| Title: | Impact Assessment (IA) |
|---|---|
| Introduction of the New Medicine Service | **Date:** 02/09/2011 |
| **IA No:** 5101 | **Stage:** Final |
| **Lead department or agency:** | **Source of intervention:** Domestic |
| Department of Health | **Type of measure:** Secondary legislation |
| **Other departments or agencies:** | |
| NHS Employers | |

## Summary: Intervention and Options

**RPC:** 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** |
| £1500m | £m | £m | No | NA |

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

Around 15 million people have a long-term condition (LTC) in England. LTCs are those conditions that cannot be cured but that can be managed to alleviate symptoms, to reduce exacerbation, relapse, and to reduce other longer-term complications. The optimal use of medicines is vital to the self-management of most LTCs, but reviews conducted across disease states and countries are consistent in estimating that around 50 per cent of medicines prescribed for LTCs are not taken as recommended. This represents a failure to translate the technological benefits of new medicines into health gain. Sub-optimal medicines use can lead to inadequate management of the LTC and a cost to the patient, the NHS and society.

**What are the policy objectives and the intended effects?**

The policy objective is for a New Medicine Service (NMS) to help people prescribed a new medicine for certain LTCs to manage their LTC and to improve their medication adherence through providing further clinical support at the outset of taking new medication in keeping with overall government health policy to involve patients in shared decision making and to optimise medicines use. The intended effects are to improve patients' medicines adherence, patients' understanding of medicines, patients' engagement with their condition, and health outcomes; as well as reducing health inequalities, and medicines wastage. By achieving the above, it is anticipated that cost savings can also be generated within the NHS.

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

**1) Do nothing;**

**2) Introduce a New Medicine Service (NMS) for new medicines prescribed for a restricted number of long-term conditions, over an initial period of October 2011 to March 2013, as an Advanced Service in the Community Pharmacy Contractual Framework. A full evaluation of the NMS will also be conducted.**

Option 2) is the preferred option as it is consistent with the aims of a coherent medicines policy to increase patient access and improve value for money. It is also consistent with the "Equity and Excellence: Liberating the NHS" white paper to expand the role of pharmacists, enhance shared decision making and to optimise medicines use. The policy design and the sub-set of conditions covered reflect evidence from proof of concept research, and an aim to maximise the short-term gains for patients and the health service from a group of key conditions. An evaluation will inform future decisions on the service.

**Will the policy be reviewed?** It will be reviewed. **If applicable, set review date:** 03/2013

| | | | | | |
|---|---|---|---|---|---|
| Does implementation go beyond minimum EU requirements? | | | N/A | | |
| 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 CO2 equivalent change in greenhouse gas emissions? (Million tonnes CO2 equivalent) | | | **Traded:** N/A | **Non-traded:** N/A | |

***I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.***

Signed by the responsible Minister: Howe Date: 19.9.11



URN 11/1109 Ver. 3.0

# Summary: Analysis & Evidence

Policy Option 1

**Description:** Do Nothing (by definition, all sections are left blank for the do nothing option)

**FULL ECONOMIC ASSESSMENT**

| Price Base Year | PV Base Year | Time Period Years | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low:** 0 | **High:** 0 | **Best Estimate:** 0 |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| **Low** | 0 | | 0 | **0** |
| **High** | 0 | | 0 | **0** |
| **Best Estimate** | | | | |

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

As this is the "do nothing" option, there are no key monetised costs.

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

As this is the "do nothing" option, there are no other key non-monetised costs.

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| **Low** | 0 | | 0 | **0** |
| **High** | 0 | | 0 | **0** |
| **Best Estimate** | | | | |

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

As this is the "do nothing" option, there are no key monetised benefits.

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

As this is the "do nothing" option, there are no other key non-monetised benefits.

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

As this is the "do nothing" option there has been no need to address any key assumptions, sensitivites, and risks in respect of the status quo.

**BUSINESS ASSESSMENT (Option 1)**

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

# Summary: Analysis & Evidence

Policy Option 2

**Description: Introduce the New Medicine Service for an initial period (October 2011 to March 2013 - but monetised for ten years) for patients prescribed a new medicine for a limited number of (long-term) conditions.**

**FULL ECONOMIC ASSESSMENT**

| Price Base Year **2011** | PV Base Year **2011** | **Time Period Years** 10 | **Net Benefit (Present Value (PV)) (£m)** | | |
|---|---|---|---|---|---|
| | | | **Low:** 210 | **High:** | **Best Estimate:** 1500 |

| **COSTS (£m)** | **Total Transition** (Constant Price) | Years | **Average Annual** (excl. Transition) (Constant Price) | **Total Cost** (Present Value) |
|---|---|---|---|---|
| **Low** | 4.5 | 1.5 | 55 | **465** |
| **High** | 8.6 | | 80 | **667** |
| **Best Estimate** | 7.4 | | 63 | 532 |

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

The key monetised costs are the NMS implementation cost and the NMS activity costs. The transitional costs are conditional implementation payments that are available from 1 October 2011 to 31 March 2012. These are estimated to be £7 million in the central scenario. In addition, there are NMS activity payments, driven by the level of NMS activity in community pharmacy. These are estimated to be a maximum of £55 million in the first full financial year of roll out.

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

There are no key non-monetised costs.

| **BENEFITS (£m)** | **Total Transition** (Constant Price) | Years | **Average Annual** (excl. Transition) (Constant Price) | **Total Benefit** (Present Value) |
|---|---|---|---|---|
| **Low** | 0 | 0 | 105 | **880** |
| **High** | 0 | | 275 | **2300** |
| **Best Estimate** | 0 | | 238 | 2000 |

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

The key monetised benefit is the reduction in the use of, and thus cost savings from, NHS resources as a direct result of the New Medicine Service. The NMS is expected to lead to lower use of NHS resources such as GP consultations, accident and emergency episodes, and hospital admissions. An academic study estimated this to be a £95.10 cost saving on average. This benefit is limited to the length of time that this impact was measured in the research (two months), per intervention.

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

Key non-monetised health benefits include the potential health gain in NMS patients as a direct result of the NMS. Health gain could potentially be measured in QALY terms. Other non-monetised benefits include a potential reduction in health inequalities, and the generation of better interprofessional relationships within the health service.

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

* 85 per cent of all community pharmacies are ready, willing, and able to deliver the NMS by 31 March 2012, and are paid £750 when meeting the criteria in this timeframe.
* An average of 0.5% of all prescriptions that are brought into a community pharmacy are eligible for the NMS.
* Pharmacies are paid by target activity bands (at an equivalent of £25 per service).
* The mean benefit is £95.10 per NMS delivered (derived over the period of NMS provision)

**BUSINESS ASSESSMENT (Option 1)**

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

**Problem under consideration:**

Just over £100 billion was spent on the NHS in England in 2009/10 (Source: HM Treasury Public Expenditure Statistical Analyses 2011, Table 1.8). A significant proportion of this expenditure, around 10 per cent, was spent on medicines (Source: NHS Prescription Cost Analysis 2010, NHS Information Centre). In the wider context, the NHS is in the midst of a Quality, Innovation, Productivity and Prevention (QIPP) challenge to improve the quality of care the NHS delivers whilst making up to £20 billion of efficiency savings by 2014-15, which will be reinvested in frontline care. This is necessary in the light of demographic change, an increased disease burden, and the current fiscal environment.

The Department of Health (England) policy on medicines and pharmacy covers every step of the journey from the development of medicines to their use by the patient. There is a coherent medicines policy to increase patient access and improve value for money. The "Equity and Excellence: Liberating the NHS" white paper highlights the need to involve patients in shared decision-making, and to expand the role of pharmacists in optimising medicines use. Optimisation of medicines use is an important element in the delivery of a coherent medicines policy. In practice, this includes looking to address the problems associated with poor medicines adherence and medicines waste.

Non-adherence to medicines use can be classified into two categories – "intentional" and "unintentional" non-adherence (NICE Clinical Guideline 76). Intentional non-adherence is defined as a situation where a patient decides not to follow the treatment recommendations, whilst unintentional non-adherence relates to where a patient has problems following a treatment plan despite their wish to do so. In general, non-adherence by patients is linked to patients' beliefs and preferences. This can include practical factors as well as the motivation to start and continue a treatment plan. Furthermore, a patient may have changing views about their need for a medicine over time. This could be driven by the side effects of a medicine, or the failure to see demonstrable improvements in their condition. On the latter point, this could be related to not being able to observe clinically measurable improvements (e.g. a sustained reduction in blood pressure) easily. Clinical guidance from the pharmacy regulator (formerly the RPSGB, now the GPhC) makes it clear that non-adherence "should not be seen as the patient's problem." In summary, non-adherence to medicines represents a potential failure to translate the technological benefits of new medicines into health gain for individuals.

A survey by the Picker Institute (2007) has reported that only 58 per cent of primary care patients who were prescribed new medicines in 2006 were given enough information about the potential side effects from medicines. Other evidence indicates that, in developed countries, adherence to medication for LTCs is around 50 per cent (WHO, 2003 – also citing earlier studies), leading to the view that "Poor adherence to treatment of chronic diseases is a worldwide problem of striking magnitude." and "It is undeniable that many patients experience difficulty in following treatment recommendations." As the burden of LTCs increases, the impact of poor medicine adherence is likely to grow.

In respect of medicines waste, a report published by the York Health Economics Consortium and the School of Pharmacy at the University of London has found that unused prescription medicines in primary care costs the NHS at least £300m million a year in England 2009, but not all of this is avoidable. The researchers estimate that £150m of the medicines waste is avoidable.

