Department of Health & Social Care

Health and Care Bill

Impact assessments summary document and analysis of additional measures

Published 10 January 2022

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Introduction

The Health and Care Bill will build on the proposals brought forward by the NHS following the publication of the Long-Term Plan. These proposals built on extensive engagement by the NHS in 2019 and were further developed in the 2021 White Paper *Integration and Innovation: Working Together to Improve Health and Social Care for All*. The Bill will advance on the collaborative working seen throughout the pandemic, to shape a system which is best placed to serve the needs of the population.

The core measures in the Health and Care Bill follow three core themes, all of which are integral for helping the system to recover from the pandemic and transform patient care for decades to come.

Firstly, the Bill aims to remove barriers which stop the system from being truly integrated, with different parts of the NHS working better together, alongside local government, to tackle the nation's health inequalities.

Secondly, the Bill aims to reduce bureaucracy across the system. DHSC wants to remove barriers which make sensible decision-making harder and distracts staff from delivering what matters – the best possible care.

Lastly, DHSC wants to ensure appropriate accountability arrangements are in place so that the health and care system can be more responsive to both staff and the people who use it.

All of these measures are intended to complement, not distract from, the transformation that is already taking place across the system. These proposals should be seen in the context of those broader reforms.

Alongside the core measures, there are additional proposals to make targeted changes to allow the government to support the social care system, to improve quality and safety in the NHS, to grant the flexibility to take public health measures and to implement worldwide reciprocal healthcare agreements.

These measures will provide a foundation to build upon and our aim is to use legislation to provide a supportive framework for health and care organisations to continue to pursue integrated care for service users and taxpayers in a pragmatic manner.

As the health and care system further emerges from the pandemic, these legislative measures will assist with recovery by bringing organisations together, removing more of the bureaucratic and legislative barriers between them and enabling the changes and innovations they need to make.

Policy proposals

The Health and Care Bill is legislating for multiple policy objectives and therefore brings forward a number of different measures. All of the policy proposals where costs and benefits have been identified have an impact assessment (IA) which discusses the options, rationale, costs and benefits in detail.

Several of the proposals are enabling powers which do not have quantifiable benefits or costs, as the impact of the policy will ultimately depend upon how the enabling powers are used. Nevertheless, a qualitative assessment of the potential costs, benefits, risks and mitigations have been included as part of this package of IAs.

Furthermore, given that there are multiple policies, several of which do not have quantifiable benefits, it was not deemed appropriate to calculate an overall Net Present Value for the relative costs and benefits across the entirety of the Bill. Rather, if costs and benefits have been quantified, then an NPV will be included in that proposals respective IA and will be considered in isolation.

Table 1 presents a summary of the IAs published alongside the Bill and the individual IA title in which they have been incorporated. Proposals on Health Service Safety Investigations Body (HSSIB), and, introducing a 2100-0530 watershed on TV and online ban for paid advertising of food and drink that are High in Fat, Salt and Sugar (HFSS) products, each have their own standalone document dedicated to that respective policy.

Table 1: Summary of proposals and where to find their associated IAs

Proposal	Impact assessment
Medicines information systems	Additional measures IA
Water fluoridation	Additional measures IA
Food information for consumers: power to amend retained EU Law	Additional measures IA
Hospital Food Standards	Additional measures IA
Medical examiners	Additional measures IA
Professional regulation	Additional measures IA
Rest of World reciprocal healthcare	Additional measures IA
Powers allowing further products to be centrally stocked and supplied free of charge to community pharmacies without the need to reimburse them under the standard NHS arrangements	Additional measures IA
Abolishing Local Education Training Boards	Core IA
Arm's-Length Bodies transfer of functions power	Core IA
Collaborative commissioning	Core IA
Competition	Core IA
Care Quality Commission reviews of Integrated Care Systems	Core IA
Data sharing	Core IA
Designating Integrated Care Boards as Operators of Essential Services under NIS Regulation	Core IA
Duty to cooperate	Core IA
Establishing Integrated Care Systems in law	Core IA
Foundation Trusts capital spend limit	Core IA
Joint Committees and Joint Appointments	Core IA
Merging NHS England and NHS Improvement	Core IA

