed on the MHRA's website (www.mhra.gov.uk) at the time.

On the close of those consultations, following consideration of responses, the then Committee on Safety of Medicines (now the Commission on Human Medicines (CHM)) recommended to Department of Health Ministers that Nurse Independent Prescribers and Pharmacist Independent Prescribers should be able to prescribe any licensed medicine for any medical condition within their competence (**options D and 5 above**). These changes were recommended to improve the quality of service to patients without compromising patient safety, increase patient choice and access to medicines and enable more flexible use of the skills of healthcare professionals. Changes to medicines and NHS regulations followed, with effect from 1 May 2006. However, the restrictions around Controlled Drugs remain.

Following amendments to medicines legislation in 2006, a number of nurses and pharmacists (both within the NHS and private sector) have undergone training in preparation for undertaking their roles as independent prescribers. Available figures confirm that for the first half of 2011 the total number of trained non-medical prescribers is as follows;

Nurse independent prescribers – 23,162 (Nursing and Midwifery Council)
Pharmacist independent prescribers – 2,011 (General Pharmaceutical Council)
Total – 25,173

In 2007 the Home Office consulted further on the changes to controlled drugs legislation. The majority of the responses supported a legislative change to expand nurse independent prescribing and to introduce pharmacist independent prescribing of controlled drugs. The proposed changes to controlled drug legislation is the final legislative change needed to provide the requisite authority for nurse and pharmacist independent prescribers to prescribe all controlled drugs within their competence.

Paramedics

The proposed changes also include amendments to authorities currently granted to paramedics in relation to the possession supply and/or administration of certain controlled drugs. Paramedics currently have authority under the Misuse of Drugs 2001 (the 2001 Regulations) to supply/offer to supply or administer specific controlled drugs under Patient Group Directions (PGD) set up under the 2001 Regulations. When PGDs were first introduced into the 2001 Regulations in 2003, no corresponding change was made to the 2001 Regulations to give authority to those acting under a PGD to possess the relevant controlled drugs such as Ketamine and Midazolam. This means that although paramedics are authorised to supply and/or administer Ketamine and Midazolam, they currently have no specific authority under the MDR to possess these drugs. As a result some Ambulance Trusts have withdrawn these drugs from use by paramedics in order to avoid any risk of prosecution. The proposed change will provide the requisite authority to paramedics acting under a PGD to possess the relevant controlled drugs such as Ketamine and Midazolam. No impact, besides the removal of the risk of prosecution, is envisaged from implementing this proposal. Paramedics are already trained to possess and administer the relevant drugs under a PGD. However, they are currently not using these drugs as a result of the anomaly identified with the law. The correction in the law will enable resumption of the use of these drugs.

Mixing of medicines

Finally, the proposed legislative amendments also include changes to enable the mixing of medicines which contain controlled drugs prior to administration. This is simply to ensure that the requisite legislative backing exists for nurses, other healthcare professionals and individuals acting in accordance with the instructions of a practitioner when mixing medicines which include controlled drugs prior to administration. Again no impact, besides the removal of the risk of prosecution, is envisaged from implementing this proposal. The Home Office and the Department of Health issued a policy statement when the current anomaly with the law was identified to enable mixing of medicines to take place until the legislation is amended. Nurses and carers currently operate under the terms of this statement and will continue to mix medicines as normal following implementation of the legislative change.

A.2 Groups Affected

Groups affected by these proposals are doctors, nurse and pharmacist independent prescribers, registered paramedics, nurses in palliative care, persons acting under and in accordance with the instructions of a practitioner and patients.

The extent to which independent prescribing by nurses and pharmacists are adopted within national health organisations (NHS) is a matter for each of the devolved administrations. These national services are not regarded as a "business, charity or voluntary organisation" for the purpose of this impact assessment. Health services provided outside the NHS and the service provided by community pharmacists, (excluding, for the purpose of this impact assessment, their NHS business operations), are regarded as businesses. However, independent prescribing by nurses and

pharmacists does not create a new regulatory environment with which the businesses must comply at the outset. Whether businesses, employers and individual health professionals offer, or train to undertake, independent prescribing in the context of this impact assessment is entirely a voluntary decision for them based on their commercial and professional judgement.

It is expected that some pharmacies and GP surgeries affected by the proposed changes will be micro businesses. As the proposals are expected to result in a net benefit it is expected that the affect on micro businesses will also be a net benefit.

A.3 Consultation

Within Government

The Home Office has consulted with the Department of Health, the Medicines and Healthcare products Regulatory Agency and the Advisory Council on the Misuse of Drugs, the statutory independent expert body which advises Government on drug issues.

Public Consultation

This proposal resulted from a Department of Health (DH) policy change. A full public consultation on the proposals was undertaken by the DH in 2005 prior to amendments to medicines legislation implementing the policy. The majority of respondents supported the proposals to expand prescribing by nurse independent prescribers and the introduction of independent prescribing by pharmacists.

In 2007 the Home Office consulted further on the changes to controlled drugs legislation. The majority of the responses supported a legislative change to expand nurse independent prescribing and to introduce pharmacist independent prescribing of controlled drugs.

Key stakeholders consulted were professional and regulatory bodies for nurses and pharmacists, medical practitioners, nurses, pharmacists and healthcare institutions.

B. Rationale

The availability of controlled drugs within the community and in healthcare is regulated due to the high risk of diversion and potential harms associated with controlled drugs when misused. Market forces do not play a part in setting up the regulatory framework under which these drugs are made available for use in healthcare. Government intervention is therefore necessary to ensure legitimate access to these drugs whilst at the same time ensuring an effective regulatory framework exists to prevent diversion and misuse.

