Title:
PROPOSALS TO INTRODUCE EXEMPTIONS FROM HUMAN MEDICINES REGULATIONS FOR ORTHOPTISTS ACROSS THE UNITED KINGDOM
IA No: 5195

Lead department or agency:
NHS England

Other departments or agencies:
Department of Health, MHRA, British and Irish Orthoptic Society (UK wide), Devolved administrations

Impact Assessment (IA)

Date: 01/02/2015

Stage: Consultation

Source of intervention: Domestic

Type of measure: Other

Contact for enquiries:
enquiries@ahp.nhs.net

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
£43.5m	£m	£m	No	NA

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

Due to consumer uncertainty and asymmetry of information, supply of medicines is controlled by government regulation. Demand is rising for ophthalmic services and efficiency is restricted by the current mechanisms; patient group directions (PGDs) which require development, renewal and update in every hospital; patient specific directions (PSDs) demand professional time to review and sign off. This can delay treatment, require additional appointments and increase cost. The system exacerbates inequalities across geographical areas and social groups and there are potential efficiencies, equity gains and improvements in experience from extending supply and administration mechanisms.

What are the policy objectives and the intended effects?

The objectives are: a) to reduce inefficiencies associated with current supply and administration mechanisms, b) to reduce inequalities in access to medicines for orthoptic patients c) to facilitate service re-design through the better use of orthoptist skills within the multidisciplinary team. Intended effects are: reducing cost of treatment while maintaining patient safety, reducing delays to diagnosis and treatment, greater choice of treatment options, improved equity of access to eye care, earlier access to ophthalmologists for patients who need their skills, enhanced experience of care, and better value in the use of resources for eye health.

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

Option 1 - No Change

Option 2 - Introduction of a specified list of exemptions to human medicines regulations for orthoptists

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

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

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

Signed by the responsible SELECT SIGNATORY: ..... Date: .....

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2014	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: £3.4m	**High:** £72.3m	**Best Estimate:** £43.5m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				**£5.2m**

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

Costs of educational programme to train orthoptists to use exemptions. Training will be undertaken by orthoptists working both within the NHS and also in non-NHS settings where a service need/role has been identified. The financial cost would be met in general by employer or education commissioners although they may be met by individuals or non-NHS organisations if working within the independent sector.

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

Enhanced clinical supervision, marginal increase only.
Time taken off work to re-attend eye clinic to access prescribed medicines.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low			Optional	**£8.5m**
High	Optional		Optional	**£77.3m**
Best Estimate				**£48.5m**

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

Reduction in clinicians' time to establish and renew patient group directionrs (PGDs). Reduction in orthoptist and ophthalmologist time requirements to obtain/sign patient-specific directions (PSDs). Reduction in multiple attendances with creation of 'one stop shops'. Reduced time away from work for parents/carers to re-attend clinic to collect a medicine where medicines are not accessible at the time of orthoptist appointment.

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

Reduction in time requirement of NHS Trusts' Medicines Review Board time to review PGDs when there is a change in the opthoptist team.
Improved patient experience.
More choice of treatment options and improved patient experience.

Key assumptions/sensitivities/risks

Discount rate 3.5%

Errors in the use of medicines exemptions.
Governance of orthoptists in the use of exemptions.
Communication of information about supply and administration of medicines (covered in risks and assumptions section in the Evidence Summary).
Acquiring sufficient information to make informed decisions around supply and administration of medicines.

BUSINESS ASSESSMENT (Option 1)

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

Evidence Base (for summary sheets)

Policy Background

The *Review of Prescribing, Supply and Administration of Medicines*[1] in 1999, chaired by Dr June Crown, proposed that prescribing rights be extended to a range of health professionals in order to improve services to patients, make better use of the skills of professional staff and thus make a significant contribution to the modernisation of the health service. Following the review, revised regulations have enabled an expansion of non-medical prescribing so that experienced nurses, optometrists, pharmacists, physiotherapists and podiatrists can train to independently prescribe medicines within their clinical competence. This has been championed through such publications as *High Quality Care for all*[2]*, Modernising allied health professions careers: a competency based career framework*[3], and more recently the *Allied health professions (AHP) prescribing and medicines supply mechanisms scoping project report*[4] and *Operational guidance to the NHS: extending the patient choice of provider*[5]*.*

Within the 'Government's response to the consultation on refreshing the mandate to NHS England, there were numerous suggestions on how to make better use of resources, one of which is the more effective use of medicines. Changes to medicines legislation, in line with these recommendations to allow eligible orthoptists to use exemptions from medicines regulations restrictions, will support changes to models of care to allow patients to access the right medicines at the right time, in the right place without any unnecessary delay.

In the publication *Five Year Forward View*[6] NHS England sets out how the health service needs to change, arguing for a more engaged relationship with patients, carers and citizens so that we can promote wellbeing and prevent ill-health. One that no longer sees expertise constrained by traditional boundaries, fragmented services, patients having to visit multiple professionals for multiple appointments. One organised to support people with multiple health conditions, not just single diseases. A future that sees far more care delivered locally but with some services in specialist centres where that clearly produces better results, and one that recognises that we cannot deliver the necessary change without investing in our current and future workforce.