***Long-Term Conditions (LTC's):***

There is a significant demand for medicines from people who have one, or multiple, long-term conditions (LTC). The General Household Survey (General Lifestyle Survey) indicates that around 15 million people have a long-term condition (LTC) in England. LTCs are those conditions that cannot, at present, be cured, but can be managed by medication and other therapies. The number of people in England with at least one LTC is expected to increase by a small amount over the next ten years. However, the distribution of those with a LTC is expected to change, as it is forecast that more people will have multiple LTCs in the future. People with LTCs use disproportionately more primary and secondary care services, thus the burden on these services is set to increase in line with the projected trend increase in the prevalence of LTCs in the population.

Sub-optimal medicines use can lead to inadequate management of LTCs and a cost to the patient, the NHS and society. In the United States, it was estimated by the National Pharmaceutical Council that the cost of illness due to non-adherence was $100 billion per annum as far back as 1993, which has been described as the nation's "other drug problem" (US National Pharmaceutical Council, 1993). The cost of illness due to non-adherence was estimated at $8 billion in 1998 in Canada (Coambs RB, et al., 1998). In the UK, it has been estimated that preventable medicines-related hospital admissions represent around 4-5% of all hospital admissions (Pirmohamed M et al., 2004).

Although an LTC cannot be cured, it can potentially be managed by medication and other therapies to provide patients with improved quality of life. Well-integrated and tailored medicines use information for people newly diagnosed with an LTC and improved medicine taking will improve quality of life, as well as health and wellbeing in individuals.

***The potential role of pharmacists in managing LTC's***

One of the delivery mechanisms for supporting LTC management is pharmacies. Individuals who use medicines to manage their LTC routinely and repeatedly have their medicines dispensed by a pharmacy.

The NICE clinical guidance (76) advocates "Involving patients in decisions about medicines", through increasing patient involvement, via better communication, more information, as well as working closely with the patient to understand the patient's perspective. In addition, it is suggested that pharmacists are active in "supporting adherence", through the assessment of adherence levels and interventions used to increase medicines adherence in patients. Moreover, the WHO report on adherence to long-term therapies notes that poor adherence to medicines provided for long-term conditions lead to "…poor health outcomes and increased health care costs." and that adherence oriented interventions "…would provide a significant positive return on investment…" In summary, better adherence of medicines can lead to better management of conditions, better health and well-being, better quality of life, and lower use of health services.

There is research evidence that a well-designed pharmacy care programme can have significant positive impact in supporting medicines adherence in people with chronic conditions. Lee JK et al (2006) undertook a multiphase, prospective study with 200 community-based patients aged 65 years or over taking at least four chronic medications. Their study included a phase of personalised medicines education, provision of an "adherence aid" (blister packs), and follow-up interventions conducted by clinical pharmacists. Blood pressure (BP) and low-density lipoprotein (LDL-C) were measured. As a next step, patients were randomised either to continue with this form of support, or to return to a baseline of usual care. The authors found that a comprehensive pharmacy care programme resulted in "substantial and sustained improvements in medication adherence among elderly patients receiving complex medication regimens." Over the study period, the authors identified improvements in levels of BP and LDL-C among patients that indicated that care programmes of this type "could lead to meaningful improvements in health outcomes." Another finding of the study was that the control group, despite showing a marked improvement whilst receiving additional care, moved closer towards their baseline adherence levels by the end of the study.

***Proof of concept research:***

There is also evidence to suggest that non-adherence to new medications for chronic conditions improve if patients are provided with support from an early stage of their diagnosis, (Barber N et al, 2004). A group of academics have undertaken some "proof of concept" research in two phases, with the first study focusing on the design of a pharmacy advice service. The second study analysed some financial/economic outcomes of providing a pharmacy advice service. First, Clifford et al. (2006) undertook some research to "assess the effects of pharmacists giving advice to meet patients' needs after starting a new medicine for a chronic condition." This involved identifying eligible patients, in this case patients in receipt of a first prescription for a new drug for a chronic condition, who were aged 75 years or older, and have had a stroke, or have cardiovascular disease, asthma, diabetes, or rheumatoid arthritis. The pharmacist advice came in the form of a semi-structured interview. Self-reported adherence was the main outcome measure, researched through a follow-up interview. Other outcome measures on the number of medicine-related problems and beliefs about the medicine were also captured. Randomisation took place, to categorise patients into an intervention and control group. Of those patients considered in the final analysis, non-adherence was lower in the intervention group (9%, 16/185), compared to the control group (16%, 31/194), P = 0.032. In summary, the authors found "…that a telephone call from a pharmacist can significantly reduce patients' non-adherence, reduce their medicine-related problems and alter their balance of beliefs about medicines." An aspect identified as a limitation was the short-term follow-up analysis of this study.

Second, the same authors, (in this case cited as) Elliot et al. (2008), conducted a study "…to assess the cost effectiveness of pharmacists giving advice via telephone, to patients receiving a new medicine for a chronic condition, in England." This involved the comparison of an intervention (i.e. patients who were given additional support by a pharmacist), and a control group (i.e. a group who had the same general characteristics but who did not receive any additional clinical support). Using prior knowledge on medicines non-adherence to design the study intervention, the researchers asked pharmacists involved in the study to telephone patients two weeks after the patient had started a new medicine for a chronic

condition. The main data outcome measures collected "…were non-adherence and cost to the UK NHS." Non-adherence was collected four weeks after the start of the medicines by a researcher. Non-adherence was self reported by the patient, and was "…defined as a self report of at least one dose of the new medicine having been missed in the last seven days." A separate questionnaire was "…sent to the patients two months after starting therapy." The questionnaire covered the use of primary care and secondary care resources, which was self-reported by patients.

A community pharmacy chain was used to recruit eligible patients for the study. Patients were included if they were 75 years or over, or had been prescribed a new medicine because of a stroke, cardiovascular disease, asthma, diabetes, or rheumatoid arthritis. Patients were randomly allocated into a treatment or control group. Some patients dropped out when their doctor took them off the new medicine covered by the study. Over two-thirds of patients responded to the questionnaires. Two hundred and five patients responded to the section on the use of NHS resources, and this group were considered in the final analysis.

The study indicated that "…non-adherence was significantly lower in the intervention group (10/87, 11%) when compared to the control group (23/118, 19%), $p<0.05$." The study assumes that the level of adherence at 4 weeks remains the same after two months, when NHS resource use data was collected.

On the costs (resource use) side, the authors found that the "Frequency of patient contact with the NHS was not significantly different between the control and intervention." Notably, when this information was combined with unit costs related to specific interventions "…the difference in costs was highly significant, suggesting that the intervention group had a significantly lower cost to the NHS." This appears to suggest that the intervention group continue to have a similar number of contacts with the NHS, but their contact takes place through less expensive interventions. Specifically, the (mean) total patient costs including GP, A&E, outpatient, inpatient costs were higher for the control group (£282.8 per patient) than the intervention group (£187.7 per patient) – a difference of £95.10 on average.

The results from this study, whilst very promising, should be interpreted with caution. The authors acknowledge that their findings are tentative as their work was designed as a feasibility study, and not an economic evaluation. It is acknowledged that the two-month follow-up period "…was not long enough to detect health related resource use triggered by non-adherence.", and "The follow-up period is also not long enough to assess the long-term impact of the intervention." In particular, the authors suggest, "A future study should also include assessment at a later time, at least six to twelve months after the intervention, to determine whether the effect is sustained…" Therefore, the benefits assessed from this study can be only attributed to the timeframe of the study without more evidence to suggest long-term sustainability.

However, the study indicates that such interventions by pharmacists are a potentially cost effective and a convenient mechanism of delivering support to people newly prescribed medicines for LTCs, notably by utilising pharmacists' particular knowledge of medicines in a clinical context. The authors argue that their findings "…provide evidence that a telephone call from a pharmacist, with the aim of solving patients' problems with a new medicine, can significantly reduce non-adherence and is less costly than usual care."

Crucially, if sustainable adherence can be achieved by such an intervention then the benefits of the intervention will accumulate over time. This can be understood in terms of accumulated health gain achieved by an individual patient, and an accumulated decrease in demand for health care services (or the use of less expensive health care) by this individual, over time. However, one might expect there to be differentials in adherence levels across patients. Therefore, the benefits (i.e. NHS resource savings) achieved by patients who showed initial adherence whilst being given direct support, but who then revert to non-adherence, are likely to dissipate. Thus, there is likely to be a trade off in net benefits across patients. For the wider policy development context, these factors would need to be understood in respect of the net benefit achievable over a long period. This includes understanding why adherence varies across patients, and whether there are other possible supplementary interventions to maintain adherence levels.

**Rationale for intervention:**

Patients with chronic conditions use a disproportionate level of health care, and there is an expectation that this burden on the health system will continue to rise. Medicines are a significant component of health care: both in terms of managing and improving chronic conditions, and in respect of the proportion of total health care expenditures that are spent on medicines. The government's medicines policy aims to increase patient access and improve value for money. A significant proportion of people do not adhere to their medicines treatment plan.

In addition, the disease burden of LTCs is unevenly distributed in the population, with LTCs having a particular correlation with age and deprivation, which can lead to increased health inequalities between different patient groups. A full equality assessment has been completed that complements and supports the analysis in this impact assessment from the equality perspective.

There is evidence to suggest that pharmacists can play a positive role in improving levels of medicines adherence and the wider understanding of medicines in patients, through well-designed interventions, such as providing ongoing clinical advice to individuals in receipt of new medication for chronic conditions.