The proposed changes do not increase the risk from these drugs as nurses, pharmacists and paramedics are fully trained to use these drugs and work under professional regulatory standards.

This proposal allows nurses and pharmacists to prescribe drugs within their competence and paramedics to possess drugs which they are legally permitted to administer. This proposal represents the final step needed to amend three legislative anomalies; to provide the requisite authority for nurse and pharmacist independent prescribers to prescribe all controlled drugs within their competence (permitted by Department of Health legislation), to allow paramedics to possess controlled drugs and to allow the mixing of medicines according with instructions provided by medical practitioners.

C. Objectives

The policy objectives are to;

1. enable nurse and pharmacist independent prescribers to prescribe all controlled drugs within their competence;
2. enable paramedics to possess the relevant controlled drugs under a Patient Group Direction (PGD); and

3. enable the mixing of medicines that include controlled drugs prior to administration.

A successful outcome of this policy will be the flexible and effective use of the professional skills of nurse and pharmacist prescribers which in turn frees up time of medical doctors to carry out more urgent duties whilst at the same time enabling prompt and legitimate access to controlled drugs for patients under an effective regulatory framework.

The effect is to;

- improve the quality of service to patients without compromising patient safety;
- make it easier for patients to get the medicines they need and increase patient choice;
- free up the time of doctors to carry out other clinical work;
- introduce more flexible team working and maximise the benefits of fully utilising professional skills.

D. Options

Option 1: is to make no changes (do nothing).

This option maintains the status quo and is not acceptable to Government or supported by the conclusions from the consultation or ACMD advice. The UK Government would not be acting to ensure patient's access to controlled drugs within an effective regulatory framework nor would it be maximising the flexible use of healthcare skills if this option is adopted. The Government would also be ignoring of the Department of Health, healthcare professionals, members of the public and the many Members of Parliament who have written to support implementation of the proposals in option 2 as soon as possible to improve patient care.

If the do nothing option is chosen the legislative anomalies will remain, along with the inefficient utilisation of resources.

Option 2: Implement legislative changes to enable nurses and pharmacists independent prescribers to prescribe all controlled drugs within their competence, paramedics to possess the relevant controlled drugs under a PGD and nurses and those acting in accordance with the instructions of a doctor to mix medicines that contain controlled drugs prior to administration.

Option 2 is the preferred option. This option will ensure patients' have access to controlled drugs under an effective regulatory framework and that the available skills in healthcare are maximised to improve healthcare services provided to patients.

E. Appraisal (Costs and Benefits)

The following analysis excludes Northern Ireland which has a separate, but similar, regulatory framework for controlled drugs. Northern Ireland will undertake a similar review process separately from the UK.

GENERAL ASSUMPTIONS & DATA
There are no baseline costs available.

The training required for the mixing of drugs and the use of controlled drugs by paramedics is currently in place and it is therefore not envisaged that the proposed changes in legislation will create any additional costs. Where these medicines are not currently utilised due to the risk of prosecution, some benefits are expected to accrue in terms of improved service to patients. However, data on volumes affected and the value of the improved service are unavailable so the benefits have not been quantified.

Total number of staff:
- Number of registered nurses in England, Scotland & Wales – 626,500
- Number of registered pharmacists in the England, Scotland & Wales – 46,024

Training:

- Estimated cost of training a non-medical prescriber - £1000 (Department of Health)
- Total number of independent prescribers trained as of October 2011:

- Pharmacists – 2,011 (General Pharmaceutical Council) (4.3% of total strength)
- Nurses – 23,162 (Nursing and Midwifery Council) (3.7% of total strength)
- Total – 25,173

Salaries

- Average yearly salary of General Practitioner – £53,781 - £81,158 (average £35.9/hr)
- Average hourly cost of a GP practise nurse – £21,176-27,625 (average £14.0/hr)
- Average hourly cost of a pharmacist – £25,528 - £34,189 (Average £17.1/hr)

Hourly salaries exclude leave (27 days per year) and are based on a 37½ working week for nurses and pharmacists and a 40 hour working week for doctors. Total number of working weeks is estimated to be 37 per year. http://www.nhscareers.nhs.uk/details/Default.aspx?Id=766)

Consultation time:

- It is not possible to estimate the total time spent on prescribing by practitioners; a NHS survey in 2006/7 reported that practitioners spent 60% (24 hours per week) of their time on clinics, consultations and prescribing. It is not possible to accurately estimate the amount of time that will be saved by GP's. For simplicity a range of between 10-20% of total consultation time spent by GP's has been estimated; this equates to a range of 2.4hrs – 4.8hrs in time saved to GPs by the proposed changes. It is assumed that this time saving will result in a transfer of 2.4-2.8 hours of time spent by trained nurses and pharmacists (25,173 in total) on prescribing.

It is assumed that a consultation with the GP/nurse will be required for a prescription to be written. Repeat prescriptions, where only a signature is required from either the nurse/GP have not been included in these calculations as it is not possible to quantify the small time costs associated with these.

Private Sector

All cost/ benefit analysis is based on information available for the public, private and third sector separately. It has not been possible to obtain data for the costs and benefits associated with medical practitioners in the private sector although it is assumed that the average costs savings will be broadly similar across all service providers.

OPTION 1 – Do Nothing

This option maintains the status quo and is not acceptable to Government or supported by the conclusions from the consultation or ACMD advice.

The do nothing option would retain the current legislative anomalies that may result in ineffective service being delivered to patients by paramedics due to restrictions of the possession of controlled drugs as well as the administration of mixed medicines. It is also likely that the inefficient use of GP resources to undertake prescribing duties, and the associated costs, would continue.