The use of medicines exemptions by orthoptists also supports the achievement of a number of ambitions across the devolved administrations such as, *Transforming Your Care: A Review of Health and Social care in Northern Ireland*[7], *Transforming Your Care: Strategic Implementation Plan*[8], *Improving Outcomes by Shifting the Balance of Care: Improvement Framework*[9], *Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision*[10],

---

[1] Department of Health (1999) *Review of Prescribing, Supply & Administration of Medicines,* London.

[2] Department of Health (2008) *High Quality Care for All: NHS Next Stage Review Final Report*. London.

[3] Department of Health and Skills for Health (2008) *Modernising Allied Health Professional Careers: a competency based career framework.* London.

[4] Department of Health (2009) *Allied health professions (AHP) prescribing and medicines supply mechanisms scoping project report.* London

[5] Department of Health (2011) *Operational guidance to the NHS: extending the patient choice of provider.* London

[6] NHS England (2014) *Five Year Forward View*, London

[7] Northern Ireland Department of Health, Social Services and Public Safety (2011) *Transforming Your Care: A Review of Health and Social Care in Northern Ireland,* Belfast

[8] Northern Ireland Department of Health, Social Services and Public Safety (2013) *Transforming Your Care: Strategic Implementation Plan,* Belfast

[9] NHS Scotland (2009) *Improving Outcomes by Shifting the Balance of Care: Improvement Framework,* Edinburgh

[10] NHS Scotland (2011*) Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision,* Edinburgh

Together for Health: A Five Year Vision for the NHS in Wales[11] and *Achieving Excellence: The Quality Delivery Plan for the NHS in Wales*[12]. These documents set out the vision for the future of the NHS which no longer sees expertise constrained by traditional boundaries, fragmented services or patients having to visit multiple professionals for multiple appointments.

Problems with the current mechanisms for supplying and administering medicines by orthoptists

Supply and administration of medicines used by orthoptists in the diagnosis and treatment of eye conditions is restricted by government legislation. Current supply and administration mechanisms allow orthoptists to supply and administer identified medicines to patients under patient group directions (PGDs), and patient-specific directions (PSDs). PGDs are written instructions for the supply and/or administration of a licensed medicine in an identified clinical situation where the patient may not be individually identified before presenting for treatment. Each PGD must be signed by both a doctor and pharmacist; and approved by the organisation in which it is to be used. A PSD is a prescriber's (usually written) instruction that enables an orthoptist to supply or administer a medicine to a named patient. PGDs have to be updated regularly (at least every two years or when there is a change of staff in a department). PSDs require review and signature in the patients' notes by a prescriber, taking time away from direct patient care. If a prescriber is not present, the patient or carer has to return to the clinic which can delay diagnosis and timely treatment.

Equity of access is constrained by PGDs and PSDs. An orthoptist employed across different hospitals may be named on a PGD in one hospital and not on another. Additionally, local guidelines define what medicines are available to an orthoptist in each hospital. These systems of access to medicines can create health inequalities across geographical areas.

It is common that a patient will need more than one medicine and if a combination of medicines is required, a number of PGDs will also be required to cover each possible combination. An example of this is in patients with dark irises whose eyes do not always respond well to a single medicine to dilate pupils. Consequently patients with dark irises may wait longer for a diagnosis if the required combination of medicines is not available under a PGD.

Orthoptists are trained to manage children with amblyopia (lazy eye) but current legislation limits the supply of cost-effective eye care for children by orthoptists. Evidence has been published to show that atropine occlusion is as effective as an eye patch to treat a child with amblyopia[13] and has a higher rate of compliance[14]. Currently, atropine occlusion (eye drops or ointment) cannot always be supplied by orthoptists under a PGD and therefore needs to be prescribed by a prescriber such as an ophthalmologist. This leads to suboptimal care for children who could benefit from timely access to atropine. Appointments could be released for patients with more complex presentations if atropine could be included in the list of medicines exemptions for orthoptists. There are 5.5 million children aged 7 years and under. It is estimated that on average 5% of children under seven years in the UK (276,500 children)

[11] NHS Wales (2011) *Together for Health: A Five Year Vision for the NHS in Wales,* Cardiff

[12] NHS Wales (2012) *Achieving Excellence: The Quality Delivery Plan for the NHS in Wales,* Cardiff

[13] Repka MX, Wallace DK, Beck RW, Kraker RT, Birch EE, Cotter SA, Donahue S, Everett DF, Hertle RW, Holmes JM, Quinn GE, Scheiman MM, Weakley DR; Pediatric Eye Disease Investigator Group. *Two-year follow-up of a 6-month randomized trial of atropine vs patching for treatment of moderate amblyopia in children*. Arch Ophthalmol. 2005 Feb;123(2):149-57.