The “Equity and Excellence: Liberating the NHS” white paper highlights that “The community pharmacy contract, through payment for performance, will incentivise and support high quality and efficient services, including better value in the use of medicines through better informed and more involved patients. Pharmacists, working with doctors and other health professionals, have an important and expanding role in optimising the use of medicines and in supporting better health. Pharmacy services will benefit from greater transparency in NHS pricing and payment for services.” There are also some general principles that have been agreed between the Pharmaceutical Services Negotiating Committee (PSNC), NHS Employers (NHSE) and the Department of Health (DH) in respect of the Community Pharmacy Contractual Framework (CPCF). This includes being committed to ensuring a contractual framework that secures a sustainable community pharmacy service for the future, and services which:

- are better for patients, meeting personal health needs, tackling health inequalities and promoting better health
- are fair to community pharmacy, encouraging better use of pharmacists’ skills and the skills of pharmacy staff and providing fair rewards for high quality services
- represent good value for public money.

Thus, there is sufficient evidence to suggest that a medicines advice service (to be called the “New Medicine Service” - NMS), with similar characteristics to the service provided during academic “proof of concept” research, might be effectively implemented on a wider scale, and over a longer period, in England. The main objective of this service would be to improve medicines adherence, and the understanding of medicines, in individuals in receipt of new medicines for chronic conditions.

**Policy objective:**

The policy objective is for the New Medicine Service to help people prescribed a new medicine for certain LTCs to manage their LTC and to improve their medication adherence through providing further clinical support at the outset of taking new medication in keeping with overall government health policy to involve patients in shared decision making and to optimise medicines use. The intended effects are to improve patients' medicines adherence, patients' understanding of medicines, patients' engagement with their condition, and health outcomes; as well as reducing health inequalities, and medicines wastage. By achieving the above, it is anticipated that cost savings can also be generated within the NHSThe NMS service should:

a) Help patients and carers manage newly prescribed medicines for a LTC and make shared decisions about their LTC

b) Recognise the important and expanding role of pharmacists in optimising the use of medicines

c) Increase patient adherence to treatment and consequently reduce medicines wastage and contribute to the Quality, Innovation, Productivity and Prevention (QIPP) agenda

d) Supplement and reinforce information provided by the GP and practice staff to help patients make informed choices about their care

e) Promote multidisciplinary working with the patient’s GP practice

f) Link the use of newly prescribed medicines to lifestyle changes or other non-drug interventions to promote well being and promote health in people with LTCs

g) Promote and support self-management of LTCs, and increase access to advice to improve medicines adherence and knowledge of potential side-effects

h) Support integration with LTC services from other providers and provide appropriate signposting and referral to these services

i) Improve pharmacovigilance

j) Through increased adherence to treatment, reduce medicines related hospital admissions and improve quality of life for patients.

**Description of options considered:**

Two options were considered for the NMS – 1) Do nothing, 2) Introduce the NMS for a restricted number of conditions.

***Option 1: Do nothing:***

Under option 1, do nothing; there is no change to the provision of advanced services within the CPCF.

***Option 2: Introduce a New Medicine Service (NMS) for new medicines prescribed for a restricted number of long-term conditions, over an initial period of October 2011 to March 2013, as an Advanced Service in the Community Pharmacy Contractual Framework:***

Policy option 2 is to introduce the NMS for new medicines prescribed for a restricted number of LTCs, over a period of eighteen months. The NMS will be evaluated over this period, and the long-term viability of the policy will be directed by the evaluation outcomes.

***Why new medicines only?***

The decision to focus on new medicines for a restricted number of conditions relates back to the research evidence available from the proof of concept work. The two related (proof of concept) studies focused on new medicines prescribed for chronic conditions. Part of the rationale around new medicines is that people make decisions about the medicines they are prescribed and whether they are going to take them very soon after being prescribed the new medicine. Hence, there appears to be a window of opportunity for a pharmacist to have a role in improving medicines adherence. The proof of concept research indicates that improvements in medicines adherence are possible. The NMS policy design follows similar principles.

***Why a limited number of LTC's?***

Policy option 2 proposes that the NMS is rolled out in respect of new medicines prescribed for a limited number of LTCs, over a time-limited period. This is intended to focus on conditions where there is a potentially large and sustainable demand on health services, and where there could be significant improvements to patients medicines adherence, health and well-being, and quality of life. The conditions/therapies proposed for inclusion in the rollout of service are:

- Asthma and COPD;
- Diabetes (Type 2);
- Antiplatelet / Anticoagulant therapy and;
- Hypertension.

***Why an Advanced Service?***

Advanced Services are services where a pharmacy has a choice of whether to provide a service. This differs from the provision of Essential Services within the Community Pharmacy Contractual Framework (CPCF). Essential Services are those services that any pharmacy must provide. This includes the dispensing of medicines, repeat dispensing and waste management.

At this stage, it is more appropriate to introduce the NMS as an Advanced Service. Advanced Services are voluntary in nature, and allow pharmacies to deliver a service as appropriate, in light of the time, space, and staff available within each individual pharmacy's business model. Moreover, the evidence presented in the "Problem under consideration" section above flags the need for more evidence, over a longer timeframe. As there are uncertainties around the long-term benefits from an intervention with the characteristics of the NMS, it is more appropriate to roll out the NMS as an Advanced Service at this stage.

***Regulatory reform considerations:***

The NMS within the CPCF is out of scope of the One In One Out (OIOO) policy, and so out of scope of the Government's micro-business moratorium, because it is part of public sector contractual arrangements. In addition, pharmacy contractors can choose to provide the NMS on a voluntary basis, which again makes this out of scope of both OIOO and the micro-business moratorium.

***Evaluation of the policy:***

The NMS is initially planned to run from October 2011 until March 2013. A full evaluation will be undertaken to analyse the impact of the NMS from a health outcome, clinical pharmacy, equality and economic perspective. The findings of the evaluation will act as key evidence to determine whether the NMS should continue beyond its initial time limit, and in what format.

Recipients of the NMS may receive health related quality of life gains. This can be broken down into the NMS playing a role in the alleviation of symptoms associated with LTC's, a reduction in exacerbation, relapse and long-term complications that cause other morbidity and the need for other health interventions. This is considered a fundamental issue for exploration during the evaluation of the NMS. The latter is likely to be very difficult to estimate and is not considered in detail in this impact assessment. Consideration of any health related quality of life gains will be undertaken in the formal evaluation of the operation of the NMS.

In operation, Option 2 is split into three stages:

- Patient engagement;
- Intervention;
- Follow up.

An outline of the full service specification can be found here - http://www.psnc.org.uk/data/files/PharmacyContract/Contract_changes_2011/outline_nms_service_spec.pdf

There is also a section at the end of this document that provides more detail on the NMS evaluation.

***Funding envelope, NMS policy design and payment structure:***

The funding envelope, policy design, and payment structure for the NMS have been agreed through negotiations between NHSE and the PSNC; which have been ratified by the DH, within the context of the CPCF. This funding envelope reflects the maximum financial costs that could be incurred by the state over the initial delivery period.

- The agreement provides up to £55 million for the NMS in financial year 2011/12 and another £55 million for financial year 2012/13.
- The funding structure for the NMS will be comprised of a conditional (fixed) implementation payment of £750 per pharmacy plus monthly target payments, based on a notional £25 per NMS provided.
- The implementation payments will only be available in financial year 2011/12. In financial year 2012/13, there will be no implementation payments.
- The use of an implementation payment is in part intended to cover any setup costs, and to provide an incentive for the early introduction of the NMS, which will allow the benefits to be realised quickly in the maximum amount of time to gather evidence on the potential costs and benefits of the NMS.
- The implementation payment will be the same, regardless of pharmacy size (which could be estimated by prescription volume, for example.)
- The value of the implementation payment has been negotiated, but has been informed by a costing exercise in respect of the different processes required by a pharmacy to be ready to implement the NMS. This includes the time cost of the pharmacist to undergo training, training costs for other pharmacy staff, and the development of standard operating procedures, as well as other system developments that incur a time and financial cost on a pharmacy.

In order to obtain the implementation payment, pharmacists will need to certify that they meet a number of conditions and have delivered the NMS at least six times prior to 31 March 2012, thus demonstrating the ability to deliver. The conditions are as follows:

- The service will be delivered by pharmacists that are qualified to deliver it;
- The premises meet the requirements of the specification;
- A standard operating procedure (SOP) is in place;
- All dispensing staff are aware of the service and the eligibility criteria;
- The contractor has been in communication with other relevant local healthcare professionals about the service (there may be a role for Local Pharmaceutical Committees and Local Medical Committees to support and facilitate these discussions).

***The NMS in practice:***

From the date of implementation (scheduled to be 1 October 2011), each pharmacy undertaking the service will be eligible to receive monthly target payments. The level of the target payments received will depend on the level of delivery against activity thresholds. These thresholds have been designed based on the likely number of participating pharmacies, the typical prescription volume of an individual pharmacy, and the degree of NMS activity by individual pharmacies. Furthermore, the basic tenet of the thresholds is to try to incentivise higher levels of activity. For example, a contractor who requires one more service to meet the next level of activity payment might work hard to identify more qualifying patients. Moreover, the possible uncertainty of the number of prescriptions processed in one month suggests that pharmacies will have an incentive to continue to deliver the NMS, to ensure they maximise the likelihood of receiving the highest level of payment possible for the NMS.