OPTION 2 – legislative changes to enable nurses and pharmacists independent prescribers to prescribe all controlled drugs within their competence, paramedics to possess drugs under a PGD and enable mixing of medicines that contain controlled drugs prior to administration.

COSTS

It is estimated that there will be an average saving to GP time of between 2.4-4.8 hours (see above). It is assumed that this time saved by GP's will be borne by nurses and pharmacists. This would equate to a cost of approx £1,579-3,224 per year for nurses and a cost of £1,928 - £3,857 for pharmacists based on average wages.

The Department of Health has confirmed that a number of nurses and pharmacists (25,173 in total) have already been trained since changes were made to medicines legislation in 2006. As a result, in the short term no training costs are envisaged. There may be future costs if additional nurses and pharmacists decide to train as prescribers, however, no figures are available on how many additional nurses or pharmacists will want to train for this purpose. For the purposes of the calculations included in this impact assessment it is envisaged that no further pharmacists or nurses will be trained. Multiplying the average costs by the volume of trained nurses and pharmacists presented a total annual cost of £40-£80 million with a best estimate of £61.

There are no costs attributable to the changes relating to paramedics. Paramedics are already trained to possess and administer the relevant drugs under a PGD.

There are no costs attributable to the changes relating to the mixing of medicines. Mixing of medicines currently takes place in accordance with the instructions of a practitioner or prescriber and under a Home Office and Department of Health policy statement. No changes will follow implementation of the proposal.

The Department of Health have confirmed that there are no additional advertising or publication costs to be incurred as a result of implementing these proposals. All publication and advertising costs will be absorbed in current budgets.

BENEFITS

Benefits accruing from this policy are two fold;

The primary benefit of the proposal is the ease of access and improvement in patient care as a result of being able to access controlled drugs at the point of need. The policy will free up GP time for more consultations leading to improved services for patients and reduce the time taken for patients to obtain prescriptions from medical services. The value of the improved service has not been quantified nor has the value of the time saved although for illustration, the Department of Transport estimate that average value of working time is £26.73 per person per hour. Any time savings achieved by patients would therefore contribute to an additional cost saving.

Savings will also be accrued by GPs who will no longer be required to undertake all prescribing activity. It is assumed that prescribing by doctors will reduce by the amount of controlled drug prescriptions issued by nurse and pharmacist prescribers (described above). The benefits associated with the saving of approximately 2.4-4.8 hours by a GP per week are £4,050 - £8,099 per year. It is assumed that the savings of each GP equate to either one trained nurse or pharmacist, results in a total benefits of £102m to £204 with a best estimate of £153m.

ONE-IN-ONE-OUT (OIOO)

<u>COSTS (INs)</u>

OIOO costs are ongoing and relate to the cost of training for nurses and pharmacists in the private and third sectors. However, there is no requirement on nurses or pharmacist in the private or third sectors to undertake prescribing duties and therefore these costs are not obligatory. A number of healthcare professionals in the private and third sectors have already undertaken training following changes to medicines legislation and are ready to undertake the role following changes to controlled drug legislation. In the long term other nurses and pharmacists in these sectors may want to undertake training to perform this role. However, no figures are available on the number of individuals likely to opt for this training.

If independent healthcare sector organisations or community pharmacies decide they wish to take the opportunity to introduce nurse or pharmacist prescribing, they will have to pay to train and maintain the accreditation of individuals with the relevant professional body. These costs will include fees payable for training courses and in some cases, provision of locum cover. The cost of training to become a prescriber is estimated at around £1,000 per trainee (Department of Health). Nurse and pharmacist prescribers also need to ensure that they keep their skills up-to-date through

Continuing Professional Development (CPD) but any costs associated with this are unlikely to be significantly different from those incurred as part of their professional role as nurses and pharmacist. Training and continuing practice development mitigates any risk associated with implementation of the policy

No separate figures are available for nurses and pharmacist in the private and third sector and calculations include currently trained private and third sector nurses and pharmacists.

BENEFITS (OUTs)

OIOO benefits accruing from this policy are two fold and are similar to those in the public sector. Primary benefit accrues to patients through the ease of access to drugs at the point of need. Nurses and pharmacists undertaking this role will free up time for practitioners to undertake more urgent tasks improving healthcare services for patients.

The secondary benefit of the proposal comes from savings to be made by doctors not having to undertake all prescribing activity. Prescribing by doctors will reduce by the amount of controlled drug prescriptions issued by nurse and pharmacist prescribers. With the saving in doctors time comes a corresponding saving in costs to the private and third sectors. Average savings are expected to be £3,440 per year.

NET

The average net saving (£3,440 per year) will be greater the average training costs (£1,000 per pharmacist/nurse trained). Costs attributable to this policy will be more than offset by corresponding savings as a result of doctors not having to undertake the prescribing activity involved. The policy is therefore expected to attract net savings in addition to improved care for patients and flexible delivery of healthcare.

F. Risks

OPTION 2 – legislative changes to enable nurses and pharmacists independent prescribers to prescribe all controlled drugs within their competence, paramedics to possess drugs under a PGD and enable mixing of medicines that contain controlled drugs prior to administration

1. Training, accreditation and regulation by professional bodies will mitigate any risks associated with these proposals. Whilst the policies ensure patients have access to controlled drugs at the point of need, nurse and pharmacist independent prescribers will only be enabled to prescribe controlled drugs within their competence and will be subject to their regulatory bodies guidance and rule when undertaking this role.

2. The implementation of this policy will also remove the risk of prosecution which currently exists to paramedics, when in possession of a controlled drug under a PGD. Any risks associated with paramedics possessing and administering the relevant drugs are mitigated by their training, accreditation and regulation by a professional body.

