EXPLANATORY MEMORANDUM TO

THE MEDICINES FOR HUMAN USE (MISCELLANEOUS AMENDMENTS) REGULATIONS 2009
2009 No. 1164

THE MEDICINES FOR HUMAN USE (PRESCRIBING) (MISCELLANEOUS AMENDMENTS) ORDER 2009
2009 No. 1165

THE NATIONAL HEALTH SERVICE (CHARGES) (AMENDMENTS RELATING TO PANDEMIC INFLUENZA) REGULATIONS 2009
2009 No. 1166

1. This explanatory memorandum has been prepared by the Department of Health and the Medicines and Healthcare products Regulatory Agency (MHRA), part of the Department of Health, and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instruments

2.1 These instruments enable special procedures to be put in place to supply pandemic related medicines to the public and to make it easier to bring additional stocks of all medicines into the country should shortages arise. They also ensure that pandemic related medicines for those receiving NHS treatment in respect to pandemic influenza and that NHS hospital services for any overseas visitor who requires treatment for pandemic flu can be provided free of charge. They also amend pharmacist emergency supply provisions at the request of a patient in normal times, as well as a pandemic, to enable 30 days supply of treatment, except for controlled drugs, with certain exceptions.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 These instruments come into force the day after they are made, in breach of the 21 day rule. The purpose of these instruments is to put in place provisions to enable an effective response to a possible influenza pandemic. The National Health Service (Charges) (Amendments Relating To Pandemic Influenza) Regulations 2009 amend regulations which impose certain charges for NHS treatment in England, so as to ensure that NHS treatment in relation to a possible pandemic influenza (in particular the supply of antivirals to the population and hospital treatment for non-UK residents) is provided free of charge. The World Health Organisation (WHO) has recently declared phase 5 of a pandemic influenza alert (human to human spread of the virus in at least 2 countries in one WHO region), indicating that a pandemic influenza is imminent, and there have been a number of cases involving person-to-person transmission in the UK. It is therefore necessary to put in place arrangements to respond to a pandemic as soon as possible.

4. Legislative Context

The Medicines For Human Use (Miscellaneous Amendments) Regulations 2009

4.1 Member States are able, under Article 5(2) of Directive 2001/83/EC (transposed into UK legislation by the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994), to temporarily authorise the distribution of an unauthorised product in response to the suspected or confirmed spread of pathogenic agents (which includes pandemic flu).

4.2 This regulation makes further amendments to the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 which specify that holders of wholesale dealer's licences comply with certain obligations. Holders of wholesale dealer's licences are unable to authorise the wholesale supply of medicinal products authorised for distribution under Article 5(2).

4.3 The Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 specify the requirements for the labelling of relevant medicinal products which are being supplied to patients. These regulations make further amendments to those Regulations to allow for reduced requirements in respect of antiviral medicines in solution for children under one year of age during a pandemic.

4.4 These regulations also amend the Medicines for Human Use (Clinical Trials) Regulations 2004 to allow for notice of urgent safety measures (taken in order to protect the subjects of a clinical trial against any immediate hazard to their health or safety and the circumstances giving rise to those measures) to be given as soon as possible to the licensing authority and an ethics committee during a period in which a disease is pandemic and is a serious risk to human health or potentially a serious risk to human health.

The Medicines For Human Use (Prescribing) (Miscellaneous Amendments) Order 2009

4.4 This Order make further amendments to the Prescription Only Medicines (Human Use) Order 1997 (the POM Order). This specifies the description and classes of medicines ("prescription only medicines" (POMs)) which, subject to exemptions specified in the Order may only be sold or supplied in accordance with the prescription of an "appropriate practitioner", and may be administered only by or in accordance with the directions of such a practitioner (section 58(2) of the Medicines Act 1968).

4.5 The Order further amends the POM Order to enable a pharmacist to make an emergency sale or supply of a prescription only medicine at the request of a dentist who is unable to furnish a prescription immediately and to make an emergency sale or supply of a quantity of a prescription only medicine, except in the case of certain controlled drugs, sufficient to provide up to 30 days' treatment to a person requesting the pharmacist to supply in the absence of a prescription from certain appropriate practitioners. It also amends the POM Order so that in the event of**,** or anticipation of**,** a pandemic disease, a pharmacist need not interview a person before making an emergency sale or supply**,** except in the case of certain controlled drugs**,** at that person's request and need only satisfy himself that the person who is to be treated with a prescription only medicine has been prescribed that medicine before and that the dosage of that medicine is appropriate for that person**.**

4.6 This Order also makes further amendments to the Medicines (Pharmacy and General Sale - Exemption) Order 1980, (the Pharmacy and General Sale Order) which specifies exemptions from the requirements for the sale or supply of POM and Pharmacy (P) medicines (normally only from pharmacies by or under the supervision of a pharmacist) and General Sale List (GSL) medicines (from lockable premises and in original manufacturer packs).