The activity targets are based on the assumption that the potential NMS caseload for each community pharmacy will be 0.5% of an individual pharmacy's prescription volume (see the risks and assumptions section, number 1). The 0.5% figure is derived from some analysis of prescriptions by some community pharmacies over a number of months. Across all pharmacies, there will be a distribution around this figure, but this distribution is not considered explicitly within the activity targets. For the analysis, and potential success of the NMS payment structure, this is a key assumption, which will require careful evaluation. This is also considered in the full equality assessment.

Those involved in the negotiations used the 0.5% proportion to develop an activity matrix. This matrix indicates how many NMS a community pharmacy would be likely to deliver in a particular month, which leads to an appropriate payment structure for the NMS. This is predicated on the 0.5% figure being an accurate probability of a patient bringing a prescription that is eligible for the NMS into a particular pharmacy, ceteris paribus. This is also achieved by considering the relative distribution of the number of pharmacies, by prescription volume (see assumptions section, number 4.)

Table (1) below, shows the number of completed interventions necessary to achieve the 20%, 40%, 60% and 80% activity thresholds for different (monthly volume) pharmacies, with the monthly target payments for achieving each activity threshold in brackets. Note, in each prescription band the midpoint in the band is used as the benchmark to apply the 0.5% figure against, e.g. category 5,501-6,500 uses 6,000 prescriptions as the midpoint.

***Table 1: 2011/12 NMS payment structure***

| Volume of prescriptions per month | Number of completed interventions necessary to achieve 20% target payment | Number of completed interventions necessary to achieve 40% target payment | Number of completed interventions necessary to achieve 60% target payment | Number of completed interventions necessary to achieve 80% target payment |
|---|---|---|---|---|
| 0-1500 | 1 (£25) | 2 (£50) | 3 (£75) | 4 (£100) |
| 1501 - 2500 | 2 (£50) | 4 (£100) | 6 (£150) | 8 (£200) |
| 2501-3500 | 3 (£75) | 6 (£150) | 9 (£225) | 12 (£300) |
| 3501-4500 | 4 (£100) | 8 (£200) | 12 (£300) | 16 (£400) |
| 4501-5500 | 5 (£125) | 10 (£250) | 15 (£375) | 20 (£500) |
| 5501-6500 | 6 (£150) | 12 (£300) | 18 (£450) | 24 (£600) |
| 6501-7500 | 7 (£175) | 14 (£350) | 21 (£525) | 28 (£700) |
| 7501-8500 | 8 (£200) | 16 (£400) | 24 (£600) | 32 (£800) |
| 8501-9500 | 9 (£225) | 18 (£450) | 27 (£675) | 36 (£900) |
| 9501-10500 | 10 (£250) | 20 (£500) | 30 (£750) | 40 (£1000) |

| | | | | |
|---|---|---|---|---|
| +1000 | (+1) (+ £25) | (+2) (+£50) | (+3) (+£75) | (+4) (+£100) |

To illustrate the matrix operating in practice, consider a pharmacy that processes 5,800 prescriptions in a particular month.

- This pharmacy would be within the 5,501-6,500 band. The midpoint used to calculate the likely number of NMS per month is 6,000.
- Using the 0.5% of prescriptions assumption, this would equate to 30 patients per month entering the pharmacy with a new prescription for a condition covered by the NMS, i.e. (6,000*0.5=30).
- To be paid at the 20% activity, this equals delivering a minimum of 6 NMS in a month, 12 NMS for 40% activity payments, 18 NMS for 60% activity payments, and 24 NMS for 80% activity payments.
- Delivery of 15 NMS in a month would be paid at the 40% activity level. Completion of more than 24 NMS in a month would be remunerated at the 80% level, i.e. a maximum of £600.
- For pharmacies that have a prescription volume above 10,500 items per month, the volume bandings will continue to increase in increments of 1,000 prescription items per month. The midpoint rule continues to apply in each banding.
- For each increment, the number of interventions required to meet the 20% activity threshold will increase by 1 (increase in payment value of £25); the 40% activity threshold will increase by 2 (increase in payment value by £50); the 60% activity threshold will increase by 3 (increase in payment value of £75); and the 80% activity threshold will increase by 4 (increase in payment value of £100).

Initially, claims for payment will be considered on a monthly basis. When a pharmacy's prescription volume varies between months, causing it to move to a different volume band, the number of interventions necessary to achieve the target payment will reflect the appropriate volume band and midpoint used as the benchmark in that band.

To incentivise pharmacies to build the service in to their core service delivery, it is planned that the 20% band will be removed in the second financial year of operation for the NMS, 2012/13. Thus in 2012/13 the target thresholds will be 40%, 60% and 80%. The table below shows the number of completed interventions necessary to achieve the 40%, 60% and 80% activity thresholds for different volume pharmacies with the monthly target payments for achieving each activity threshold in brackets (from April 2012):

***Table 2: 2012/13 NMS payment structure***

| Volume of prescriptions per month | Number of completed interventions necessary to achieve 40% target payment | Number of completed interventions necessary to achieve 60% target payment | Number of completed interventions necessary to achieve 80% target payment |
|---|---|---|---|
| 0-1500 | 2 (£50) | 3 (£75) | 4 (£100) |
| 1501 - 2500 | 4 (£100) | 6 (£150) | 8 (£200) |
| 2501-3500 | 6 (£150) | 9 (£225) | 12 (£300) |
| 3501-4500 | 8 (£200) | 12 (£300) | 16 (£400) |
| 4501-5500 | 10 (£250) | 15 (£375) | 20 (£500) |
| 5501-6500 | 12 (£300) | 18 (£450) | 24 (£600) |
| 6501-7500 | 14 (£350) | 21 (£525) | 28 (£700) |
| 7501-8500 | 16 (£400) | 24 (£600) | 32 (£800) |
| 8501-9500 | 18 (£450) | 27 (£675) | 36 (£900) |
| 9501-10500 | 20 (£500) | 30 (£750) | 40 (£1000) |

| | | | |
|---|---|---|---|
| +1000 | (+2) (+£50) | (+3) (+£75) | (+4) (+£100) |

The planned evaluation of the NMS is to help inform future policy decisions, notably the long-term viability of the NMS, and, if it were to continue, the design of the NMS. At this stage of evaluation, it will be important to analyse a number of policy design questions, as well as the overall performance of the NMS in respect of its health improvement, clinical pharmacy, equality and economic objectives. If funding the NMS is judged to be worthy of extension beyond March 2013, it may be necessary to adjust the structure of the NMS to ensure that it is fit-for-purpose in meeting its overarching aim and objectives.

For example, it will be important to test the 0.5% of prescriptions assumption. If evidence indicates that this figure is not accurate, it could affect the operational effectiveness of the activity matrix. Moreover, it will be important to understand the distribution around the 0.5% of prescriptions assumption. It is fair to assume that in some geographical areas pharmacies may be more or less likely (relative to the mean) to encounter NMS cases. Thus, how the chosen delivery structure operates in respect of the natural distribution of cases is an important question to answer in relation to the effectiveness of the initial rollout of the NMS.

Notably, it is worth highlighting that any significant variation in the distribution of eligible patients per pharmacy might lead to difficulties for some pharmacies in consistently meeting the minimum activity levels (20% in 2011/12 and 40% in 2012/13). In addition, there could be issues in being able to move between activity levels, or, in some extreme cases, it could create a disincentive to continue delivering the NMS where the available NMS caseload in a locality is markedly higher than the 80% threshold. This disincentive could also occur “at the margins” between activity thresholds. This may influence the pharmacies that are willing to deliver the NMS on an ongoing basis. A factor (covered within the assessment of impacts on equality) relates to how the NMS policy design will affect provision of the NMS in deprived areas, where one might expect the profile of patients to be at the upper tail of the NMS distribution. However, if there is a relatively larger number of pharmacies available in these areas, as basic economics might suggest, then this is likely to be less of an issue. Therefore, pharmacies in areas with disproportionately high levels of potential NMS patients should be able to access eligible patients relatively easily – although there could be more pharmacies competing for the same patients. Hence, there should be the prospect for good coverage of patients in such areas.

However, the incentive for pharmacies to continue to deliver the NMS above the minimum level required to receive the maximum payment is an interesting policy design question for the evaluation.

**Monetised and non-monetised costs and benefits of option 2 (including administrative burden):**

***Sector-specific statistics and assumptions:***

The latest official statistics show that there were 10,691 pharmacies in England on 31 March 2010 (Source: NHS Information Centre). One has to consider the change in the number of pharmacies from this date, to the point of rollout, as well as over the NMS delivery period. Applying recent trends, we might expect there to be around 11,000 community pharmacies in England on 1 October 2011 (see the risks and assumptions section, number 2). However, this is merely an assumption, and is not an official statistic. No estimate of a change in the number of pharmacies from 1 October 2011 to 31 March 2013 is considered in the cost-benefit analysis.

It is estimated that 85 per cent of community pharmacies in England will be ready, willing, and able to deliver the NMS (see risks and assumptions, number 3). This is based upon the proportion of pharmacies who can deliver Medicine Use Reviews (MUR). Delivery of the MUR has required pharmacies to invest time in preparing the appropriate standard operating procedures (SOP), as well as investing in changes to their premises, through the building of consultation rooms. It has taken many years to get to the 85 per cent coverage of pharmacies who deliver MUR’s today; because the biggest hurdle to delivering the MUR is the building of a consultation room. The condition of requiring a consultation room also applies to the NMS.