3. Current restrictions on the possession of certain controlled drugs by paramedics may result in less effective substances being used on patients. There is a positive risk that changes in legislation may result in more effective controlled drugs being used by paramedics which may result in improved patient care.

4. There are no risks associated with the changes relating to mixing of medicines. Nurses and persons who need to mix medicines that include controlled drugs prior to administration currently do so under and in accordance with the instructions of a practitioner or prescriber. The specific instructions under which these medicines are mixed and administered mitigate any risks associated with the mixing of medicines.

G. Enforcement

Enforcement of the proposed policy will be undertaken by health regulatory bodies, Accountable Officers, professional bodies and other relevant governmental agencies responsible for the provision of healthcare and management of medicines in England and the Devolved Assemblies.

H. Summary and Recommendations

The table below outlines the costs and benefits of the proposed changes.

Table H.1 Costs and Benefits

Option	Costs	Benefits
2	£505m	£1272m
	Cost to nurses and pharmacists	Benefits to GPs in prescribing time

Option 2 is the preferred option. This option will ensure a maximisation of the flexible use of the skills of healthcare professionals leading to improved services, whilst at the same time ensuring patients have access to controlled drugs under an effective regulatory framework.

The overall effect of the proposals under this option is a net savings to healthcare organisations, flexibility in the use of healthcare skills, removal of the risk of prosecution and improved patient access to controlled drugs at the point of need. No initial costs are envisaged when these proposals are implemented as healthcare professionals are already trained to undertake these tasks. Any future costs relating to the training of healthcare professionals are also far outweighed by the benefits to be derived from implementing this policy.

Any risks associated with this option are mitigated by the training, accreditation and regulation of healthcare professionals by their regulatory and professional bodies. Healthcare professionals are also expected to adhere to the requirements placed on them when prescribing, possessing or administering controlled drugs under the legislative framework.

I. Implementation

The Government plans to implement these changes on [Insert Text].

J. Monitoring and Evaluation

The effectiveness of the new regime would be monitored by health regulatory bodies in England and the Devolved Administrations under the regulatory framework governing medicines and controlled drugs and also through the oversight of Accountable Officers.

K. Feedback

Feedback on the proposed changes will be sought from regulatory and professional bodies for doctors, nurses, pharmacists, the Department of Health, patient representative bodies and the Medicines and Healthcare products Regulatory Agency.

Title: Impact Assessment of amendments to anabolic steroid and human growth hormone legislation **IA No:** HO **Lead department or agency:** Home Office **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 09/02/2012 **Stage:** Final Stage **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries**: Des Niimoi (020 7035 3533) Desmond.niimoi@homeoffice.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
N/A	N/A	N/A	No	N/A

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

Anabolic steroids and Human Growth Hormones are Class C drugs under the Misuse of Drugs Act 1971 and Schedule 4, Part II drugs under the Misuse of Drugs Regulations 2001. It is not an offence to possess or to import or export these drugs "in the form of a medicinal product by any person for administration to himself". The current provisions make it difficult to enforce the legislation, UK border officials are unable to question the end user/importer at the point of entry, or easily identify the importer from the import declaration for postal imports, to determine whether the importation is for personal use and lawful . The term "medicinal product" also causes confusion in practice, with definitional uncertainty and a lack of clarity in the absence of case law whether counterfeit steroids fall within its definition.

What are the policy objectives and the intended effects?

The policy objectives are to reduce availability and misuse of these drugs through restricting importation and exportation of anabolic steroids and Human Growth Hormones for personal use to personal custody, and to remove the term "medicinal product" from the legislation to provide clarity in the enforcement of the legislation or legal framework under the 1971 Act and the 2001 Regulations.The intended effects are to make postal and courier imports from the internet illegal, in accordance with the original policy intent of the personal exemption provisions, with a corresponding reduction in the availability of these drugs and better interpretation and enforcement of the legislation by UK border officials.

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

Option 1: No change
Option 2: Restrict importation and exportation of drugs in Schedule 4 Part II to the 2001 Regulations for personal use to personal custody and remove the term "medicinal product" from the 2001 Regulations.
Option 2 is the preferred option

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 06/2016

Does implementation go beyond minimum EU requirements?			Yes		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** No	**Small** No	**Medium** No	**Large** No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

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: Lord Henley Date: 27th March 2012

Summary: Analysis & Evidence

Policy Option 2

Description: Restrict importation and exportation of drugs in Schedule 4 Part 11 to the 2001 Regulations for personal use to personal custody and remove the term 'medicinal product' from the 2001 Regulations.

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** N/A

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A		Optional	**Optional**
High	N/A		Optional	**Optional**
Best Estimate	-			**N/A**

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

N/A

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

The proposal would have no cost to business or the public sector. There is estimated to be a small cost to individuals who will no longer be able to import anabolic steroids or Human Growth Hormones via internet or courier services. The number of individuals this will affect is not known.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	-			**N/A**

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

N/A

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

The public sector will benefit from increased clarity of the legislation and UK Border Officials will no longer have to spend time trying to identify the owners of imported anabolic steroids or Human Growth Hormones. There is expected to be a reduction in the number of individuals presenting with side-effects from these drugs, at a reduced cost to the NHS due to the restriction in availability of the drugs.

Key assumptions/sensitivities/risks — **Discount rate (%)** -

They key assumptions are that: 1) Anabolic steroids and Human Growth Hormones purchased online originate from countries outside the UK; 2) Courier costs are paid to businesses outside of the UK and in the countries where the export of the drug takes place. There is a risk that reducing individuals' choice of places to purchase these drugs may lead to a reliance on the illicit market.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:				In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:**	0	**Net:** -	No	N/A

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

The Advisory Council on the Misuse of Drugs (ACMD) – the independent expert body that advises Government - considered the misuse of anabolic steroids in January 1993 – it had previously considered them in 1988 - and concluded that the misuse of steroids (and other related substances) did constitute a social problem – a key criteria which needs to be satisfied under the Misuse of Drugs Act 1971 before a particular substance can be brought within its controls. It therefore recommended that legislative controls should be introduced - aimed at the activities of unscrupulous illicit suppliers and traffickers who fed anabolic steroid misuse - but that an offence of simple possession would be "undesirable as it would criminalise a whole group of people".