4.7 The Order further amends the POM Order and the Pharmacy and General Sale Order to provide for the supply of a medicine during a pandemic in accordance with a protocol approved by a specified body for the purpose of treating a pandemic disease which is a serious risk to human health or potentially a serious risk to human health.

The National Health Service (Charges) (Amendments Relating To Pandemic Influenza) Regulations 2009

4.8 The National Health Service (Charges) (Amendments Relating to Pandemic Influenza) Regulations 2009 make amendments relating to charges for NHS services, for the purpose of creating new exemptions from in relation to treatment for pandemic influenza. They amend the National Health Service (Charges for Drugs and Appliances) Regulations 2000 ("the 2000 Regulations") and the National Health Service (Charges to Overseas Visitors) Regulations 1989 ("the 1989 Regulations"). The 2000 Regulations prescribe the charges for the supply of a drug or appliance on the NHS in England, the circumstances in which a charge shall, or shall not, be made and the patients who are exempt from such charges. The 1989 Regulations impose charges in respect of the provision of certain NHS treatment to persons who are not ordinarily resident in the United Kingdom, and sets out exemptions from such charges.

5. Territorial Extent and Application

5.1 The Medicines For Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 and the Medicines For Human Use (Miscellaneous Amendments) Regulations 2009 apply to all of the United Kingdom.

5.2 The National Health Service (Charges) (Amendments Relating To Pandemic Influenza) Regulations 2009 apply to England.

6. European Convention on Human Rights

6.1 As the instruments are subject to the negative resolution procedure and do not amend primary legislation, no statement is required.

7. Policy background

- ***What is being done and why***

7.1 The changes form part of the Government's strategy for ensuring the continued availability of and easy access to prescription only medicines for human use and NHS treatment within the UK during an emergency occasioned by a pandemic or in the anticipation of an imminent pandemic. The changes are aimed primarily at the emergence or possible emergence of pandemic influenza but are sufficiently wide to ensure that the arrangements can also be put in place for any anticipated or actual pandemic disease which could pose a serious or potentially serious risk to human health. The arrangements will be kept under review to ensure that they remain appropriate. Further Statutory Instruments may be made at a later date, in order to deal with other aspects of the Government's response to the pandemic.

The Medicines For Human Use (Prescribing) (Miscellaneous Amendments) Order 2009

The Medicines For Human Use (Miscellaneous Amendments) Regulations 2009

7.2 The Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 specify the requirements for the labelling of relevant medicinal products which are supplied to patients. The arrangements for treating symptomatic patients provide for those aged under one year to be supplied with an antiviral solution, which will be reconstituted into a solution by pre-identified hospital pharmacy manufacturing units. These units will provide a dispensing label for the soluble product and a comprehensive leaflet will be provided. Dispensed medicines would normally require a number of details to be added at the time of supply, but much of this information will be available on the label from the hospital manufacturing unit or on the accompanying leaflet. As an antiviral solution dispensed for the treatment of a child under the age of one year will have been supplied specifically for the purpose of treating a disease which is pandemic or is imminently pandemic and either a serious potentially serious risk to human health**,** the policy intention is to enable a reduced dispensing requirement only in these limited circumstances. The Regulations are therefore to be amended to allow for a reduced dispensing labelling requirement to cover the patient's name, date of dispensing,dose volume,and instructions for use.
7.3 Pharmacists can make an emergency sale or supply for a limited treatment period of a POM, including certain controlled drugs, at the request of a doctor, nurse independent prescriber, community practitioner nurse prescriber, pharmacist independent prescriber, optometrist independent prescriber or supplementary prescriber pending the production of a prescription from that prescriber within 72 hours. Furthermore, a pharmacist can make a similar emergency sale or supply in response to a request from a person when that medicine has in the past been prescribed that medicine by one of the prescribers listed above. The opportunity is being taken to rectify to exclusion of dentists who in other aspects of legislation have the same standing as doctors.

7.4 In considering a request for an emergency sale or supply of a POM, including certain controlled drugs, which has been previously prescribed by one of the practitioners listed at paragraph 7.2, a pharmacist is required to have interviewed the person requesting the supply. This requirement would be difficult to maintain during a pandemic when it is likely that medicines will have to be requested and collected on behalf of those that need them. For the period of the pandemic. the pharmacist need only satisfy himself that the person who is to be treated with a prescription only medicine has been prescribed that medicine before and that the dosage of that medicine is appropriate for that person. The Regulations amend the POM Order to enable a pharmacist to make an emergency sale or supply of a quantity of a POM, except in the case of certain controlled drugs, sufficient to provide up to 30 days' treatment during the pandemic and in normal times, more closely reflecting a normal course of treatment.