[14] Holmes JM, Beck RW, Kraker RT, et al., Pediatric Eye Disease Investigator Group. *Impact of patching and atropine treatment on the child and family in the amblyopia treatment study*. Arch Ophthalmol. 2003;121(11):1625–1632

experience eye problems and 50% of children with eye problems (138,250 children) require treatment for amblyopia.[15] [16] [17] [18]

Rationale for intervention

An Allied Health Professions (AHPs) Prescribing and Medicines Supply Mechanisms Scoping Project was undertaken in 2009 to establish whether there was evidence of service and patient need to support extending prescribing and medicines supply mechanisms available to AHPs. The project found there was a strong case in support of exemptions for the specific list of medications used in the diagnosis and treatment of disorders of binocular vision.

A lack of capacity prevented the development of this for orthoptists. The drivers in the system are now stronger and make the case in support of exemptions for orthoptists. For example, an increase in orthoptic led services and satellite clinics, mean that increasingly orthoptists need to be able to have access to the medicines patients require for diagnosis and/or treatment. Introducing exemptions from the Human Medicines Regulations for orthoptists could lead to improvements in patient quality including outcomes, experience and safety.

Economic case

There are mechanisms to improve the supply and administration of medicines, and increase the range of services that can be provided by orthoptic practitioners to meet increasing demand for eye care. Health gains and cost reductions could be achieved by diagnosing and treating eye morbidity earlier, improving patients' experience of care, reducing the need for additional clinic appointments and reducing inequalities in access to eye care. This could lead to overall efficiency in the health system if these gains outweigh the additional risks of relaxing regulations on medicine supply in eye health.

Policy objectives

The intended effects of introducing exemptions from the Human Medicines Regulations 2012 for orthoptists are:

- equal access to medicines for all patients with eye problems;
- improved patient experience;
- improved choice and convenience for patients and carers;
- improved use of orthoptists' skills;
- reduced unnecessary administrative burden on health care professionals associated with PGDs;
- releasing orthoptist and ophthalmologist time by reducing the need for PSDs;
- improved children's access to evidence-based treatment for amblyopia;
- reduced need for an additional clinic visit for patients, just to obtain medicines;
- better health and wellbeing for all patients with eye problems;
- facilitating service re-design;

[15] Eibschitz-Tsimhoni M, Friedman T, Naor J, Eibschitz N, Friedman Z. *Early screening for amblyogenic risk factors lowers the prevalence and severity of amblyopia*. J AAPOS 2000;4:194-9

[16]. Barrett BT, Bradley A, Candy TR. *The relationship between anisometropia and amblyopia*. Prog Retin Eye Res 2013; 36: 120–158

[17] C. Williams, R.A. Harrad, I. Harvey, et al. S*creening for amblyopia in preschool children: results of a population-based, randomised controlled trial*. ALSPAC Study Team. Avon Longitudinal Study of Pregnancy and Childhood Ophthalmic Epidemiol, 8 (2001), pp. 279–295

[18] Holmes JM, Clarke MP. *Amblyopia*. Lancet. 2006 Apr 22;367(9519):1343-51

Description of options considered (including do nothing);

Option 1:'No Change'

It is convention to include a 'no change' option in an impact assessment. This option is to maintain the status quo and has costs and benefits of zero. All costs and benefits of other options are calculated relative to this. This option involves no initiation of specific measures in terms of supply and administration for orthoptic patients, and therefore continuation of current supply and administration. This would result in the continuation of the limitations of clinical practice described earlier.

Option 2: Introduce exemptions to medicines legislation for orthoptists.

Orthoptists would be able to supply and administer the medicines on an approved exemptions list within their scope of practice and competence without the need for a PGD or a PSD. The proposed list of medicines can be found in section 6 of the document 'Consultation on proposals to introduce exemptions from human medicines regulations restrictions for orthoptists across the United Kingdom.'

The list of medicines that could be supplied and administered by orthoptists exempt from medicines legislation would be updated and maintained by the Medicines and Healthcare Products Regulatory Agency (MHRA). All qualified orthoptists who are registered with the Health and Care Professions Council (HCPC), and meet other entry requirements would be eligible to undertake training on a voluntary basis which if satisfactorily completed would enable them to be annotated on the HCPC register as being qualified in the use of exemptions.

Monetised and non-monetised costs and benefits of each option (including administrative burden);

Overview of costs and benefits associated with Option 2: Introduce exemptions to medicines legislation for orthoptists.

Costs:

Option 2 will require orthoptists to be trained in the use of exemptions and require them to be away from work for up to two days.

Benefits

Option 2 will result in cost savings in the following areas:

Reduction in development, renewal and update costs of PGDs because orthoptists will be able to supply medicines to dilate the pupil without the need for a PGD once orthoptists are annotated on the HCPC register to use exemptions.

Reduction in time needed to seek clinical review and signature in the patients' notes from a prescribing clinician for medicines that are currently prescribed to individual patients under PSDs.