The British Crime Survey 2010/11 found that 0.2% of 16-59 year olds and 0.3% of 16-24 yr olds reported illicit use of anabolic steroids in the last year.[1] The misuse of anabolic steroids is a social problem due to the potential health risks that use of anabolic steroids can create. The physical effects of anabolic steroid use range from skin problems, such as acne, to more harmful effects such as liver damage and cardiovascular problems.[2] As the majority of users inject anabolic steroids, they are also at risk of a number of serious harms which include: 1) damage to the injection site as a result of poor injecting technique; 2) bacterial and fungal infections as a result of poor injecting technique, contaminated drug products, and sharing vials and/or reusing injecting equipment; and 3) blood-borne viruses such as HIV and Hepatitis B as a result of sharing used injecting equipment or sharing vials with others.[3]

There are special concerns about the use of anabolic steroids by young people as the use of these substances can lead to virilisation and, more broadly, potentially disrupt the normal pattern of growth and behavioural maturation.[4]

An additional social problem arises from substandard and counterfeit anabolic steroids on the illicit market. The ACMD found that in the UK many anabolic steroids used in 'stacking' (whereby users combine several different types of anabolic steroids) are either not available as licensed products or may only be licensed as part of veterinary medicinal products.[5] Whilst there is a paucity of data on the structure of the illicit market, data suggest it is comprised from three sources of products:

1) Products purportedly manufactured legitimately (typically) in middle-income countries (such as China and India) where drug regulatory oversight and enforcement is weak.[6]
2) Products manufactured and/or packaged in clandestine 'underground' laboratories of varying capacity and quality which, because they exist outside of the drug regulatory system, the products cannot demonstrate sufficient 'quality, safety and efficacy'.[7]
3) Legitimate products manufactured in high-income countries that are: purchased over-the-counter (including internet sales) in countries where this practice is lawful or where regulatory oversight and enforcement is weak; diverted to the illicit market through theft; unlawfully resold; or prescribed/dispensed as a result of fraud.[8]

In November 1994, the Home Secretary accepted the ACMD advice – confirming that anabolic steroids would be brought under the control of the 1971 Act as Class C drugs under Part III of

---

[1] Drug Misuse Declared: Finding s from the 2010/11 British Crime Survey, Tables 2.2 and 2.6

[2] ACMD, Consideration of the Anabolic Steroids, September 2010, p.26

[3] Ibid, p.26

[4] Ibid. p.25,

[5] Ibid,, p.30

[6] World Health Organization, (2004), WHO medicines strategy 2004-07, Countries at the core, Geneva, Switzerland: World Health Organization

[7] Medicine and Healthcare Products Regulatory Authority (2007) Rules and guidance for pharmaceutical manufacturers and distributors 2007, London, United Kingdom: Pharmaceutical Press

[8] ACMD, Consideration of the Anabolic Steroids, September 2010, p.31

Schedule 2 to the Act and that they should be listed in Schedule 4 of the Misuse of Drugs Regulations but with additional import/export restrictions. It was to be an offence under the Act to produce, supply or possess/import/export **with intent to supply** without a licence.

However, in line with ACMD advice, it was not to be an offence under the Act to simply possess anabolic steroids when in the form of a "*medicinal product*". In the absence of a simple possession offence, it was therefore considered to be anomalous and contrary to EU restrictions to make the importation or exportation of the substances for personal use an offence i.e. to have a stricter regime of controls at ports. Permitting importation for personal use was consistent with permitting simple possession inland. However, in all other circumstances importation and exportation would require a Home Office licence, and carrying out such activity without a licence would be an offence.

The ACMD advice was implemented through the Misuse of Drugs Act 1971 (Modification) Order 1996 and the Misuse of Drugs (Amendment) Regulations 1996, which came into force on 1st September 1996, introducing controls on 54 anabolic substances that had previously been prescription only medicines. These 54 substances became Class C drugs under the Act and Schedule 4 Part 1 drugs under the Misuse of Drugs Regulations 1985. (By the Misuse of Drugs Act 1971 (Modification) Order 2001 those substances contained in Schedule 4 Part 1 were transferred to Schedule 4 Part II; there were no changes to the level of control). As advised by the ACMD simple possession and importation of Schedule 4 Part II drugs when in the form of a medicinal product for self administration were not made an offence under the 1971 Act.

In January 2005, ACMD gave further consideration to the drugs that should be included in the legislative measure. As well as anabolic steroids, beta-2-agonists and growth hormones were considered for control. The ACMD acknowledged that people involved in sporting activities took a wide range of substances; the most common reasons cited included legitimate therapeutic purposes, performance continuation, performance enhancement and recreational use. ACMD considered anabolic steroids, androgenic steroids, human growth hormones; and adrenoceptor stimulants. These substances could perhaps be said to be characterised by the fact that they have an androgenic (or masculinising) effect or an anabolic effect that stimulates the development of muscle mass or that they stimulate growth. The ACMD also took into account the anabolic and androgenic substances which are banned in sport and the International Olympic Commission (IOC) list.

The anabolic substances now listed in Part II of Schedule 4 of the Regulations are exempt from the general prohibition on possession of controlled drugs under section 5(1) of the 1971 Act when they are in the form of a medicinal product i.e. there are no restrictions on their simple possession or importation when in the form of a medicinal product for personal administration.