7.5 Subject to exemptions specified in the POM Order, POMs may only be sold or supplied from a pharmacy by or under the supervision of a pharmacist in accordance with the prescription of an "appropriate practitioner", and may be administered only by or in accordance with the directions of such a practitioner (section 58(2) of the Medicines Act 1968). These Regulations amend the POM Order and Pharmacy and General Sale Order respectively to provide for the supply of medicines during a pandemic, or in anticipation of an imminent pandemic, in accordance with a protocol which contains criteria as to symptoms and treatment and other requirements and which has been approved by a specified body.

The National Health Service (Charges) (Amendments Relating To Pandemic Influenza) Regulations 2009

7.6 The 2000 Regulations provide for charges to be recovered from patients for the supply of drugs or appliances on the NHS in England. The amending instrument amends the Regulations to create a new exemption from charging where drugs are supplied by NHS bodies in response to a pandemic influenza outbreak. The amendment will remove the charge to ensure that drugs such as antivirals can be distributed by Primary Care Trusts free of charge, so there is no additional administrative burden in the process and to ensure that cost is not a barrier to people taking up these medicines.

7.7 The 1989 Regulations provide for charges to be recovered from persons not ordinarily resident in respect of certain NHS treatment in England and Wales, in particular hospital treatment. The amending instrument amends the Regulations, in relation to England, to add pandemic influenza to the list of diseases (such as tuberculosis and Severe Acute Respiratory Syndrome (SARS)) in respect of which no charge is collected. This is to ensure that there is no barrier to overseas visitors in England being given NHS treatment for pandemic influenza thus ensuring that the risk to public health from symptomatic visitors is minimised.

- ***Consolidation***

The Medicines For Human Use (Prescribing) (Miscellaneous Amendments) Order 2009

The Medicines For Human Use (Miscellaneous Amendments) Regulations 2009

7.8 A review of medicines legislation is currently underway. The first stage of the review, will lead to consolidation, is currently underway and that work is expected to be completed in 2010.

The National Health Service (Charges) (Amendments Relating To Pandemic Influenza) Regulations 2009

7.9 In relation to the 2000 Regulations, the charging arrangements in respect of people with long term conditions are currently the subject of a review by Professor Ian Gilmore. The need for consolidation will be considered once Professor Gilmore's recommendations have been considered. Professor Gilmore will report to Ministers in Summer 2009.

7.10 In relation the 1989 Regulations these have already been assessed as in need of consolidation after a number of stand alone amendments in recent years. Consolidated regulations are expected to be laid by the end of the year.

8. Consultation outcome

The Medicines For Human Use (Prescribing) (Miscellaneous Amendments) Order2009

The Medicines For Human Use (Miscellaneous Amendments) Regulations 2009

8.1 The proposed amendments were subject to public consultation and advice from the Commission on Human Medicines (CHM). There were 40 replies to the consultation from professional bodies, from pharmaceutical and other industries, from the NHS and individuals. All were supportive of the proposed amendments to medicines legislation , which were recognised as an appropriate balance betweensafeguarding public health and ensuring that medicines reached those who needed them during the unusual and demanding circumstances of a pandemic.

The National Health Service (Charges) (Amendments Relating To Pandemic Influenza) Regulations 2009

8.2 There has been no consultation on these Regulations.

9. Guidance

9.1 The Department of Health is providing guidance to those who will be involved in the operation of these changes. Guidance is being issued on the operation of the Assessment & Collection Centres, which will handle antiviral distribution to the public. Protocols have been developed for assessment of symptomatic patients and supply of antiviral medicines. These are being provided directly to named contacts for onward cascade, but will be published on the

Department of Health website as soon as this can be arranged. Specific guidance is being prepared for pharmacists and it is hoped to arrange publication shortly.

10. Impact

10.1 The Medicines For Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 and the Medicines For Human Use (Miscellaneous Amendments) Regulations 2009 impact on business, charities or voluntary bodies is principally to benefit patient care by maintaining the continued manufacture and supply of medicines and by providing improved access by patients to the medicines they require. The National Health Service (Charges) (Amendments Relating To Pandemic Influenza) Regulations 2009 have no impact on business, charities or voluntary bodies.