Reduction in patients' (and carers') time to return to clinic to access prescriptions that requires a PSD when a clinician is not present in clinic to provide one at the time.

Health gains from a reduction in delay in access to medicines although this gain is only marginal and not quantifiable, and therefore is not monetised.

Monetised costs

Cost of *training*

Costs of educational programmes for supplying and administering medicines under exemptions from the Human Medicines Regulations 2012.

Figures for October 2014 showed there were 1362 UK based orthoptists registered with the HCPC, and that there are approximately 60 newly qualified practitioners a year. Where there is an identified service need, all orthoptists who meet the entry criteria would be eligible to undertake training to use exemptions if the legislation were to be changed. It is estimated by the British and Irish Orthoptic Society (BIOS) that 20% of qualified orthoptists would undertake training in the first year, with approximately 15% in the second and third years. These proportions include demand for training newly qualified practitioners.

Estimates suggest a training course for orthoptists to use exemptions would cost between £495 and £545 (based on a telephone survey of providers by BIOS, November 2014). Approximately 272 orthoptists would enter the training programme in the first year and 204 in the second and third years. (Appendix, table 1)

Assuming the lower cost estimate per person for a training course (£495) the ten-year discounted training costs would be between £519,000 and £572,000 depending on the cost of the course. (Appendix, table 2).

In the longer term (after 5 years) it is planned that this education programme would be subsumed into undergraduate training courses in-line with other professions such as optometrists and podiatrists. At this point, all orthoptists would qualify with the exemptions annotation on the HCPC register.

Cost of staff replacement while on training

Although staff may not be replaced while on training, there is an economic value of their lost time as it will be reflected in diminished service provision or otherwise; this cost is proxied by assuming full back-cover. The training programme is estimated to take advanced practitioners out of service for 2 days of the year, which could be backfilled by Agenda for Change Band 6 orthoptists who would be required to cover a 7.5 hour shift. The hourly cost of staff covering colleague's absence is assumed to be lower as overheads do not have to be included as there are no (or marginal) capital or management costs.

The total discounted 10-year financial cost of staff backfill while training was estimated to be £724,000 (Appendix, table 2).

Total financial and opportunity cost of training and staff backfill

The total financial cost was estimated to be between £1.2 million and £1.3 million depending on uptake.

Given the NHS budget constraint, both the cost of the training and the cost of staff backfill will inevitably displace health services that would have been provided to patients; this is the opportunity cost of the proposal. Following current DH guidance, the opportunity cost is calculated at one Quality Adjusted Life Years (QALY) per £15,000. The stream of QALYs foregone is then discounted at a rate of 1.5% per year. The social value of the displaced QALYs is re-monetised at a value of £60,000 per QALY, representing the social value of a QALY (what people are on average willing to spend to improve their healthy life expectancy by one QALY).

DH guidance advises that each QALY could also generate on average £14,000 of wider societal benefit (for example by reducing dependency). In this consultation draft, the wider societal benefit has not been calculated.

The discounted opportunity cost was estimated to be £5.2 million over ten years (Appendix, table 3).

Non-monetised costs

Option 2: Introduce exemptions to medicines legislation for orthoptists.

There are no identifiable additional health risks associated with orthoptist supply and administration of medicines via exemptions than are currently covered by the current supply and administration of medicines via PGDs and PSDs.

The quality-adjusted life year (QALY) loss associated with side-effects is likely to be negligible as most medicines used by orthoptists are diagnostic and short-acting, and therefore have transient and limited side-effects such as temporary blurring of vision and stinging of the eyes.

It is not expected that an automatic increase in salary will result from the completion of training. Some orthoptists who have completed training may move into new roles or take on new responsibilities depending on the service needs. On its own, training in the use of exemptions by orthoptists would not be sufficient grounds for a salary upgrade.

There are minimal risks of additional adverse events associated with the use of exemptions by orthoptists; they already supply most of these medicines under PGDs and PSDs every day in their current practice [see Risks section below].

Monetised benefits

Option 2: Introduce exemptions to medicines legislation for orthoptists.

Reduction in patient group directions for medicines

No published evidence was identified to estimate cost saving. All estimates are based on the expert opinion of the membership of BIOS.

The hours of administrative time required to develop, renew and update PGDs in every hospital that employs orthoptists is estimated per PGD as follows: orthoptist - four hours; consultant time - half an hour; hospital pharmacist 10 minutes. The total cost of updating a PGD was calculated by multiplying administrative time by staff costs. The total estimate was £339 (Appendix, table 4). The cost impact across individual hospitals depends on the number of PGDs to be renewed and/or updated per year. A high estimate of 3 (PGDs per hospital (low estimate 1, best guess 2) was used. Assuming there are 174 hospitals that employ orthoptists, the best estimate of the total cost was calculated in order estimate the cost savings each year depending on the number of orthoptists able to supply by exemptions. If all orthoptists could supply under exemptions, then the financial impact would be between £59,000 and £177,000 per year, and the best estimate was £118,000 (Appendix, table 5).