National Tariff	Core IA
New trusts	Core IA
Provider selection and Choice	Core IA
Public Health power of direction	Core IA
Reconfiguration of services: intervention powers	Core IA
General power to direct NHS England	Core IA
Special Health Authorities Time Limits	Core IA
The NHS Mandate (and Better Care Fund)	Core IA
Amendment on Cancer Outcomes in the NHS Mandate	Core IA
Triple Aim	Core IA
Workforce duty	Core IA
Adult social care – assurance	Social Care IA
Adult social care – discharge to assess	Social Care IA
Adult social care – provider payments	Social Care IA
Proposals with standalone IAs	
Health Service Safety Investigations Body (HSSIB)	
Introducing a 2100-0530 watershed on TV and online ban for paid advertising of food and drink that are High in Fat, Salt and Sugar (HFSS) products	

Interactions between proposals

The proposals in the Bill should be seen as multiple policy proposals which are mutually reinforcing, rather than policies to be viewed in isolation. Therefore, there are interdependencies between the proposals, whereby the success of one proposal may depend on the impact of another. This is particularly true of proposals relating to the three principles underlying the Bill, which are being put in place to foster collaboration across the health and care system and are covered in the Core IA. Potential interdependencies are outlined below, although this list is not exhaustive and further details can be found in the specific analyses for each proposal.

The Triple Aim and Duty to Cooperate proposals introduce enabling powers which make it more likely that other proposals will have a system benefit (e.g. appropriate joint working by ICSs). The benefits derived from these proposals will depend on the success of other measures to deliver beneficial system change. Further detail can be found in the respective sections in the Core IA.

The Professional Regulation proposals have potential interdependencies with the ALB transfer function proposal, and, with other existing policies related to health and social care. This is explored in more detail in the Professional Regulation section of the Additional Measures IA.

For the public health measures related to obesity, namely those concerning the advertising of HFSS foods and Food information for consumers: power to amend retained EU Law, the impact of these policies on public health may be difficult to disaggregate as they are part of a wider programme of supporting the public to make better informed choices for their health.

Specific Impact Tests

In most cases the proposals brought forward in the health and care bill introduce enabling powers, and so the impacts of the proposals will not materialise until secondary legislation is finalised and implemented. Therefore, at secondary legislation stage, more detailed analysis of the finalised policy will be undertaken, which will also include detailed analysis of specific impacts, such as those on the justice system, trade and the environment where appropriate.

Equality

The policy measures in the accompanying IAs have undergone a full equalities assessment as set out in the Statutory Equality Duties Guidance.

Human rights

Restrictions on High in Fat, Salt and Sugar (HFSS) products advertising raised potential issues of freedom of expression on the part of businesses to promote their products. However, restrictions on these freedoms can be made where they are proportionate to protect health.

There are no foreseen impacts of the other proposals on human rights.

Privacy

The powers that enable data to be required from adult social care providers may have an impact on privacy depending on the form of data required. Any requests that relate to identifiable information will be subject to existing data protection legislation and individual privacy tests will be undertaken as appropriate. Similarly, the power to extend NHS Digital's (NHSD) powers to enable it to require data from private providers may also have an impact on privacy and NHSD will ensure that appropriate safeguards are in place.

Justice system

Justice impacts are anticipated for the HSSIB, Medicines Information Systems and Triple Aim proposals.

Restrictions on HFSS advertising may result in some enforcement actions reaching the courts, although this number is expected to be very small.

New burdens for local government

No new burdens on local authorities are anticipated at this stage from the primary legislation. However, this will be continually under review as the government continue to finalise these proposals through guidance and secondary legislation. A new burdens assessment will be developed in advance of implementation of the proposals (by Royal Assent). As such we expect to produce a new burdens assessment for the Adult Social Care Assurance proposals but will continue to keep other areas of the Bill under review.

Competition and innovation

The proposal in the Core IA relating to competition intends to change the roles in respect of competition of the Competition and Markets Authority (CMA) and NHS Improvement (Monitor functions). The proposal aims to create a more nuanced approach to certain NHS transactions that gives greater weight to collaboration. The potential impacts of this on competition are outlined in the Core IA.

The proposals relating to provider selection and choice may have impacts on competition at secondary legislation stage. At this point a competition impact test will be completed.

Restrictions on HFSS advertising may result in impacts on competition and innovation, which are explored in this proposal's standalone IA.