10.2 The impact on the public sector is to enable the health service to make fully flexible use of its staff at a time when staff numbers able to work because of sickness may be reduced and increased public demand for the service for the same reason. The changes also benefit patient care by maintaining the continued manufacture and supply of medicines and by providing improved access by patients to the medicines they require

10.3 An Impact Assessment is attached to this memorandum for the medicines legislation changes. An Impact Assessment has not been prepared for The National Health Service (Charges) (Amendments Relating To Pandemic Influenza) Regulations 2009.

11. Regulating small business

11.1 The legislation is not expected to generate any additional costs to small business. There were no significant affects on the costs of compliance to businesses and no adverse impact on any competition, equality or environmental issues

12. Monitoring & review

12.1 The Department of Health and the MHRA will monitor these provisions for their effectiveness in supporting the health service response to a pandemic and review them once pandemic alert levels have returned to normal.

13. Contact

13.1 Anne Thyer at the MHRA (tel: 0207 084 2642, or e-mail: anne.thyer@mhra.gsi.gov.uk) can answer any queries regarding the Medicines For Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 and The Medicines For Human Use (Miscellaneous Amendments) Regulations 2009 .

13.2 In relation to The National Health Service (Charges) (Amendments Relating To Pandemic Influenza) Regulations 2009 as they amend the National Health Service (Charges for Drugs and Appliances) Regulations 2000, Eleanor Shenton at the Department of Health Tel: 020 7972 2923 or e-mail: eleanor.shenton@dh.gsi.gov.uk can answer any queries regarding the instrument

13.3 In relation to The National Health Service (Charges) (Amendments Relating To Pandemic Influenza) Regulations 2009 as they amend The National Health Service (Charges to Overseas Visitors) Regulations 1989, David Pennington at the Department of Health Tel: 0113 254 5257 or e-mail: david.pennington@dh.gsi.gov.uk can answer any queries regarding the instrument

Summary: Intervention & Options

Department /Agency:	Title:	
MHRA/DH	Impact Assessment of maintaining acess to medicines in the event of a pandemic	
Stage: Final	**Version:** Final	**Date:** 4 May 2009
Related Publications: DH National Framework for Responding to an Inflenza Pandemic		

Available to view or download at:

http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/index.htm

Contact for enquiries: Anne Thyer **Telephone:** 020 7084 2642

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

In the event of a pandemic it is likely that a vastly increased number of people will contact NHS services for advice, diagnosis, treatment and medicines, in particular antivirals. The UK currently has a stockpile of antivirals for 50% of the population, but other medicines could become in short supply. Estimates suggest that a pandemic could, in one way or another, affect up to 50% of the population. Special measure are therefore required to safeguard supplies of medicines and their availability to those that need them during a pandemic.

What are the policy objectives and the intended effects?

to ensure the continued supply of medicines and easy access for those that need them during a pandemic through legislative changes and streamlined working processess and to make corresponding amendmdnts to NHS Pharmaceutical services regulations to support those arrangements.

What policy options have been considered? Please justify any preferred option.

Option 1: No action - this would result in severe impact on availability of medicines. Option 2a & 2b: proposed amendments to selected legislation to ensure flexibility across a range of medicines legislation during a pandemic, coupled with changes to processes and procedures to support those flexibilities. Option 3-6 in combination: Lift all legislation covering the supply of medicines and health consumables; issue guidance for local Primary Care Organisations' action; identify Contractor Service Continuity Planning Action or expand prescribing flexibilities for community nurses.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

the policy will be reviewed on a regular basis to ensure arrangements remain appropriate for deading with an actual or threatened pandemic

Ministerial Sign-off For Final Stage Impact Assessments:

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:

Dawn Primarolo .....Date: ***6th May 2009***

Summary: Analysis & Evidence

Policy Option: Option 2	Description: chnages in medicines legislation to enable supply of medicines via national "flu line"

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	Costs included in the DH national flu service business case. Not provided due to "commercial confidentiality"
£	
Average Annual Cost (excluding one-off)	
£	**Total Cost** (PV) **£**

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

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**	Patients: Health benefit of antiviral supply : Health benefit of continued supply of medicines to those that need them
£	
Average Annual Benefit (excluding one-off)	
£ 31.5bn	**Total Benefit** (PV) **£ 31.5bn**

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

the main benefit is in terms of continued supply of medicines to those affected by pandemic flu which in turn will reduce costs on emergency treatment by the NHS

Key Assumptions/Sensitivities/Risks

Assumption is that up to 50% of population could be affected by pandemic flu or the impact of the pandemic. This could result in shortages of medicines or difficulties in distribution due to depleted workforce in NHS or pharmaceutical industries

Price Base Year 0	Time Period Years	**Net Benefit Range** (NPV) **£**	**NET BENEFIT** (NPV Best estimate) **£**