The vast majority of pharmacies are therefore well placed to deliver the NMS as they already have consultation rooms. In general, the marginal cost of delivering the NMS is relatively lower than when

MURs were rolled out as an Advanced Service. For example, having to undertake work to be ready to deliver MUR developed the appreciation of preparing SOP's. In addition, the investment in the consultation room has already been made, so if nothing else, a pharmacy business will have an incentive to maximise their investment in a consultation room. Hence, we might expect those who are able to deliver MUR to deliver the NMS.

The cost of the NMS over the period can be considered in a number of dimensions. At the upper bound, the maximum cost, to the NHS, of the NMS will be £55 million in both 2011/12 and 2012/13. If the NMS were to cost more than £55 million per financial year over this period then the excess cost is to be offset within the wider CPCF funding. Benefits are expected to increase the greater number of patients that receive the service.

***Costs:***

In light of the policy design, and agreement to undertake a full evaluation of the NMS policy, the cost-benefit analysis looks at the net benefits of the NMS over a reasonable period (ten years). Implicit in the policy design is the potential to stop the NMS after an eighteen-month period if the outcomes observed in practice do not provide a sufficient justification of the policy in operation. Hence, for illustrative purposes in this impact assessment, it is instructive to consider the likely cost of the NMS in 2011/12 and 2012/13 against the potential monetised benefits of the NMS, as well as considering plausible scenarios for a ten-year projection of costs and benefits.

To do this, one must identify a plausible range of uptake scenarios for the NMS. This is necessary due to the way the NMS will operate at the outset – i.e. pharmacies will be set activity targets to receive payments. There is no strong evidence available on the likely speed of uptake of the NMS by community pharmacies. However, the investment in infrastructure and history of delivering MURs indicate that community pharmacies should be ready, willing and able to deliver the NMS in a short timeframe. This could be viewed as a reasonably conservative assumption. Uptake also needs to be understood in the context of the payment mechanism – i.e. the 20%, 40%, 60%, 80% activity payments matrix.

The structure of how the NMS is delivered will affect the actual cost of delivering the NMS in 2011/12 and 2012/13. For example, one might expect there to be a period of transition for pharmacies taking up the NMS. This will be partly driven by the ease, and time taken, to train staff and prepare the pharmacy to be ready to deliver the NMS. Moreover, the cut-off date for receiving implementation payments (31 March 2012) may result in a spike of NMS activity towards the end of financial year 2011/12. In addition, there may be a period of transition until pharmacies have a better feel for the number of patients bringing in an NMS-qualifying prescription into their respective pharmacies – the 0.5% question; and whether the incentive to deliver more NMS (and to thus receive higher payments) works in practice. Hence, there might be some movement around the activity thresholds at the outset of the NMS. Pharmacists may also make conscious decisions on when to offer the NMS if they do not think they can reach the next target payment band, or have in fact reached the 80% band, in a particular month. Sufficient evidence of truncated activity could indicate that an alternative payment structure would create better incentives to deliver the NMS more widely. This will be an important issue to understand in the evaluation of the NMS.

To recap, the introduction of the NMS is planned for 1 October 2011. In practice, this means that there are six months in financial year 2011/12 for the NMS to be delivered by pharmacies. As noted above, in addition to activity payments over the six-month period there will be a window for pharmacies to claim an implementation payment of £750. In financial year 2012/13, the NMS will be delivered throughout the full financial year, with payments based on service delivery only.

In financial year 2011/12, the implementation payments are (as a central scenario) forecast to be £7 million. This is based upon 85 per cent of all pharmacies being ready, willing and able to deliver the NMS, having met criteria laid out in the terms of service. For the purpose of this impact assessment, this is considered a transition cost. In respect of sensitivity analysis, if only 50 per cent of pharmacies took up the implementation payment, this would amount to just over £4 million. If all community pharmacies qualified for the implementation payment, this would cost just over £8 million in implementation payments.

In respect of the ongoing ("average annual") costs of the NMS, a number of scenarios have been considered, based upon the target activity payments. In addition to the issues described above in relation to the transition period for the NMS, the ongoing costs of delivery will be dependent on:

1) The proportion, and distribution, of prescriptions that are eligible for the NMS;

2) The propensity to deliver the NMS by pharmacies/pharmacists.

Thus, it is clear that it is very difficult to predict the likely outcome in advance of the policy rollout as there is no equivalent example available. A key provision in place is that a maximum of £55 million funding has been allocated for the NMS. Any surplus cost incurred by delivering more NMS than budgeted for will be offset from the wider CPCF funding. Therefore, the levels of risk to NHS budgets associated with the NMS are reduced.

It is highly unlikely that the NMS will cost £55 million in practice in 2011/12, as there is only a six-month delivery window and even if 85 per cent of pharmacies delivered the NMS at 80% activity levels from the outset, the total transition and activity cost would be less than £55 million. However, in this situation, in future (full) financial years the total activity cost would be significantly higher. Thus, it is less clear whether the full funding envelope would be used in the full financial year 2012/13. This would depend on the level of uptake of the service by community pharmacy, and the strength of the initial policy assumptions.

It is difficult to forecast the likely uptake of the NMS within activity bands. Therefore, the scenarios used to understand low, medium, and high uptake are based upon simple assumptions (see risks and assumptions, number 4). For the central scenario, the first six months of activity is laid out in Table 3. This assumes a gradual increase in activity, and within bands of activity, over the six months to 31 March 2012.

***Table 3: First six months of NMS activity – 1 October 2011 to March 31 2012 (Central Scenario)***

| **Central Scenario** | **20%** | **40%** | **60%** | **80%** | Inactive |
|---|---|---|---|---|---|
| Month 1 | 20% | 10% | 10% | 0% | 60% |
| Month 2 | 20% | 20% | 10% | 10% | 40% |
| Month 3 | 20% | 20% | 20% | 10% | 30% |
| Month 4 | 20% | 20% | 20% | 15% | 25% |
| Month 5 | 15% | 25% | 25% | 15% | 20% |
| Month 6 | 10% | 25% | 30% | 20% | 15% |

In practice, this distribution of activity could be quite different. For example, pharmacies that undertake all the necessary work to start the NMS on 1 October 2011, and whom can access eligible patients, could hit the 80% target in the first month (see risks and assumptions number 5). Moreover, there may be pharmacies that deliver a number of NMS between two payment bands, or who choose to refrain from delivering the NMS in a particular month, as they are unlikely to reach the next payment band. Hence, there will be natural variation around the number of NMS delivered, and actual payments made. Overall, for the purpose of illustration and simplicity, this uptake scenario is a plausible method of quantifying a likely cost of the NMS activity payments in 2011/12. Using this uptake profile, the estimated cost of the activity payments is approximately £17 million. This is equivalent to 700,000 NMS. It should be noted that this is not an official forecast of NMS activity, and in fact, the funding envelope is flexible to higher levels of activity. The total cost of the NMS in 2011/12 is the sum of the (transitional) implementation payments and the activity payments, which is (£7 million + £17 million =) £24 million.

In the full financial year 2012/13, one might expect the uptake of the NMS to continue to increase. Furthermore, it has been agreed that the 20% activity band is to be removed in April 2012. This is intended to create an incentive for pharmacies to deliver more NMS, i.e. the minimum payment band will be based upon reaching 40% delivery at the 0.5% of prescriptions assumption. Assuming that this does not lead to some pharmacies discontinuing the NMS (e.g. if they were unable to meet the 40% activity level, and therefore stopping offering the NMS), the profile in the central scenario is assumed to reach a steady-state position after nine months. Here, one-quarter of all pharmacies qualify for the 40% activity payment, just over one-third receive the 60% activity payment, and another quarter receive the maximum 80% activity payment. There is no increase in the proportion of active pharmacies (i.e. 85 per cent) after six months of delivery. This proportion of activity is applied across the 10-year cost-benefit analysis. Other long-term assumptions are laid out in the risks and assumptions section, numbers 6, 7, 8 and 9.

***Table 4: 2012/13 NMS activity (Central Scenario)***

| Central Scenario | 20% | 40% | 60% | 80% | Inactive |
|---|---|---|---|---|---|
| Month 7 | 0% | 35% | 30% | 20% | 15% |
| Month 8 | 0% | 30% | 35% | 20% | 15% |
| Month 9 | 0% | 25% | 35% | 25% | 15% |
| Month 10 | 0% | 25% | 35% | 25% | 15% |
| Month 11 | 0% | 25% | 35% | 25% | 15% |
| Month 12 | 0% | 25% | 35% | 25% | 15% |
| Month 13 | 0% | 25% | 35% | 25% | 15% |
| Month 14 | 0% | 25% | 35% | 25% | 15% |
| Month 15 | 0% | 25% | 35% | 25% | 15% |
| Month 16 | 0% | 25% | 35% | 25% | 15% |
| Month 17 | 0% | 25% | 35% | 25% | 15% |
| Month 18 | 0% | 25% | 35% | 25% | 15% |

As discussed above, there are only NMS activity payments in 2012/13. Under the central profile of activity in Table 4, the cost of the NMS is £55 million, i.e. what has been budgeted for during the initial roll out of the NMS. This is equivalent to approximately 2 million NMS.

The impact assessment has only considered the financial delivery cost of the NMS. At this stage, there are no anticipated non-monetisable costs of the NMS. The full evaluation of this policy will consider the range of health improvement, clinical pharmacy, equality and economic outcomes.