Small and micro business assessment (SaMBA)

The proposals related to data sharing, provider selection and choice, medicines information systems, hospital food standards, Food information for consumers: power to amend retained EU Law and reciprocal healthcare arrangements for rest of world countries may have impacts on small or micro businesses. It is not possible to provide a robust estimate of these costs, or give details of exemptions, until use of the powers is decided upon or finalised. There is a commitment to examining these impacts if and when secondary legislation is introduced. Further details are given in the respective IA sections.

Trade

The proposals related to provider selection and choice, and reciprocal healthcare arrangements for Rest of World countries may have impacts on international trade if secondary legislation is brought forward. DHSC will engage with the Department for International Trade at this point to dully assess these impacts.

Post Implementation Review (PIR)

The government is committed to evaluating the policies it implements. In line with this, a PIR should be undertaken usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations: have achieved their objectives; are having any unintended consequences; have objectives that remain appropriate; are still required and remains the best option for achieving those objectives; and, whether the objectives could be achieved in another way which involves less onerous regulatory provision to reduce the burden on business and/or increase overall societal welfare[1].

The exact details of the PIR for the proposals in these IAs will be set out at implementation of the Bill, following the introduction of secondary legislation. In particular, this is because many of these proposals are enabling powers and the details of the final policy will not be finalised until the secondary legislation stage. This means that the specific plans for the PIR cannot be finalised until the final form of the policy, and the specific outcomes it is likely to affect, are known. Initial planning for the PIR is currently underway. For example, a review may examine the effectiveness of establishing Integrated Care Systems in law at encouraging integration in the health system, and, encouraging effective commissioning of health services for patients. Any review relating to the Core measures should refer to the three guiding principles running through all proposals in the Bill.

Some proposals which have standalone IAs, such as the proposal concerning advertising of foods and drinks which are High in Fat, Salt and Sugar (HFSS), have committed to completing a PIR. Details of PIR plans are outlined in these standalone IAs.

[1] Department for Business, Energy and Industrial Strategy, “Producing Post Implementation Reviews”, July 2018. [Online]. Available: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/726992/producing-post-implementation-reviews-pir.pdf

Impact assessments of additional measures

The proceeding section is the impact assessment for several *additional proposals to support social care, public health, and quality and safety*.

Title: Health and Care Bill 2021 **IA No:** 9570 **RPC Reference No:** RPC-DHSC-5082(1) **Lead department or agency:** Department of Health and Social Care (DHSC) **Other departments or agencies:** NHS England and NHS Improvement	Impact Assessment (IA) **Date:** 10/01/2022 **Stage**: Final **Source of intervention:** Domestic **Type of measure:** Primary legislation **Contact for enquiries:** Not applicable

Summary: Intervention and Options

RPC Opinion: GREEN

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

Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status
Unquantified	Unquantified	Unquantified	Non qualifying provision

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

Demographic and social changes have, for a number of years, been changing the shape of the demands on the health and care system. This Bill intends to implement the lessons learned from the evolution of the entire Health and Care System, as well as the specific experience of responding to an unprecedented public health emergency during the Covid-19 pandemic. The measures considered in this impact assessment are targeted to address specific problems and remove legislative barriers to allow front line staff and the government to deliver care more efficiently and maximise opportunities for improvement. This is with the ultimate of aim of supporting the system in helping people to live healthier, more independent lives for longer.

What are the policy objectives of the action or intervention and the intended effects?

Measures considered in this impact assessment relate most directly to the fourth principle of the Health and Care Bill, which have the aim supporting social care, public health, and quality and safety. For example, the proposals examined in this impact assessment are targeted changes which will enable government to more effectively support the social care system, and, implement comprehensive reciprocal healthcare arrangements with Rest of World countries (outside the European Economic Area and Switzerland). The impact assessments for seven proposals relating to the fourth principle have been collated in this single document as they all entail small or unquantifiable impacts.

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

This IA covers legislative changes developed by the Department of Health and Social Care, working with a breadth of stakeholders including NHS England & NHS Improvement, and the Ministry for Housing, Communities and Local Government. Given the complexity of the package of measures, this IA is focussed primarily on the leading options for each of the proposals and specific legislative changes. Impacts are by default compared against a 'do-nothing' option, although in some cases alternative policy options are outlined.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** Not applicable

Does implementation go beyond minimum EU requirements?		N/A		
Is this measure likely to impact on international trade and investment?		No		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

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

Signed by the responsible Minister: _____ Date: 10/01/2022

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

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

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

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

The proposals set out in this IA are complex and to a significant extent consist of creating enabling powers which either lead to practical but limited changes; require secondary legislation or consultation before practical changes can occur; and/or, require system behavioural change before practical changes come into force. It is not possible to robustly estimate an overall cost impact by affected groups, but despite this, costs which may be incurred following secondary legislation have been outlined as best as possible at this stage. The medicines information systems section contains an illustrative example of monetised impacts if those enabling powers were used. An assessment of impacts on businesses, including small or micro businesses, and wider impacts such as those on the environment, trade and competition, will be completed where appropriate alongside secondary legislation.