What is the geographic coverage of the policy/option?				UK	
On what date will the policy be implemented?				when required	
Which organisation(s) will enforce the policy?				DH/MHRA	
What is the total annual cost of enforcement for these organisations?				£ n/k	
Does enforcement comply with Hampton principles?				Yes	
Will implementation go beyond minimum EU requirements?				No	
What is the value of the proposed offsetting measure per year?				£ N/A	
What is the value of changes in greenhouse gas emissions?				£ N?A	
Will the proposal have a significant impact on competition?				No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large	
Are any of these organisations exempt?	No	No	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** £ N/A

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

INTRODUCTION

1. Influenza pandemics (pandemic flu) are natural phenomena that tend to occur two or three times each century. Their severity has ranged from something similar to seasonal flu to a major threat, with many millions of people worldwide becoming ill and a large proportion of these dying (such as the "Spanish Flu" of 1918/19). No country can expect to escape the impact of a pandemic entirely. When it arrives, most people are likely to be exposed to an increased risk of catching the virus at some point. Influenza pandemics therefore pose a unique international and national challenge. As well as their potential to cause serious harm to human health, they threaten wider social and economic damage and disruption as large numbers of people become ill and/or need to care for members of their household who are ill and are consequently unable to pursue their normal activities. Measures to prevent, detect and control pandemics require coordinated international effort and cooperation. One country's action – or inaction – potentially affects many others.

2. Although it is highly likely that another influenza pandemic will occur at some time, it is impossible to forecast its exact timing or the precise nature of its impact. This uncertainty is one of the main challenges for policy makers and planners. Even if – as seems likely – a pandemic originates abroad, it will probably affect the UK within two to four weeks of becoming an epidemic in its country of origin. It could then take only one or two more weeks to spread to all major population centres here.

3. A key element in the planned UK response to an influenza pandemic is to provide affected people with medication to mitigate the effects of the virus, treat complications arising from sickness with the virus and ensure that those who need medicines to treat other conditions can continue to receive them. This Impact Assessment outlines the options we have examined to maintain people's access to key medicines during a pandemic flu and assesses our favoured options.

4. This document should be read in conjunction with the "National Framework for responding to an influenza pandemic" (and related clinical guidelines) which sets out the likely pandemic planning assumptions to deal with the health and social aspects. To see the full Framework visit the website http://dh.gov.uk/pandemicflu

5. A pandemic flu is likely to place enormous pressure on the health and social care system. This pressure will include the mass distribution of flu related medicines, primarily antivirals via the National Flu-Line or the mass administration of vaccines (when they become available). At the same time, people with long term and chronic illness - some of which can be exacerbated by flu - are often dependent on their medicines to maintain a stable life. Any disruption to their supply may lead to deterioration in their conditions. This could mean higher rates of emergency call outs or hospital admissions for non-flu related illness. In addition, key health and social care staff may be asked to prioritise services for those who are seriously ill over those who need routine appointments (e.g. for repeat prescriptions) and alternatives will be needed to support those who need those routine appointments. A pandemic may also affect the normal supply chain for delivery of medicinal products.

PURPOSE AND INTENT

6. The key aim is to ensure that people have ready access to the medicines they need and that they can access them safely. This will enable health and social care workers to support patients within the law in the complex and difficult circumstances of a pandemic flu. The changes outlined in this Impact Assessment will operate only in the event of a pandemic or as a result of a pandemic outside the UK having a potential or actual detrimental effect on the supply of medicines within the UK.

7. This document outlines the options considered, the assumptions made and the costs and benefits concluded for our favoured option (both the monetised and non-monetised).

BACKGROUND

8. In normal situations, patients access primary care (such as their GP, key health worker or high street pharmacy) safely and effectively through a variety of tried and trusted processes. In each of these processes, health and social care workers are guided by professional codes and legal frameworks in their care and support of patients. However, in the event of a pandemic flu, both access to, and use of, these services would be under intense pressure

9. The UK's preparedness plans are based on modelling where up to half the population could become infected during the course of the pandemic flu, which might last fifteen weeks and could be followed by shorter outbreaks. Therefore we can expect some health and social care professionals to be ill themselves or away from work caring for their families. In order to make the best use of the resources available to the population, those health professionals able to work will need to focus their time on those who are most ill.