***Benefits:***

It is envisaged that the successful implementation of NMS will:

- Improve patient adherence which will generally lead to better health outcomes;
- Increase patient engagement with their condition and medicines, supporting patients in making decisions about their treatment and self management;
- Reduce medicines wastage;
- Reduce hospital admissions due to adverse events from medicines;
- Lead to increased Yellow Card reporting of adverse reactions to medicines by pharmacists and patients, thereby supporting improved pharmacovigilance;
- Receive positive assessment from patients;
- Improve the evidence base on the effectiveness of the service;
- Support the development of outcome and/or quality measures for community pharmacy.

Of the potential benefits listed above a number of them are very difficult to quantify in monetary terms. In addition, we may observe additional benefits of the NMS through better health outcomes (i.e. alleviation of symptoms, reduced exacerbation and relapse, and a reduction in other long-term complications) that result as a knock-on effect of the NMS. These quality of life measures will be investigated further during the evaluation of the NMS. However, some of the benefits listed above can be quantified. For example, a relative reduction in hospital admissions directly attributable to the NMS can be considered in terms of NHS cost savings. These savings can be viewed as benefits generated by the NMS.

At this stage, existing evidence from the proof of concept paper (Elliot et al., 2008) is used as the central estimate of the potential benefits from the NMS. What this means in practice for the central scenario is that there is a (mean) difference in cost, i.e. the cost saving potentially realisable from the intervention (i.e. equivalent to the NMS) used in the proof of concept paper, compared to the do nothing option. The proof of concept study identified a (mean) differential in resource cost to the NHS of £95.10. This sustainability of the benefit can only be isolated to the period of the study. However, it does not alter the assumed value of the benefit. Therefore, this is assumed to be at worst a short-term incremental benefit over a period where the pharmacist can play an active role in advising a patient to use their medicines more effectively. There is evidence, for example, Lee JK et al (2006), to suggest that the benefits of such interventions diminish over time, to the point where the patient may revert close to their original levels of adherence. The result of this, in respect of the NMS, is that over the intervention period there is a marked impact on alleviating symptoms, and reduced exacerbation and relapse, which generates real

(financial) savings for the health service. However, this also suggests that any potential reduction in other long-term complications is unlikely to result.

This figure is used as the central monetised benefit in the cost-benefit analysis scenario (see risks and assumptions, number 8). This can be translated, for each NMS delivered, that there is a monetised benefit achievable because of a reduced need for NHS services (for two months). It is virtually impossible at this stage to predict whether the specific NMS interventions, i.e. for patients newly prescribed medicines for one of the conditions listed, will result in sustained benefits beyond two months. This is a key issue that the evaluation will address, which may result in evidence to help adapt or extend the NMS.

What we might expect is a range of outcomes, where in some cases the NMS has a clear impact on a patient's adherence, and subsequent health outcomes, which is sustainable. In other cases, some patients may respond positively to the NMS, but once the intervention has stopped, the level of adherence diminishes (and therefore the potential positive health outcomes and financial benefits generated by the NMS diminish also.) Crucially for this impact assessment there is a cost directly associated with this specific intervention, which is assumed to generate a benefit of £95.10 per intervention. This figure is in part derived by the timeframe of the analysis. If this was a sustainable intervention, then the benefits will accumulate over time, over and above the level estimated after two months.

In the low benefit scenario, for the purpose of simplicity and proportionality, the lowest benefits potentially achievable from the NMS, the benefit is set at 50 per cent of £95.10.

Another benefit of undertaking a time-limited roll out and evaluation is that the evaluation's findings may also guide policymakers towards appropriate, potentially more resource efficient, supplementary interventions to the NMS that could help to retain the initial positive impact of the NMS, beyond the period that the NMS can have an impact on patient adherence.

The strength of the £95.10 central assumption is closely tied to the strength of the "proof of concept" research (please see the full papers for a more complete analysis of the strengths and weaknesses of the research.) It should be acknowledged that a number of factors dictate that the potential benefits achievable by the NMS could differ with the results of the proof of concept study. For example, the cohorts of patients who qualify for the NMS compared to the proof of concept study will not be the same. Differences in the methodologies used could result in different outcomes as well. The respective interventions will take place at different periods, and therefore the monetary values are not directly equivalent, i.e. £95.10 at the time of the proof of concept study is not worth £95.10 today. In addition, the underlying unit costs of different NHS interventions are likely to be different. Advancements in treatments available to patients at the time of the NMS roll out could result in different health improvement and economic outcomes that are not directly comparable with the proof of concept study.

These issues are not considered explicitly in this impact assessment because of proportionality. There is reassurance that the time limited nature of the NMS, as well as the planned evaluation, will draw out some of the key findings necessary to determine the long-term viability of the NMS.

However, overall, the proof of concept paper is deemed a solid foundation for the analytical aspects of implementing the NMS, and is therefore considered fit-for-purpose for this impact assessment.

***Projecting Costs and Benefits over a ten-year period:***

A ten-year cost-benefit analysis of the NMS has been completed. A number of assumptions are required to undertake this analysis. The full background to these assumptions is listed in the Risks and Assumptions section below. This includes more consideration of the strengths and weaknesses of the various assumptions used in this impact assessment.

Crucial to modelling a long-term scenario for the NMS is the consideration of the various dynamics in the pharmaceutical services market. These dynamics include modelling the increasing demand for prescriptions (estimated to be around 5 per cent per year), and general market inflation.

For simplicity, the NMS payment level of £25 is kept flat in real terms over the 10-year timeframe. The worst-case (highest) cost scenario inflates the £25 by 2% from March 2013 onwards (i.e. costs will increase by 2% real each year.)

The assumed benefit per NMS is kept flat at £95.10 (real terms) in the central scenario and assumed to be half of this (£95.10*0.5 =) £47.55 in the worst case (lowest benefits) scenario. The number of NMS delivered is uprated in light of the positive trend in the demand for prescriptions. This is achieved in

practice by taking the projected number of NMS from 2012/13 and inflating this number by 5 per cent year-on-year.

The main workings undertaken to calculate the net benefit (in constant prices year-on-year) and in present value terms (aggregated over 10 years) is presented in table 5, below. The evaluation costs have been included, and are smoothed over the 18-month period, i.e. 6/18 of the cost in 2011/12, and 12/18 of the cost in 2012/13.

***Table 5: Costs, benefits, and net benefits (constant price & aggregated present values) for option 2***

Central Scenario  Monetary figures are in constant prices unless indicated

| Year | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Discount Rate | Present Value |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Implementation payment | | | | | | | | | | | | |
| (Assumed) Number of pharmacies | 11,000 | 11,000 | 11,000 | 11,000 | 11,000 | 11,000 | 11,000 | 11,000 | 11,000 | 11,000 | | |
| Proportion of pharmacies who receive an implementation payment | 85% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | | |
| Number of pharmacies who receive implementation payments | 9,350 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| Value of implementation payment | £750 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | £0 | | |
| **Total implementation payment** | **£7,000,000** | **£0** | **£0** | **£0** | **£0** | **£0** | **£0** | **£0** | **£0** | **£0** | | |
| Estimated number of NMS delivered in a year | 700,000 | 2,200,000 | 2,300,000 | 2,400,000 | 2,600,000 | 2,700,000 | 2,800,000 | 3,000,000 | 3,100,000 | 3,300,000 | | |
| Activity payment | | | | | | | | | | | | |
| (Assumed) Payment per NMS | £25 | £25 | £25 | £25 | £25 | £25 | £25 | £25 | £25 | £25 | | |
| **Total activity payment** | **£17,000,000** | **£55,000,000** | **£58,000,000** | **£61,000,000** | **£64,000,000** | **£67,000,000** | **£70,000,000** | **£74,000,000** | **£78,000,000** | **£81,000,000** | | |
| **Total evaluation cost** | **£150,000** | **£300,000** | **£0** | **£0** | **£0** | **£0** | **£0** | **£0** | **£0** | **£0** | | |
| **Total Cost (implementation + activity payments + evaluation cost)** | **£25,000,000** | **£55,000,000** | **£58,000,000** | **£61,000,000** | **£64,000,000** | **£67,000,000** | **£70,000,000** | **£74,000,000** | **£78,000,000** | **£81,000,000** | **3.5%** | **£500,000,000** |
| Benefits | | | | | | | | | | | | |
| (Assumed) benefit per NMS | £95.10 | £95.10 | £95.10 | £95.10 | £95.10 | £95.10 | £95.10 | £95.10 | £95.10 | £95.10 | | |
| **Total benefit** | **£66,000,000** | **£208,000,000** | **£220,000,000** | **£231,000,000** | **£243,000,000** | **£255,000,000** | **£268,000,000** | **£281,000,000** | **£295,000,000** | **£310,000,000** | **3.5%** | **£2,000,000,000** |
| **Net benefit** | **£41,000,000** | **£153,000,000** | **£162,000,000** | **£170,000,000** | **£179,000,000** | **£188,000,000** | **£198,000,000** | **£207,000,000** | **£217,000,000** | **£229,000,000** | **3.5%** | **£1,500,000,000** |

*The figures in the table are rounded*

*NB – the evaluation costs have been smoothed out over the 18-month evaluation period.*

## Rationale and evidence that justify the level of analysis used in the IA (proportionality approach):

Following the HM Government "IA toolkit – How to do an Impact Assessment", the level of analysis used in this IA is justified as follows (using a simple Low, Medium, High scale):

i) The level of interest and sensitivity surrounding the policy:

**Medium** – This policy reflects a step in the direction toward providing a range of clinical pharmacy services, of which there are strong and varied stakeholder views. In light of the level of stakeholder engagement in this process, the overall level of interest and sensitivity surrounding introducing the NMS is medium.