Reduction in patient-specific directions for medicines (prescriber present)

BIOS estimated that it takes approximately 5 minutes of a prescribing clinician and orthoptist time to obtain a PSD if the prescriber is present while the patient is in clinic. Also that up to five PSDs per orthoptist is required per week for dilation medicines that fall outside a PGD. The cost saving depends on the number of orthoptists with exemptions to supply and administer medicines (up to 50% projected after 5 years), the number of PSDs per week required, the proportion of PSDs that would be avoidable and the number currently required.

The highest estimate of the total cost saving per year for the NHS (assuming all orthoptists could supply medicines under exemptions) was £3.5 million per year assuming 95% of 5 PSDs per orthoptist per week could be avoided, and the lowest estimate was £74,000 assuming 10% of one PSD per orthoptist per week could be avoided under option 2. The best estimate

was £1.9 million per year assuming 5 PSDs of which 50% could be avoided. (Appendix, table 6)

Reduction in patient-specific directions for medicines that dilate the pupil (prescriber not present)

If a prescriber is not present when a PSD is required, the patient has to return to the clinic to collect medicines. It is estimated by BIOS that one patient per week per hospital needs to return to the clinic for this reason. The estimate assumes 174 NHS hospitals have clinics employing orthoptists. The cost saving if all hospitals benefited from this change in regulation is estimated to be between £95,000 and £189,000, depending on how many return visits could be avoided (Appendix, table 7). The best guess is the most conservative (lower) estimate reported here.

Reduction in PSDs to supply atropine occlusion to treat amblyopia in children:

A PSD may be required for an orthoptist to supply atropine. If a prescriber is present in clinic to obtain a PSD and a PSD is required, there is a cost of the ophthalmologist and orthoptist time to acquire a PSD. The cost-saving if all orthoptists could supply under exemptions was £159,000 (assuming 10% children were eligible for treatment with atropine) to £795,000 (assuming 50% of children were eligible for atropine (Appendix table 8).The best guess was the higher estimate reported here (50% children eligible for treatment with atropine).

Not all hospitals require a PSD for atropine so this cost saving is likely to be an over-estimate.

Total financial savings and opportunity cost of savings in health service utilisation

Total discounted ten-year cost savings were estimated to be between £1.9 million and £17.4 million with a best guess estimate of £10.9 million (Appendix, table 9).

Following current DH guidance, the opportunity cost is calculated at one Quality Adjusted Life Years (QALY) per £15,000. The stream of QALYs foregone is then discounted at a rate of 1.5% per year. The social value of the displaced QALYs is re-monetised at a value of £60,000 per QALY, representing the social value of a QALY (what people are on average willing to spend to improve their healthy life expectancy by one QALY).

DH guidance advises that each QALY could also generate on average £14,000 of wider societal benefit (for example by reducing dependency). In this consultation draft, the wider societal benefit has not been calculated.

The total discounted opportunity cost was estimated to be between £8.6 and £77.3 million, reflecting the wide uncertainty in the assumptions. The best guess estimate was £48.5 million (Appendix, table 9).

Non-monetised benefits

Option 2: Introduce exemptions to medicines legislation for orthoptists.

Improvements in health as a result of earlier access to treatment - this is thought to be marginal as the delay in treatment to access a prescribing clinician would not cause a long-term detriment to health-related quality of life.

Improvements in patient experience.

Improved accountability and responsibility for medicines supplied/administered as no prescriber would be asked to prescribe for a patient not directly under their care.

Reduced time away from work and school to attend clinic appointments as the additional health gain would only make the intervention more cost-effective.

Net present value

The net present value of the change in legislation, not taking into account any change to service configuration is between £3.4 million and £72.3 million, reflecting the wide uncertainty in the estimates. The best guess estimate of net present value was £43.5 million (Appendix, table 10). Estimates used for the highest, lowest and best guess estimates of net present value are presented next to table in the appendix.

Longer term changes in local service configuration

Supply of medicines under exemptions by orthoptists could lead to the development of orthoptist-led clinics for the management of eye conditions requiring regular review. This could reduce costs of service delivery and increase choice, access and patient experience.

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

The estimate of monetised benefits shown above indicate that under conservative assumptions, this change in regulations is likely to be cost saving over ten years. Additional savings would further increase the cost-effectiveness of this proposal. It is therefore justified to describe but not quantify the value of these benefits, especially since the scale and value of these benefits will be difficult to quantify given that there is no robust evidence on which to base any estimates of effectiveness.

Risks and assumptions;

Supply and Administration – To alleviate the risk of unsafe or inappropriate supply and administration, an orthoptist using exemptions should know what medication the patient is currently taking including over-the-counter and herbal preparations before supplying and administering new medicines. Supply of medicines is not an activity that occurs in isolation. Information must be shared with other health professionals who need to know the information for the benefit of the patient and this will include the patient's GP. Where possible, the orthoptist using exemptions to supply and/or administer medicines should have access to other professionals' prescribing decisions where they impact upon their own decisions. This will include communication across NHS-private practice boundaries where it is necessary to ensure that clinicians have appropriate information to inform their practice.