In 2010 the ACMD again considered the evidence on anabolic steroids and Human Growth Hormones, including the legislative framework governing these drugs. The ACMD found that the current legal framework which permits imports (or exports) of steroids for self-administration and does not require the drugs to be personally transported/imported can pose problems where steroids are imported via post or courier. Border force officials can be unable, in these circumstances, to determine whether the products are for personal use as they are unable to question the importer at point of entry and may not necessarily be able to identify the importer from the import declaration. To establish whether imported items are for personal use will necessarily involve a potentially costly investigating by UK Border Force officials as to the circumstances in which the drugs are being imported.[9] The ACMD therefore recommends that the legislation is made clearer by the imposition of a personal custody requirement for importation and exportation. This would make internet purchases and imports via post or courier illegal because they would not be on the person. Availability of these drugs for non-medicinal reasons would therefore be restricted, and the ability to enforce the existing legislation would be improved.

The ACMD also advises that the term "medicinal product" does not serve a recognised purpose and should be removed from the legislation. The definition of "medicinal product" is one that appears to have caused confusion, particularly among users and enforcement. The ACMD has discussed the definition of 'medicinal product' which is defined in the Medicines Act 1968 and whether it has been harmonised to the current definition used in medicine law afforded by

[9] ACMD, Consideration of the Anabolic Steroids, September 2010, p.43

European Directive 2001/83/EC. Further, such definitional uncertainty has implications for personal possession offences where there is confusion between applying the term 'medicinal product' to only those substances that have received marketing authorisation (i.e. to the exclusion of counterfeit products) or whether it should be applied in terms of the directive, i.e.:

a) "Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;
b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis"

From a public health perspective the confusion could act as a barrier and prevent users from engaging with health services: some users may think that the steroids they possess are unlawful as they are not 'medicinal products' (i.e. not legitimate as they have not been granted a marketing authorisation and/or might be counterfeits). Moreover, for enforcement, the application of a strict definition of a medicinal product (i.e. one with marketing authorisation) may lead to prosecution of those who are believed to possess products that do not have a marketing authorisation and/or might be counterfeit.

Removing the term "medicinal product" would have the effect of encouraging users to engage with health services and prevent prosecution due to possession of products that do not have a marketing authorisation and/or might be counterfeit.

From the proposals criminal prosecution will continue to be limited to illicit steroid dealers, suppliers, manufacturers and traffickers who profit from this trade. As the health related harms associated with the use of anabolic steroids are not of the severity of those associated with a number of other Class C drugs e.g. ketamine, the ACMD recommended that it should not be an offence under the Misuse of Drugs Act 1971 to simply possess anabolic steroids for personal use. Retaining the lack of a possession offence emphasises the ongoing need to focus on public health.

The Government has considered two options intended to address the misuse of anabolic steroids and Human Growth Hormones. These considerations are set out in this impact assessment.

A.2 Groups Affected

Groups affected by the policy are:

- members of the public who seek to enhance their physical image or sporting prowess through the use of anabolic steroids (e.g. body builders). Members of the public who need anabolic steroids for medicinal purposes and who are legitimately prescribed anabolic steroids and Human Growth Hormones will *not* be affected by this proposal.
- Health agencies who treat the adverse effects of anabolic steroid or HGH misuse
- Enforcement agencies who monitor importation, exportation and possession of these drugs and tackle illegal activity.

A.3 Consultation

Within Government

The Home Office has consulted with the Department of Health in deciding its preferred options.

Public Consultation

The Government has considered the recommendations of the Advisory Council on the Misuse of Drugs.

B. Rationale

The misuse of anabolic steroids and Human Growth Hormones imposes a cost to society in the form of health service costs due to the harmful effects misuse can have. Government intervention is necessary to protect the public from this cost and from the harmful effects of these drugs.

Existing legislation does not sufficiently prevent misuse due to the possibility of obtaining the drugs via the post, courier service or the internet and the difficulties this imposes on enforcement officers in identifying illegal intentions. Further Government intervention is therefore required to ensure the legislation on controlled drugs is clear, effective and can be enforced, and that the public are adequately protected from the costs of misuse.

C. Objectives

The policy objectives are to provide clarity and enable more effective enforcement of legislation relating to anabolic steroids and Human Growth Hormones. A successful outcome will be a reduction in the number of anabolic steroid and Human Growth Hormone imports and thus a reduction in the re-supply, use/misuse of these drugs by those who have not been prescribed the drugs for medical conditions.

D. Options

<u>Option 1:</u> Make no changes (do nothing).

This option maintains the status quo and would allow the importation of anabolic steroids and Human Growth Hormones for personal use via the post and courier to continue. Enforcement officers would continue to face difficulties in trying to identify the importer from documentation and to establish the purpose and the circumstances under which the drugs are being imported. This option is not supported by the ACMD advice or by Government.

<u>Option 2:</u> Restrict importation and exportation of drugs in Schedule 4 Part II to the 2001 Regulations to personal custody and remove the term "medicinal product" from the 2001 Regulations.

This option would remove the term "*medicinal product*" from the legislation and restrict importation of anabolic steorids and Human Growth Hormones to personal custody. This would provide clarity and enable more effective enforcement of the legislation. UK Border officials would be able to enforce the legislation better as the importer would be available for questioning to determine the purpose and circumctances of the importation. This option complies with ACMD advice and is the Government's preferred option.

Restricting importation to personal custody would;

- reduce the amount of these drugs in circulation and therefore lead to a reduction in the risk of misuse.
- enable border officials to enforce the law at the point of entry, detain all unaccompanied imports and destroy these further reducing the amount of Schedule 4 Part II drugs in circulation in the UK.
- continue to limit criminal prosecution to illicit steroid dealers, suppliers, manufacturers and traffickers who profit from this trade.