First, this is in part due to the fact that the NMS roll out has been designed by NHSE and the PSNC, which is intended to balance the needs of the state and the needs of the community pharmacy sector.

Second, the time limited nature of the policy, and an agreement to undertake a thorough evaluation of the NMS will ensure that any future decisions on the long-term viability of the NMS are based upon sound evidence on the health gain, clinical pharmacy, and economic costs and benefits of the NMS in practice.

Third, however, whilst there is a recognised problem for consideration, of which pharmacists can play an important role in tackling, other groups might also consider themselves well placed to deliver the NMS.

ii) The degree to which the policy is novel, contentious or irreversible

**Low –** Whilst this is a new type of Advanced Service, it builds upon the foundation of existing Advanced Services (Medicine Use Reviews) and existing academic research (the proof of concept study). The time limited nature, and process for evaluating the policy, controls for any contentious or irreversible factors.

iii) The stage of policy development

**Low -** The stage of policy development is reasonably advanced, as this impact assessment seeks to measure the impacts of an NMS to be rolled out in October 2011. This impact assessment also attempts to offer a balanced opinion on the potential strengths and weaknesses of the initial policy design. Despite some potential weaknesses in the policy design, the role of the formal evaluation will be to provide an overall judgement on the merits of the NMS. The findings of the evaluation will play an important role in the decision to continue the NMS or not, and whether the policy would require refinement in the event of continuation.

iv) The scale, duration and distribution of expected impact

**Low** - The NMS itself is anticipated to impact upon 0.5 per cent of all prescriptions (on average) that a pharmacy dispenses. This is a small proportion of all prescriptions. The nature of the service will involve direct interventions to eligible patients over a relatively short period, most likely a few months. The service itself, and the benefits of the service, will be skewed towards those who are prescribed a new medicine for one of the conditions covered in the service agreement. The overall scale, duration and distribution of expected impact is anticipated to be small, short and narrow respectively.

v) The level of uncertainty around likely impacts

**Medium** – There is a degree of uncertainty around the likely impacts of the NMS. There is confidence that the NMS can have a positive impact on patients, enhancing the role of clinical pharmacy and the wider health service. A key issue is the magnitude of the positive impact.

The process of policy development, and analysis of impacts in this impact assessment, has sought to use the best, and most appropriate evidence available to make robust judgement on the likely impacts of the NMS.

However, there is uncertainty around a number of important assumptions, and the likely outcome of the assumptions being incorrect.

This includes a) whether the 0.5 per cent assumption for the number of prescriptions is sound; b) the distribution around the 0.5 per cent assumption; c) how community pharmacies who deliver the NMS will respond to the incentives implicit within the policy design; and d) the benefits that can be generated across a number of dimensions.

The financial benefits rely upon estimates generated through academic research. The “proof of concept” research offers a balanced perspective of the respective strengths and weaknesses of their findings, which are reflected in the original papers.

Despite this level of uncertainty in rolling out the NMS, the net benefits are expected to be positive. In addition, undertaking a formal evaluation of the NMS is viewed as the most appropriate method of gathering the evidence required to determine the long-term viability of the NMS as a service within the CPCF.

vi) The data already available and resources required to gather further data

**Low -** The data available to assist in the quantification of costs and benefits is limited. This is restricted to a handful of academic papers, and some independent research conducted by a small group of community pharmacies on the likely proportion of prescriptions who would qualify for the NMS. The process of quantifying a potential financial saving to the NHS from the NMS is a significant and complicated undertaking, which requires detailed evidence of patient interaction with the health service over an extended period.

Thus, it is viewed that the process of designing an appropriate delivery model for the NMS, and the decision to gather the full complement of evidence through an evaluation, is the best approach to determining the long-term net benefits of the NMS.

vii) The time available for policy development

**Low -** The time available for policy development was sufficient. The process involved a careful negotiation and agreement between NHSE and PSNC, within the boundaries of the CPCF. As per point vi) the limits on being able to gather evidence without actually “piloting” the NMS, suggest that

their use of the available academic studies and sector-specific analyses was appropriate to agree the NMS policy design. This impact assessment has added a number of questions to the evaluation specification, and the evaluation is seen as the best mechanism to inform the future policy development agenda.

**Risks and assumptions:**

1. It is assumed that 0.5 per cent of all prescriptions will be eligible for the NMS. This is based upon some analysis of prescriptions by some pharmacies, which was validated by NHSE and PSNC. Based upon the analysis it is expected that the market average of eligible prescriptions is 0.5 per cent. However, there will undoubtedly be some distribution around the mean value, and the size of the distribution will dictate the appropriateness of the chosen payment structure in operation. A distribution has not been modelled into the payment structure. This could result in some variation in uptake of the NMS by pharmacies, or some difficulty in meeting payment targets. For simplicity, the 0.5 per cent assumption, and the payment structures, does not vary by scenario. Variation in activity is captured in assumption.

2. The number of pharmacies is estimated to be just over 11,000 for October 2011. This is not an official statistic. This is based upon the last official statistic reported (by the NHS Information Centre) of 10,691 at 31 March 2010, and the modelling of the general upward trend in the number of pharmacies. This number does not vary by scenario. This assumption is considered robust for the purpose of the NMS analysis.

3. The central assumption for the likely proportion of community pharmacies who will undertake the minimum requirements to qualify for the NMS implementation payments is based upon the proportion of community pharmacies capable of delivering MURs – 85 per cent. This proportion is viewed as a reasonable, but fiscally conservative, assumption on the likely uptake of the implementation payment. Pharmacies who deliver MURs have already invested in necessary infrastructure, e.g. consultation rooms, which would make the delivery of the NMS more straightforward (and which are required to deliver the NMS). Delivery of MURs is assumed a signal of willingness to deliver other clinical pharmacy services such as the NMS. In the highest cost scenario, all pharmacies are assumed to take up the implementation payment, and in the lowest cost scenario, 50 per cent of pharmacies are assumed to qualify for the implementation payment.

4. Different activity profiles are assumed by scenario (central, low and high uptake). This drives the projected number of NMS delivered. No provision is made for activity between activity bands, where a pharmacy may deliver more NMS than the number required at the lower activity band, but not enough to be paid at the next activity band. Hence, in the analysis the payments are exactly £25 per NMS, which may differ in practice. It could also lead to a higher benefit being achieved relative to actual expenditure (as in theory the highest payment is £25 per NMS, but this could be lower in practice). In the central scenario, 85 per cent of pharmacies will be delivering the NMS after six months. After nine months, this profile reaches a steady state where 25 per cent of pharmacies are in the 40% activity band, 35 per cent in the 60% activity band, and 25 per cent in the 80% activity band. This profile is assumed to remain the same over the ten-year projection. There is no strong evidence to support the activity profiles. Assuming 85 per cent of pharmacies will be actively delivering the NMS after six months may be a moderately conservative (higher cost) assumption. Some evidence from the rollout of MURs indicates a slow uptake profile over a number of years. In the low uptake scenario, the transition to higher levels of activity payments are slower than in the central scenario, and moderately lower in steady-state (35 per cent at 40% activity, 30 per cent at 60% activity, and 20 per cent at 80% activity.) In the high uptake scenario, there is a continued increase in the proportions at higher activity bands. After 15 months from roll out steady state is reached, where 10 per cent of all pharmacies provide 40% activity, 10 per cent provide 60% activity, and 65 per cent of pharmacies provide 80% activity.

5. The distribution of prescriptions, by band, is based upon evidence sourced from the NHS Information Centre. Thus, it is considered robust. One issue is that the date to which the proportion refers is different to the roll out date for the NMS. Thus, the market for prescriptions will be larger by the point of NMS roll out, and therefore we would expect there to be some difference in the distribution of prescriptions in October 2011. The consequence is that the profile may overestimate the number of pharmacies in lower activity bands, and under estimate the number of pharmacies in higher activity bands. This is not expected, at this stage, to have a major impact on the general findings of the NMS analysis. This issue will be considered within the NMS evaluation.

6. The number of NMS delivered over time takes account for the growth in the number of prescriptions over time. The uptake profiles drive the number of NMS activity until March 2013. From this date, the total number of NMS delivered in one year is inflated by 5 per cent, year-on-year. This may be a slight underestimate as the original profiles were driven by evidence from a point in time prior to October 2011. The funding envelope is however flexible to higher activity. The 5 per cent annual uplift is based on recent trends and is considered robust. The percentage applied does not vary by scenario - as each scenario is at a different level of NMS delivery by March 2013.

7. The payment per NMS from 2013/14 onwards (i.e. beyond the initial NMS roll out) is kept flat in real terms over the remaining years in the central scenario, i.e. no real terms inflation is applied. In the worst (higher cost) scenario, the NMS payment level is inflated by 2 per cent (real) from 2013/14 onwards.