An orthoptist using exemptions must make it clear to the patient that medicines supply and/or administration cannot be undertaken in isolation. The orthoptist should inform anyone else who may be in a position to prescribe for that patient of their actions to avoid medicines errors. This is most likely to be the patient's general medical practitioner, but may also include other health and social care professionals. If the patient refuses to consent to sharing such information the orthoptist should offer an explanation of the risks of not doing so. If the patient continues to refuse to give consent, the orthoptist should consider which course of action, including not supplying medicine, would be in the best interests of the patient. This must be documented in their records.

Level of training and education – There is strict eligibility criteria for orthoptists to undertake training for exemptions. The candidate must:

a) Be registered with the HCPC as an orthoptist;

b) Be professionally practising in an environment where there is an identified need for the individual to regularly use exemptions;

c) Be able to demonstrate support from their employer;

d) Be able to demonstrate medicines and clinical governance arrangements are in place to support safe and effective use of exemptions;

e) Be able to demonstrate how they reflect on their own performance, and take responsibility for their own Continuing Professional Development (CPD) including development of networks for support, reflection and learning;

f) Provide evidence of a Disclosure and Barring Service (DBS) check within the last 3 years.

Any orthoptist using exemptions will only be able to supply and administer medicines from the list of exemptions within their scope of practice and competence. There is always a risk associated with medicine use. Orthoptists already have a history of using medicines safely and effectively through PGDs and PSDs and all orthoptists are familiar with these medicines and will have the necessary training.

The Health and Care Professions Council (HCPC) have the authority to approve education programmes for the provision of exemptions training for orthoptists. A *Draft Outline Curriculum Framework for Education Programmes to Prepare Orthoptists to use Exemptions* has been developed.

Monitoring and evaluation

As part of the work to take forward independent prescribing by physiotherapists and podiatrists, the project team worked with the Research and Development Directorate at the Department of Health (DH) to agree funding and a specification for an evaluation. DH initiated an open tender process and the University of Surrey was awarded the contract to undertake an evaluation of independent prescribing by physiotherapists and podiatrists. The study has commenced and is expected to be completed in early 2016. We intend to follow a similar approach in respect of exemptions for human medicines regulations for orthoptists.

Summary and preferred option with description of implementation plan

This section is to be completed after consultation only

Appendix – Orthoptists

Option 2 - Exemptions to Medicines Act for specified medicines

Projected demand, training costs and opportunity cost of training

Estimates of values and assumptions:
Uptake of training was based on estimates from BOIS members and education providers. Orthoptists currently practicing was taken from HCPC list of registered practitioners (hcpc –uk.org.uk, accessed November 2014).

Table 1. Projected demand for training and numbers entering training by orthoptists, years 1-10

N = 1362	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total
% in training	20%	15%	15%	5%	5%	5%	5%	5%	5%	5%	
Cumulative % trained	20%	35%	50%	55%	60%						
Number in training	272	204	204	68	68	68	68	68	68	68	1,158

Estimates of values and assumptions:
Cost of training valued as £495 per participant (lowest estimate) and £545 (highest estimate) based on estimated provided by Higher Education Institutes to BIOS (November 2014)
Discount rate: 3.5%

Table 2: Projected financial cost of training and staff backfill, years 1-10

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total
Training cost (low estimate)	£134,838	£97,709	£94,405	£30,404	£29,376	£28,382	£27,423	£26,495	£25,599	£24,734	£519,365
Training cost (high estimate)	£148,458	£107,578	£103,940	£33,475	£32,343	£31,249	£30,193	£29,172	£28,185	£27,232	£571,826
Cost of staff backfill	£188,093	£136,299	£131,690	£42,412	£40,978	£39,592	£38,253	£36,960	£35,710	£34,502	£724,492
Total (low estimate)	£322,931	£234,008	£226,095	£72,816	£70,354	£67,975	£65,676	£63,455	£61,309	£59,236	£1,243,857
Total (high estimate)	£336,551	£243,878	£235,631	£75,887	£73,321	£70,842	£68,446	£66,132	£63,895	£61,735	£1,296,318

Total discounted ten-year financial and opportunity cost of training, cost of training courses and staff backfill

Estimates of values and assumptions:
Cost of backfilled staff is estimated at £22 per hour, based on Personal Social Services Research Unit (PSSRU) (2014) Unit costs for Band 6 staff, excluding qualifications and overheads.
Total time for backfill is based on an 8-hour shift and 2 training days per orthoptist. Discount rate: 3.5%
Assumes a low estimate of uptake of training

To estimate the opportunity cost of health care displaced by training and staff replacement, the financial cost (actual spend) was translated into quality adjusted life years (QALYs) at a rate of £15,000 per QALY. The social value of the health benefit displaced by orthoptist training (course fees and backfilled time) was calculated by re-monetising the QALYs displaced at a rate of £60,000 per QALY.