Removing the term "medicinal product" would;

- provide clarity for the public and for enforcement partners under the legislation and encourage misusers to seek help where adverse effects occur through the use of unlicensed products.

A third option would be to remove the exemptions on possesssion of anabolic steroids and Human Growth Hormones for personal use under the Misuse of Drugs Regulations 2001 and make possession and importation for personal use as offender under the Misuse of Drugs Act 1971. This option has not been developed further as it would criminalise a minority of individuals who use anabolic steroids and Human Growth Hormones for personal use. The ACMD recommended retaining the lack of a possession offence as improved tailored intervention and education messages aimed at anabolic

steorid users would be more effective than criminalsing users and further pushing the issue underground.10

Option 2 is the preferred option and is supported by ACMD advice.

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA

- Anabolic steroids and Human Growth Hormones purchased online originate from countries outside the UK
- Courier costs are paid to businesses outside of the UK and in the countries where the export of the drug takes place.

OPTION 2 – Restrict importation and exportation of drugs in Schedule 4 Part II to the 2001 Regulations to personal custody and remove the term "medicinal product" from the 2001 Regulations.

COSTS

Business

- There will be no cost to UK business as it is an offence under the 1971 Drugs Act to produce, supply or possess/import/export with intent to supply a Class C drug without a license.
- The proposals are simply providing clarity in the enforcement of the legislation under the 1971 Act and the 2001 Regulations and the only people to have benefited from the lack of clarity are users of anabolic steroids, who could import the drugs from online services or via courier, and businesses outside the UK.
- It is not expected that UK postal services will be affected from this proposal as postal charges for importations are paid to operators outside of the UK.

Public Sector

- There are no costs to the public sector flowing from this policy. The exemption provisions currently available under UK legislation for importing anabolic steroids and Human Growth Hormones are applicable only to individuals. The changes proposed to this exemption will therefore have no impact on the public purse.
- In 2010/11 there were 674 seizures of anabolic steroids by police forces and UKBA, quantified at 2.8 million doses.[11] These seizures may have been of drugs intended for supply. How many more will be seized due to the change in legislation from these proposals cannot be estimated as we do not know how many of these drugs are imported for personal use.
- Any short term costs associated with the seizure and destroying of postal packages at the borders following the law change will be absorbed within current UKBA contracts for disposal of seized goods. However, this will still come at an opportunity cost to the UKBA who will have to spend more time disposing of these illegal imports.
- Removal of the term ‘medicinal product’ should not have any impact on the public sector as it aims to end misinterpretation of when it is an offence to possess anabolic steroids or Human Growth Hormones.

[10] ACMD, Consideration of the Anabolic Steroids, September 2010, p.43

[11] Seizures of Drugs in England and Wales, 2010/11, Home Office Statistical Bulletin. For statistical purposes the quantities seized are expressed in doses, using a notional 6.17 doses to the gramme (this is based on 162mg being the 2005 average weight of a steroid tablet)

Individuals

- Users of anabolic steroids and Human Growth Hormones for personal use, such as bodybuilders, will suffer from a reduction in availability of the drugs due to the proposals preventing importation via courier or post from non-UK suppliers.
- The number of individuals affected cannot be quantified as we do not have any information on how many individuals purchase anabolic steroids or Human Growth Hormones from overseas for personal use.
- Removal of the term 'medicinal product' should not have any negative impact on individuals as in practice it has not been seen to serve a useful purpose and has only caused confusion for both individuals and enforcement officers.

BENEFITS

Business

- The proposals have no impact on UK business therefore there are no benefits to business.

Public Sector

- Anabolic steroid abuse has been associated with a wide range of adverse side effects ranging from skin problems to more serious effects such as liver disease, heart problems and the spread of HIV due to needle-sharing.[12] Preventing the purchase of anabolic steroids and Human Growth Hormones from the internet via courier/postal services should reduce the number of misusers.
- Those that abuse anabolic steroids or Human Growth Hormones are likely to need professional medical help at some point in time. This is a cost to the public purse. A reduction in the number of users and the amounts of these drugs being used will ultimately lead to a reduction in the number of those seeking medical help for any side effects suffered. This is a non-cashable benefit to the public sector.
- The expected benefits derived by the public sector from this policy cannot be quantified as it is not known how many individuals are misusing anabolic steroids or Human Growth Hormones.
- In addition UK border officials will spend less time trying to identify importers from paperwork accompanying postal imports or the circumstances under which anabolic steroids and Human Growth Hormones are being imported as all unaccompanied imports will be seized and destroyed. The savings attributable to this cannot be quantified as there is no data on the number of packages UK border officials have struggled to identify nor the time it takes to attempt to identify the package.
- Removing the term "Medicinal product" will end the confusion for enforcement officers and provide the clarity needed to effectively and consistently enforce the current legislation. The term 'Medicinal product' is currently being inconsistently interpreted due to the separate definitions from the Medicines Act 1968 and the current definition used in medicine law from the European Directive 2001/83/EC. It has also been found that confusion exists between applying the term 'medicinal product' to only those substances that have received marketing authorisation (i.e. to the exclusion of counterfeit products) or whether it should be applied in terms of the directive.
- For enforcement, removal of a strict definition of a medicinal product (i.e. one with marketing authorisation) will prevent the possibility of prosecution of those who are believed to possess products that do not have a marketing authorisation and/or might be counterfeit

Individuals

- A reduction in the ease of access of anabolic steroids and Human Growth Hormones for personal use will benefit individuals who are damaging their health from abuse of these drugs.