8. The assumed benefit per NMS (i.e. the conceptual intervention versus control) is based on the difference in NHS costs incurred by a patient who receives the NMS and, conceptually, an equivalent patient who does not receive the NMS (i.e. do nothing.) The “proof of concept” paper is used as an estimate of the likely benefit of delivering an NMS - £95.10 per NMS. This figure is kept flat, in real terms, over the 10-year projection. In the low benefits scenario, i.e. the lowest benefit achievable, the assumed benefit is 50 per cent of the central scenario in a particular year. The strength of the level of likely benefit per NMS is dependent on the relative strength of the proof of concept paper. The cost estimates are based upon self-reporting of patients, and do not use official NHS data. The short timeframe and the small sample size of the “proof of concept” paper may result in markedly different findings from the NMS roll out. Crucially, one can only consider the benefit measured over the period of the intervention from the proof of concept, two months. In respect of the net benefit of the intervention, this is estimated to be £95.10. Conceptually, after two months, any sustained effect of the NMS will result in accumulated benefits over and above the figure calculated after two months. For patients where the impact diminishes after the intervention it is assumed the benefit reverts to zero. The actual benefit may also be a variable factor over time, as it will be driven by individual circumstances (i.e. individual propensity to visit a GP, accident and emergency, as well as wider health outcomes). Advances in the quality of treatments available, and improvements in the wider delivery of healthcare in England may also influence the “true” benefit of the NMS over a longer period. It was noted in the main text that the £95.10 of the proof of concept study is not equivalent to £95.10 today in relation to the time of the study, and likely variation in the underlying unit cost of NHS interventions. However, for simplicity, and proportionality, this figure is not adapted in the impact assessment. Disentangling these issues in the NMS evaluation will be important for further investigation and analysis.

9. The standard government discount rate of 3.5% is applied to scenarios presented in present value terms.

**Direct cost and benefits to business calculations (following OIOO methodology)**

Introduction of the NMS within the CPCF is out of scope of the One In One Out (OIOO) policy, and so out of scope of the Government's micro-business moratorium, because it is part of public sector contractual arrangements. Contractors choose to provide NHS pharmaceutical services and in doing so must meet the terms and conditions specified, and receive payment, set by the CPCF. Unlike essential (or core) services, which all pharmacies must provide, the NMS is an advanced service, and thus voluntary, provided pharmacy contractors meet accreditation requirements for personnel and premises, which again makes this out of scope of both OIOO and the micro-business moratorium.

**Wider impacts:**

***Equality Assessment:***

A full equality assessment of the NMS policy has been completed.

***Competition Assessment:***

*Would the proposal directly limit the number or range of suppliers?*

Introducing the NMS is not expected to directly limit the number or range of suppliers in the market for pharmaceutical services.

*Would the proposal indirectly limit the number or range of suppliers?*

There is no evidence to suggest any indirect impact on the number or range of suppliers in the affected market.

*Would the proposal indirectly limit the ability of suppliers to compete?*

The proposed approach is not expected to indirectly limit the ability of suppliers to compete.

*Would the proposal reduce the incentives of suppliers to compete vigorously?*

The proposed NMS is more likely to increase the incentive to compete, as the opportunity to deliver value-adding clinical pharmacy services is being developed further.

***Small Firms Impact Test:***

The small firms impact test covers "Any proposal that **imposes** or **reduces** the cost on business…"

Contractors, including small firms, choose to provide NHS pharmaceutical services and in doing so must meet the terms and conditions specified, and receive payment, set by the CPCF. Furthermore, the NMS is an advanced service, and thus voluntary, provided pharmacy contractors meet accreditation requirements for personnel and premises, compared to essential (or core) services, which all pharmacies must provide. Thus, the NMS does not impose any (or reduce the) cost on business, and is therefore outside of the scope of the small firms impact test.

***Health Impact Assessment:***

The health impacts of the proposed policy have been considered in the main Evidence section of this document.

*Will your policy have a significant impact on human health by virtue of its effects on the following wider determinants of health (income, crime, environment, transport, housing, education, employment, agriculture, social cohesion)?*

The proposed policy option could play a role in educating individuals better about using and understanding the role of medicines. This could translate into increased medicines adherence and understanding of medicines; as well as greater awareness of the role that pharmacists can play in advising patients that could lead to positive impacts on human health.

*Will there be any significant impact on any of the following lifestyle related variables (physical activity, diet, smoking, drugs or alcohol use, sexual behaviour, accidents and stress at home or work)?*

The proposed policy option is intended to link the use of newly prescribed medicines to lifestyle changes or other non-drug interventions to promote well being and promote health in people with LTC's.

*Is there likely to be a significant demand on any of the following health and social care services (primary care, community services, hospital care, need for medicines, accident or emergency services, social services, health protection and preparedness response)?*

If the NMS is able to reap the potential benefits listed within this impact assessment, then it is likely to result in a reduction in demand for some of the more costly health and social care services, such as the demand for primary care, hospital care, and accident and emergency services; or a reduction in overall demand.

In respect of medicines, successful delivery of the NMS may lead to a greater demand for the medicines needed to manage a LTC, but would also reduce the *potential* demand for medicines needed for conditions that result from exacerbation and other long-term complications (which may require more extensive, and costly, interventions). The evaluation will consider this issue.

***Environmental impacts:***

*Will the policy option have any significant environmental impacts?*

There is no reason to expect the proposed policy option to have significant environmental impacts.

***Greenhouse Gas Impact Assessment:***

The anticipated impact on Greenhouse Gas emissions has been addressed in the Summary: Intervention and Option page at the top of this document. There are no impacts anticipated.

***Justice system impacts:***

*Does the proposal affect the justice system?*

There are no anticipated impacts on the justice system.

***Rural Proofing:***

There are no anticipated impacts on rural communities.

***Human Rights:***

*Will the proposals have 'human rights' implications?*

There are no anticipated impacts on Human Rights.

***Sustainable Development:***

There are no anticipated impacts on Sustainable Development.

**Summary and preferred option with description of implementation plan:**

In summary, the NMS is expected to provide a number of quantifiable and unquantifiable benefits to people who are given a new medicine for a condition covered by the service, and who receive the NMS. The NMS is also likely to benefit the wider health service. This includes a number of important benefits, including improving medicines adherence and a reduced demand for some costly NHS resources. In general, it could lead to a more efficient use of the resources available for health care in England.

The estimated costs are lower than the estimated benefits. The non-monetised benefits would also be expected to be greater than the non-monetised costs. Thus, there are sufficient grounds for implementing the NMS in some form, thus dismissing the “do nothing” option.

The evidence presented in this impact assessment for option 2 should be considered illustrative at this stage, as, for the economic component of the policy analysis, it mainly relies upon proof of concept academic research. Despite being a robust research, the authors of this study have noted the need for a longer evaluation of outcomes to determine the full benefits of an intervention with the characteristics of the NMS. This is in part the rationale for the 18-month roll out of the NMS, accompanied by an evaluation of the policy.

From available evidence, it is clear that interventions like the NMS can have positive impacts on medicines adherence, health outcomes, and on the use of finite health resources. What will be important to understand better is the sustainability of clinical interventions by pharmacists on LTCs. Sustainability could generate accumulated benefits, both health and economic, over time. The purpose of the proposed NMS evaluation will be to try to isolate these impacts, to deepen the evidence base around clinical pharmacy interventions of this type.

At this stage, the evidence available suggests that the NMS should deliver net benefits of at least £210 million (discounted) in the worst-case scenario (i.e. highest cost and lowest benefit) over a 10-year period. This is purely in cash terms, and does not consider the potential wider health and economic benefits of the NMS, or the notion that £1 saved from a health intervention is worth £2.40. In the central scenario, net benefits are estimated at £1.5 billion (discounted) over a 10-year period.

***Table 6: Costs, Benefits, and Net Benefits (discounted by 3.5%) – final conclusions***

| OPTIONS (against Option 1) | COSTS (£) | | BENEFITS (£) | | NET BENEFITS | Equality/Other Impact | QIPP Compliance |
|---|---|---|---|---|---|---|---|
| | Central | Worst | Central | Worst | Central | | |
| Option 2 - remove the restriction | £530,000,000 | £670,000,000 | £2,000,000,000 | £880,000,000 | £1,500,000,000 | | |

## Evaluation:

The NMS will be rolled out from 1 October 2011 for 18 months. NHSE and PSNC have been working to prepare all the necessary guidance to assist community pharmacies who choose to deliver the NMS.

In respect of a Post-Implementation Review (PIR), a full evaluation of the NMS will be completed. There is a live invitation to tender currently under way.

***Basis of the review:***

There is a commitment to undertake a formal evaluation of the NMS. This evaluation is expected to feed into a decision making process for the future of the NMS in 2013.

***Review objective:***

The review will try to determine the effects of the New Medicines Service on patients' adherence to medications, patients' understanding of medicines, patients' health status and outcomes, patient and professional experience, interprofessional relationships, and the cost-effectiveness and cost-utility of this advanced service. Patients' adherence and cost-effectiveness/utility are the principal outcomes.

***Review approach and rationale:***

The review will be an in-depth evaluation, and is expected to include a quantitative and qualitative analysis of patients', pharmacists' and general practitioners' experiences (including integrated working between health care professions) and perceptions of the NMS's processes and procedures. This detailed approach was seen as the most appropriate to answer the various challenging questions posed of the NMS to justify its long-term viability as a service in the CPCF, which may lead to amending the policy by broadening or narrowing the approach.

***Baseline:***

The bid chosen to deliver the NMS evaluation will be expected to have identified an appropriate baseline to conduct the necessary analysis of the baseline, and to meet the wider objectives of the review.

***Success criteria:***

The success criteria will be demonstrable evidence of the NMS having a positive impact on adherence, understanding, health status and outcomes on patients', and whether the NMS has positive cost-effective or cost-utility outcomes. Finally, positive feedback on patient and professional experience, and the development of better interprofessional relationships will be taken into consideration.

***Monitoring information arrangements:***

The invitation to tender for the New Medicine Service has an "Outline Service Specification" that indicates that pharmacy records for the service will be defined nationally, and will include, method of entry to service, patient demographic details, registered GP practice, details of new medicine(s), method of intervention and follow-up, outcome of intervention, follow-up, and reasons for referrals.

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