Table 3. Total discounted ten-year financial and opportunity cost of training, cost of training courses and staff backfill

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Total
Financial cost	£322,931	£234,008	£226,095	£72,816	£70,354	£67,975	£65,676	£63,455	£61,309	£59,236	£1,243,857
Opportunity cost	£1,346,205	£975,511	£942,523	£303,550	£293,285	£283,367	£273,785	£264,526	£255,581	£246,938	£5,185,270

Valuation of benefits

Option 2 - Exemptions to Human Medicines regulations

Financial cost of renewing and updating patient group directions (PGD)

Estimates of values and assumptions:

Estimates the total cost if all orthoptists could supply under exemptions to Human Medicines regulations restrictions
The cost of the Medicines Review Panel is not included as the estimated time and cost to review a PGD is not possible to identify the professionals involved or quantify their time commitment
The cost of an orthoptists at grade Agenda for Change 8a is not reported in the PSSRU data so the estimated cost was taken from a clinical psychologist on the same salary band.

Table 4. Financial cost of renewing and updating patient group directions (PGD)

Professional group	Hours	Unit cost per hour	tal cost per PGD	Source PSSRU 2013/14
Orthoptist manager (Agenda for Change Band 8)	4	59	£236	Based on a Band 8 estimate in PSSRU Unit Costs of Health and Social Care 2012/13
Consultant ophthalmologist	0.5	99	£50	Ibid, per contracted hour
Hospital pharmacist	0.17	41	£7	Ibid.
Total			£339	Rounded to nearest £

Estimates the total cost if all orthoptists could supply under exemptions to Human Medicines Regulations restrictions
Total cost saving calculated by multiplying the cost saving per clinic by the number of hospitals employing orthoptists in the NHS

Table 5. Financial cost per hospital and for the NHS of renewing PGDs

	Total no. PGDs per year	**Cost saving per clinic***	**Number NHS hospital trusts employing orthoptists**	**Total cost saving NHS per year**
Low estimate	1	£339	174	£59,044
High estimate	3	£1,018		£177,132
Best estimate	2	£679		£118,088

*values rounded to nearest pound.

Financial cost saving from a reduction in patient-specific directions (PSDs)

a) Financial costs associated with PSDs (when a prescribing clinician is present)

Estimates of values and assumptions:

Estimates the total cost if all orthoptists could supply under exemptions to Human Medicines Regulations (necessary to calculate the cost for a proportion of the workforce trained in medicines exemptions). Assumes salary costs are for a Band 6 orthoptist and a specialist registrar (PSSRU 2013/14).

Cost per orthoptist per week is calculated by multiplying the cost of a PSD (£11.50) by the number of PSDs per week, by the % avoidable

Annual cost per orthoptist is calculated by multiplying the cost per orthoptist per week by 48 weeks. The total annual cost saving to the NHS is calculated by multiplying the cost per orthoptist per year by the number of orthoptists practising in the NHS (approximately 1362).

Table 6. Financial cost of PSDs (prescribing clinician in clinic).

Estimated no. hospitals employing orthoptists in eye clinics			174
Estimates	Most favourable	Least favourable	Best estimate
PSDs per week	5	1	5
time required	5	5	5
Cost of a PSD per week	£11.50	£11.50	£11.50
% avoidable	95%	10%	50%
Cost saving per orthoptist/week (n-1362)	£53.83	£1.13	£28.33
Cost saving per orthoptist / year (48 working weeks)	£2,584	£54	£1,360
Total cost impact per year if all orthoptists were trained to supply medicines under option 2.	£3,519,408	£74,093	£1,852,320

b) Financial costs associated with PSDs (when a prescribing clinician is not present)

Estimates of values and assumptions:

Estimates the total cost if all orthoptists could supply under exemptions to Human Medicines Regulations restrictions

Assumes no seasonal variation in demand for PSDs

Total savings per week calculated by multiplying the cost of a PSD (£11.50) by the demand per week for a PSD (1 to 2), by the number of

NHS hospitals with clinics employing orthoptists (n = approximately 174)

Table 7: Estimated cost of return visits to access medicines

Estimates	Most favourable	Least favourable	Best estimate
Additional visits by patients / carers per hospital per week if prescribing clinician not present:	2	1	1
Total saving per week	£3,944	£1,972	£1,972
Total saving per year	£189,312	£94,656	£94,656

Financial savings from a reduction in PSDs to supply atropine for amblyopia

Estimates of values and assumptions:
Estimates the total cost if all orthoptists could supply under exemptions to Human Medicines Regulations restrictions. Number of children in the UK is based on ONS estimates for live birth cohorts to 2013.
5% of children have eye problems, 50% children with eye problems have amblyopia. Assumes eligibility of 10% (least favourable to option 2) to 50% (most favourable to option 2) for the treatment of amblyopia with atropine. Total cost per year is calculated by multiplying the number of children with amblyopia (approximately. 138,250) by the proportion eligible for treatment (10% to 50%), and cost of a PSD (£11.50).