[12] ACMD, Consideration of the Anabolic Steroids, September 2010,

- Ending the use of online and courier services will protect individuals from the potential risks involved in using unrestricted controlled drugs which are imported without being quality checked.
- The expected benefits cannot be quantified as it is not known how many individuals are currently misusing anabolic steroids or Human Growth Hormones nor the number importing them using online/courier services.
- Removal of the term 'medicinal product' will end the confusion over its definition in relation to anabolic steroids and Human Growth Hormones. Confusion over definition could act as a barrier and prevent users from engaging with health services as some users may think that the steroids they possess are unlawful as they are not 'medicinal products' (i.e. not legitimate as they have not been granted a marketing authorisation and/or might be counterfeits).
- An increase in clarity of the legality of the possession of anabolic steroids and Human Growth Hormones will encourage individuals to engage with health services without the fear that they are breaking the law.

Net Effect

- Overall it is considered likely that the benefits from the proposals will outweigh the costs. However, it has not been possible to quantify there benefits and costs. The main benefits to arise from the proposals are:

    - Restricting importation of Schedule 4 Part II drugs to personal custody will reduce the amount of these drugs in circulation and therefore their misuse. This will have an impact on the number of misusers who are likely to need treatment for the adverse effects of experimenting with these drugs. There is therefore a benefit for the wellbeing of users and subsequent savings to the public purse.
    - Restricting importation to personal custody would also mean border officials do not have to undertake unnecessary investigations into each importation. Unaccompanied imports will be detained and destroyed at the ports. This will lead to time savings. Any costs associated with the disposals will be absorbed in existing Border Force contracts for destroying seized goods at the ports.
    - Removing the term "medicinal product" from the legislation will also provide clarity for the public and for enforcement partners. It is also expected that users will be more likely to seek help where adverse reaction occur through the use of counterfeit products. There will be no risk in this instance of prosecution for possessing an unlicensed product. This will ensure immediate access to medical treatment and improve the well being of misusers.

ONE-IN-ONE-OUT (OIOO)

COSTS (INs)

There are no costs envisaged for the third or private sectors or to micro business. Any loss of trade from the shipment of imports of anabolic steroids will apply to businesses in the originating country. Any loss of income as a result of reduced shipments or trade will therefore occur outside of the UK and falls outside the scope of this impact assessment.

Although importation for personal use is permitted under UK legislation, any further supply of anabolic steroids and Human Growth Hormones imported into the UK amounts to the supply of a controlled drug in breach of provisions under the Misuse of Drugs Act 1971. No data exists on further resupply of imported anabolic steroids and Human Growth Hormones within the UK. For the purposes of this impact assessment any loss of trade from such illegal supply has been ignored as such re-supply takes place in contravention of the law.

BENEFITS (OUTs)

No benefits accrue to the third or private sector from this proposal.

NET

N/A

F. Risks

OPTION 2 – Restrict importation and exportation of drugs in Schedule 4 Part II to the 2001 Regulations to personal custody and remove the term "medicinal product" from the 2001 Regulations.

There is no precedent for removal of the term 'medicinal product'. However, legal advisors have confirmed that under the rules on free movement of goods set out in the Treaty on Functioning of the European Union, the changes can be made on the basis of public policy and protection of health and life of human. If the legislation is applied uniformly, as regards nationals of different member states, arbitrary discrimination contrary to the relevant EU law should not arise.

There may be an unexpected cost to UK postal services due to the reduction in use of overseas courier services but this may be absorbed by excess demand.

Reducing the choice for users of anabolic steroids and Human Growth Hormones may encourage them to turn to the 'Black market' where the drugs are illegally produced without the quality checks required for legal production. However, this risk is considered to be low in comparison to the benefits in Option 2 as most users of anabolic steroids are law-abiding citizens.

G. Enforcement

Enforcement of the policy will be undertaken by the UK Border Force who are responsible for maintaining border controls and by police forces.

H. Summary and Recommendations

The table below outlines the costs and benefits of the proposed changes.

Table H.1 Costs and Benefits

Option	Costs	Benefits
2	£- (PV over 10 years)	£- (PV over 10 years)
	Cost to (not quantified) Individuals who will no longer be able to purchase anabolic steroids or Human Growth Hormones online or via courier services.	Benefits to (not quantified) The public sector as UK Border Officials will not have to spend time trying to identify the owner of imported anabolic steroids or Human Growth Hormones. There is expected to be a reduction in the number of individuals presenting with side-effects from these drugs, at a reduced cost to the NHS due to the restriction in availability of the drugs. An increased clarity in the legislation will prevent misinterpretation.

Option 2 is the preferred option. The harms associated with the use/misuse of these drugs require Government to act through effective legislation to protect the public. There are benefits to be derived from implementing the proposal through a reduction in medical needs associated with misuse of these drugs. Those who need these drugs for medical purposes will continue to have access through lawful prescribing and dispensing and will not be impacted by the proposal.

The current provisions can be difficult to enforce. Implementing the proposal will enable the UK Border Force to assess each importation by questioning the importer at the point of importation without having to undertake unnecessarily time consuming and expensive investigations. Besides the “no possession offence”, the current provisions do not provide any other benefits. The current proposal maintains the “no possession offence” in addition to the benefits to the health of users, reduction of healthcare needs and the clarity and enforceability of the legislation.

Although there is a cost to legitimate users, the benefits of the proposals are expected to outweigh this.

I. Implementation

The Government plans to implement these changes on [**Insert Text**].

J. Monitoring and Evaluation

The effectiveness of the new regime would be monitored by the Home Office and the Department of Health through the British Crime Survey.

K. Feedback

Feedback will be sought from the UK Border Force