RATIONALE FOR GOVERNMENT INTERVENTION

10. It is believed that these factors will create pressure on current processes both from increased demand for services and from staff shortages. With no action taken, the Department of Health believes there might be significant delays for some patients in accessing advice and essential medicines, or they may not be able to access them at all during the peak period of a pandemic flu. This would create distress and ill health for patients and still further pressure on the infrastructure of the NHS. It is also believed that health and social care staff might, with the best intentions, breach regulations or professional guidance in order to supply medicines and healthcare products, leaving themselves personally liable. We want to create maximum flexibility within a safe framework which enables health services to draw on all the staff resources available to it to provide the care that the public needs.

11. A key part of the health response to a flu pandemic is the provision of antiviral medicines for those affected and the Government has stockpiled these. The Department of Health has identified that special arrangements are needed for the supply of these medicines to the public so as to complement rather than further disrupt local healthcare arrangements and to make the minimum necessary use of healthcare professionals.

OPTIONS

12. The Department initially examined five options based on a planning assumption that a pandemic influenza would have an infection rate of between 25-50% (previous pandemics have had an infection rate of between 25-35% of population):-

- Option 1 Do not act
- Option 2 Proposed amendments to selected legislation
    i. 2a : Changes in medicines legislation to enable supply of medicines via national flu line
    ii. 2b Limited amendments to medicines legislation concerning manufacture, distribution, changes to marketing authorisations and supply of medicines, including controlled drugs, during a pandemic
- Option 3 Lift all legislation covering the supply of medicines and health consumables
- Option 4 In combination with option 3, issue guidance for local Primary Care Organisations' action

- Option 5 In combination with option 3, identify Contractor Service Continuity Planning Action

- Option 6 Amend medicines legislation to introduce/expand prescribing flexibilities for community nurses

13. Option 2 was determined within the Department of Health as the only option offering benefits, within acceptable monetary and non-monetary costs, on the basis that the pandemic flu infection rate will not exceed 50% of the population. (In the unlikely event of an infection rate beyond 50% there may be a need for civil contingency action.) Broadly, it was felt that this was the only option which would ensure a coherent national system with sufficient safeguards in place to enable the health services to cope with significant additional demands on resources at a time when those resources are depleted by staff absence. The possible amendments in Option 2 were supported during the initial consultation from November 2007 – February 2008, although some new proposals have subsequently been developed. No responses received in response to the 2007/08 consultation supported any of the other options which were outlined in the Impact Assessment attached to that consultation. Options 3-5 were considered to wide-ranging to properly safeguard public health even in a pandemic and that the non-quantified risks were disproportionate.

14. The MHRA, with the Department of Health and the Home Office, are proposing a number of specific amendments to legislation, following the initial consultation between November 2007 and February 2008. The proposed amendments in this second consultation are based on the responses from external stakeholders to the 2007/2008 consultation. The proposed amendments are in the areas of maintaining supplies of essential medicines, medical devices and health consumables, introducing flexibilities around manufacturing, inspections, dispensing and supply of medicines, reviewing and providing guidance on regulations relating to controlled drugs and facilitating the mass distribution of flu related medicines to people who are showing symptoms of flu.

15. The specific proposals for amendments to legislation supported following the 2007-2008 consultation and taken forward in this consultation are set out below.

Measures providing access to stockpiled medicines

A. prescription only medicines can be supplied without a prescription and need not be supplied from registered pharmacy premises – This allows, for example, the flu-line to authorise the supply of antivirals and enables antiviral collection centres to operate from premises which are not pharmacies.

The Department of Health in England and the Devolved Administrations plan to set up a National Flu Line service to enable symptomatic patients to have rapid access to antiviral treatment. The key functions of the National Flu Line service will be to:

1. provide callers with access to automated information on pandemic-related issues
2. assess callers to determine their eligibility for antiviral medicine treatment (ie whether they are symptomatic and can take the first dose within 48 hours of onset of symptoms)
3. authorise antiviral medicine treatment if appropriate
4. refer eligible callers (in practice collection will be by a family member, friend or carer of the patient) to an antiviral collection point to collect the patient's antiviral medicine, or to another part of the

health and social care system, as appropriate (eg where the caller has further higher-level needs).

B. expand the current legislation to enable businesses to extend the scope of their Occupational Health Schemes, if they wish, to supply anti-viral medicines to members of the households of their employees

Measures easing access to essential medicines

A. introduce a provision to introduce some changes to legislation to ease medicines supply prior to a pandemic being declared in the UK – as other countries on whom we rely for supplies of medicines or medicinal substances may be affected before the UK

B. enable the pandemic arrangements to remain in place for 6 – 9 months after a pandemic has ended in the UK with quicker return to normal for some medicines If required **–** this allows time for the pharmaceutical supply chain to recover to normal but enables the earlier full regulation of medicines where that is to the benefit of patients and public health.