Table 8. Financial savings from avoiding unnecessary PSDs for atropine under different assumptions about the demand for atropine in children with amblyopia

Number of children under 7 years in the UK			5,530,000
No. children under 7 years with eye problems in the UK (5%)			276,500
No. children with amblyopia (50%)			138,250
	Most favourable	Least Favourable	Best estimate
% children eligible for atropine	50%	10%	50%
Total cost PSDs per year	£ 794,938	£ 158,988	£ 794,938

Total ten-year discounted financial savings and opportunity costs (social value) of reduced demand for PGDs and PSDs, by proportion of the orthoptist workface trained to supply medicines under exemptions to Human Medicines Regulations restrictions.

Estimates of values and assumptions:

Assumes no benefits of training accrue in year 1 and benefits accrue as a proportion of the total number of orthoptists who have been trained (all previous years)
Most favourable estimate assumes low cost of training (least favourable, high cost, best guess, low cost), three PGD renewals per hospital per year avoided (least favourable, 1 , best guess 2), 15 PSDs avoided per hospital per week (least favourable 1, best guess 5), 2 re-booked appointments saved per week (least favourable 1, best guess 1)
Annual savings calculated by multiplying the cumulative proportion of orthoptists trained in using exemptions by the total cost saving reported in table 8. Discount rate: 3.5%

Following DH guidelines, the opportunity cost of savings in health care utilisation was estimated by converting the financial cost (actual spend) into health benefits as quality adjusted life years (QALYs) at a rate of £15,000 per QALY. The social value of freeing up health services to treat other people was calculated by re-monetising the QALYs displaced at a rate of £60,000 per QALY. Re-monetised QALYs were discounted at a rate of 1.5% per year.

Table 9. Total ten-year discounted financial savings and opportunity costs (social value) of reduced demand for PGDs and PSDs, by proportion of the orthoptist workforce trained to supply medicines under exemptions to Human Medicines Regulations restrictions.

Year	1	2	3	4	5	6	7	8	9	10	Total discounted
Cumulative % trained in the workforce		20%	35%	50%	55%	60%	60%	60%	60%	60%	
Financial savings – highest estimate		£881,681	£1,490,766	£2,057,648	£2,186,872	£2,305,003	£2,227,056	£2,151,745	£2,078,981	£2,008,677	£17,388,430
Financial savings – lowest estimate		£97,559	£164,955	£227,681	£241,980	£255,051	£246,426	£238,093	£230,042	£222,263	£1,924,050
Financial savings - best estimate		£552,657	£934,445	£1,289,779	£1,370,779	£1,444,827	£1,395,968	£1,348,761	£1,303,151	£1,259,083	£10,899,450
Opportunity cost – highest estimate		£3,596,218	£6,200,376	£8,726,778	£9,457,592	£10,164,899	£10,014,679	£9,866,679	£9,720,866	£9,577,208	£77,325,295
Opportunity cost – lowest estimate		£397,926	£686,079	£965,628	£1,046,494	£1,124,758	£1,108,136	£1,091,760	£1,075,625	£1,059,729	£8,556,135
Opportunity cost - best estimate		£2,254,188	£3,886,532	£5,470,136	£5,928,226	£6,371,582	£6,277,421	£6,184,651	£6,093,252	£6,003,204	£48,469,193

Cost-benefit analysis

Option 2 - Exemptions to Human Medicines regulations restrictions for specified medicine

Ten-year discounted net present value

Estimates of values and assumptions:

Most favourable estimate assumes the cost of training varies is £545 (£495 least favourable, best estimate £495)
3 PGDs avoided per hospital (least favourable 1 PGD, best guess 1 PGD)
5 PSDs a week at 5 minutes, 95% of which are avoidable (least favourable assumes 1 a week, 5 minutes, 10% avoidable, best estimate is 5 a week, 5 minutes, 50% avoidable)
2 return visits avoided per week (least favourable, one appointment, best guess, one appointment)
Assumes no benefits are incurred in year that a student is in training.

The net benefit is the difference in social value (measured as opportunity cost not financial costs) between benefits and costs.

Table 10. Ten-year discounted net present value

Year	1	2	3	4	5	6	7	8	9	10	Total
Least favourable	-£1,346,205	-£577,585	-£256,444	£662,078	£753,209	£841,391	£834,351	£827,233	£820,044	£812,791	£3,370,865
Most favourable	-£1,291,725	£2,660,185	£5,295,996	£8,435,512	£9,176,176	£9,893,000	£9,751,975	£9,612,858	£9,475,628	£9,340,263	£72,349,869
Best estimate	-£1,291,725	£1,318,156	£2,982,152	£5,178,871	£5,646,810	£6,099,683	£6,014,716	£5,930,830	£5,848,015	£5,766,260	£43,493,767