C. enable wholesale dealers to supply unlicensed medicines if equivalents with UK licences run out

D. streamline processes for receiving, assessing and authorising a range of variations to licences issued by the MHRA – this will enable variations which ease supply problems to be implemented quickly while retaining legal safeguards on the safety and quality of medicines

E. enable certain prescription only medicines to be supplied without a prescription and to be supplied from premises other than registered pharmacy premises – this could enable any locally held supplies to be made available to patients who need them under arrangements made by local NHS bodies

F. allow supply of expired and returned medicines – this gives pharmacists the option of making supplies go further by giving patients medicines which are past their licensed expiry date or which have been returned to the pharmacy by a patient who no longer requires them. This would be at the pharmacist's discretion and they will be given guidance to help them use that discretion

G. allow prescription only quantities of medicines to be supplied through combination of pharmacy and General Sales List packs – this gives pharmacists more flexibility in being able to supply prescription only quantities of medicines where supplies were in shortage

H. allow a pharmacist to reach a decision about emergency supply of medicines during an influenza pandemic without the need to have interviewed the patient. (This proposal is in additon to the permanent changes proposed in paragraph 16 below but will apply only for the period of the pandemic.)

I. A number of proposals governing the supply of controlled drugs during an influenza pandemic, eg diamorphine, methadone:

a. Extend repeat dispensing to Schedule 2 and 3, the first supply to be made within 28 days at prescriber's discretion

b. discretion to supply contrary to the instalment prescription but only in certain respects, e.g. the intervals at which the dosages can be supplied

c. allow emergency supply of controlled drugs (5 days for Schedule 2 and 3 and up to 30 days for Schedule 4 and 5) by pharmacists

d. allow a doctor to administer, prescribe and/or supply diamorphine for the management of addiction without a Home Office licence -

e. controlled drugs must, so far as circumstances permit, be kept in a locked cabinet or safe that shall be securely fixed to a wall or floor but the remaining requirements of Schedule 2 of 1973 Regulations do not apply.

J. A number of proposals for changes to arrangements for NHS pharmaceutical services in England and Wales. (NB: These changes are subject to separate legislation and are not dealth with in this IA.):

a. RPSGB to register alternative premises as temporary registered pharmacy premises

b. the Annual Return due in January will be replaced by a commitment to submit the Return within 6 weeks of the announcement of the end of the pandemic emergency

c. allow a contractor to notify the appropriate Primary Care Trust (PCT) of alternative registered temporary pharmacy premises

d. contractors may vary their hours or temporarily to suspend all provision of NHS services provided they give 24 hours' prior notice to the PCT

Proposals to permanently amend legislation governing the emergency supply of medicines (and not restricted to an influenza pandemic)

16. Following support from the 2007-2008 consultation that permanent changes should be made to legislation covering the emergency supply of medicines, the proposals are to

a. allow supply for up to 30 days

b. enable dentists to request emergency supply

BENEFITS AND COSTS

17. The costs and benefits of the 2007-2008 proposals for changes to medicines legislation in the event of a pandemic flu outbreak were evaluated in a previous document: "Possible amendments to medicines and associated legislation during an influenza pandemic" published in November 2007 [http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_080768

18. Since this evaluation, the proposals have been modified. However it is not expected that changes in the proposals will result in significantly different net impacts.

19. This section explains the costs and benefits expected to arise from the current proposals, and makes reference to the previous evaluation, where appropriate, in order to indicate the expected magnitudes of these effects.

Summary of benefits and costs

20. By convention, all impacts affecting government expenditure are reckoned as costs. All other impacts are accounted as benefits. The large number of proposed amendments to legislation are expected to have two main beneficial impacts. First, they will enable rapid

delivery of the UK stockpile of anti-viral medicines. Second, they will ameliorate expected problems for patients in accessing other medicines needed in a flu outbreak, and medicines unrelated to flu. In addition to these positive benefits, relaxing the current legislative constraints on supply of medicines could have some offsetting negative health consequences.

21. The main cost impacts are the expenses incurred in allowing access to the stockpile of anti-viral medicines, and the secondary implications of relaxing medicines supply restrictions on NHS spending.

Benefits

22. By convention, all policy impacts except those affecting government expenditure are accounted as benefits.

Benefits of delivering the anti-viral stockpile

23. The health benefit of delivering the UK stockpile of anti-viral medicines has previously been estimated at **£64 bn**[1]. Under standard assumptions for the magnitude and timing of the outbreak, this benefit has previously been estimated to correspond with a present value of **£31 bn** ["Possible amendments to medicines and associated legislation during an influenza pandemic" published in November 2007 [http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_080768].

24. It is considered reasonable to regard the impact of the measures proposed in this document as enabling the health benefits of the anti-viral stockpile to be realised, because without them it could not be delivered. However this implies that any previous stages in this process (eg purchasing the stockpile) had zero health benefit – because the stockpile could not have been delivered without the provisions discussed here. It would be better practice to aggregate all the costs implied in anti-viral provision, in order to avoid double-counting of the resulting health benefits.

25.

26. Further health benefits will result from freeing capacity in the NHS that would otherwise be engaged in ensuring flu medicines are supplied.

Benefits of maintaining access to other medicines

27. Measures proposed for easing restrictions on the supply of other medicines will benefit patients who would otherwise be unable to access treatments they need. It has previously been estimated that these measure would lead to the restoration of at least **10%** of the pre-outbreak level of medicines supply, corresponding to a present value of **£260m** [: "Possible amendments to medicines and associated legislation during an influenza pandemic" published in November 2007 [http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_080768]].

[1] DH Pre-Pandemic Flu Business case, Annex B. Assumptions: clinical attack rate 25%; antiviral effective; no effective vaccination. This analysis assumes that the allocation of antiviral according to this system is as expected in the previous calculation – i.e. that the antivirals will not be mis-allocated by the flu line and occupational health services, in comparison to the allocation system assumed previously.

28. Besides the positive health benefit of enabling access to medicines, measures that will relax restrictions on the supply of drugs could have some negative consequences. These negative impacts have not been quantified.

29. Possible negative impacts include

- More medication errors, leading to additional health problems for patients
- Patients receive medication packs with which they are not familiar
- Loss of some patient safeguards
- Patients use revised procedures to stockpile medicines

Costs

30. By convention, impacts affecting government spending are accounted as costs.

Costs of enabling access to anti-viral medicines

31. The costs of providing access to the stockpile of anti-viral medicines have not been provided as they are commercially sensitive

Costs of enabling access to other medicines

32. The proposals for lifting constraints on supply of other medicines are expected to incur additional costs for the NHS. These have not been evaluated in detail as the costs are commercially sensitive.

33. Possible costs include

- Payments to pharmacies, who must sustain costs of changed supply mechanisms
- Prescription Pricing Division administration costs
- Higher unit costs as pharmacies use smaller pack sizes
- Additional healthcare interventions required because of medication errors

Outcome of consultation

33. Forty (40) replies were received to the public consultation. All were supportive of the proposals which were regarded as an appropriate balance between safeguarding public health and ensuring that medicines reached those that needed them during the unusual and demanding circumstances of a pandemic. The consultation ended before the recent emergence of swine flu but this has evidenced the need for the arrangements proposed in the original consulations.

34. None of the proposals in the consultation were regarded as having a adverse effect on any equality issue as they are aimed at ensuring a continued supply of medicines to the UK population during the emergency situation of a pandemic. Specific details are set out in the following paragraphs.

Small Firms Impact Test

35. Small business are not considered to be disadvantaged by the proposals as they enable businesses involved with all aspects of medicines and devices for human use to continue to undertake their normal business during a pandemic with streamlined regulatory processes.

Competition Assessment

36. The proposals are not considered to have any actual or potential impact on business competition as they enable businesses involved with all aspects of medicines and devices for human use to continue to undertake their normal business during a pandemic with streamlined regulatory processes.

Equality Impact Assessment:

37. No Equality Impact Assessment is required as the proposed policy has no disproportionate impact on race or other relevant equalities. The proposed policy will not have any disproportionate impact on rural populations.

Legal Aid, Sustainable Developments, Carbon assessment, other environmental issues

38. There are no impacts on environmental, sustainable development or carbon offsetting from these proposals. There are no implications for Legal Aid from these proposals.

Post-implementation review

39. These proposals will be kept under review to ensure that they remain fit for purpose in ensuring the continued availability of medicines during a pandemic. In addition they will be reviewed at the cessation of pandemic.

Summary and Recommendations

40. Option 2 was determined within the Department of Health as the only option offering benefits, within acceptable monetary and non-monetary costs, on the basis that the pandemic flu infection rate will not exceed 50% of the population. (In the unlikely event of an infection rate beyond 50% there may be a need for civil contingency action.) Broadly, it was felt that this was the only option which would ensure a coherent national system with sufficient safeguards in place to enable the health services to cope with significant additional demands on resources at a time when those resources are depleted by staff absence

Specific Impact Tests: Checklist

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	Yes	No
Sustainable Development	Yes	No
Carbon Assessment	Yes	No
Other Environment	Yes	No
Health Impact Assessment	Yes	No
Race Equality	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	Yes	No
Rural Proofing	Yes	No

Annexes

None