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

The proposals set out in this IA affect NHS providers, commissioners and arms' length bodies, as well as local authorities, social care providers, and independent organisations providing health and care service. However, as many of these proposals introduce enabling powers, any costs will depend upon how those powers are exercised. If secondary legislation were to be enacted, then an assessment of costs will be completed at that point if appropriate.

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

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

Benefits relating to these proposals have not been monetised in this IA as a robust estimation of likely effects is not possible. This is because the likely effects of, for example, an enabling power will depend upon how those powers are exercised. If secondary legislation were to be enacted, then an assessment of benefits will be completed at that point if appropriate.

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

The package of measures clarifies the law and streamlines the process for delivering on manifesto commitments. It is not possible to monetise the benefits of enabling powers, as the specific circumstances under which those powers may be exercised will influence the potential costs and benefits. If secondary legislation were to be enacted, then an assessment of benefits will be completed at that point if appropriate. However, examples of potential benefits from the proposals in this IA include reduced bureaucracy, and therefore, reduced burden on policymakers and providers, improved service provision to patients, and, more informed patients.

Key assumptions/sensitivities/risks — Discount rate (%): N/A

It is difficult to fully determine the impact of these proposals quantitatively, as they are designed to advance ambitions which have been prevalent in the NHS for several years. There is a risk associated with any change programme, even if intended to be limited, that resources are spent on implementing a new system to the detriment of output. A further risk is that some proposals are enabling measures and do not contain substantive provisions. It is therefore difficult to assess with any certainty what the impact of the measures will be, as the detail those final proposals to be able to assess their impacts is not currently available. Any policy that will be implemented using the regulation-making powers provided in these proposals in future will be required to develop an impact assessment as appropriate.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: Not a qualifying provision
Costs: N/A	**Benefits:** N/A	**Net:** N/A	

Health and Care Bill: Evidence base for impact assessment

Background and overview

The government are bringing forward a Health and Care Bill which builds on the experience of previous reforms of the health and care system, as well as the specific experience of responding to an unprecedented public health emergency in the Covid-19 pandemic.

The measures considered in this impact assessment are targeted to address specific problems and remove legislative barriers to allow front line staff and the government to deliver care more efficiently and maximise opportunities for improvement.

They are not intended to address all the challenges faced by the health and social care system. Instead, these measures are targeted changes to allow the government to support the social care system, improve quality and safety in the NHS, grant the flexibility to take further public health measures and to implement worldwide comprehensive reciprocal healthcare agreements.

The government is undertaking broader reforms to social care and public health which will support the system in helping people to live healthier, more independent lives for longer. As with the core proposals impact assessment, many measures covered in this impact assessment will introduce enabling powers and, will require further secondary legislation before they come into force.

Scope of the additional measures impact assessment

There are three guiding themes running through the core proposals in the Health and Care Bill. These are: *working together and supporting integration; reducing bureaucracy; and ensuring accountability and enhancing public confidence.* Alongside the core measures, there are additional proposals to make targeted changes to allow the government to support the social care system, improve quality and safety in the NHS, to grant the flexibility to take public health measures and to implement worldwide comprehensive reciprocal healthcare agreements.

The seven proposals considered in this impact assessment relate most directly to a*dditional proposals to support social care, public health, and quality and safety*. The analyses have been collated in this single document as they all entail small or unquantifiable impacts. Several other additional proposals, such as those relating to social care, have standalone IAs due to the size of the potential impact or because the complexity of the analysis warranted a separate document. Readers should refer to the impact assessments summary document for direction on where to find analysis on the other proposals in the Health and Care Bill.

Post Implementation Review (PIR)

The exact details of the PIR for the proposals analysed in this IA will be set out following the introduction of secondary legislation. Please refer to the Impact Assessment Summary Document for further justification.

Summary of the costs, benefits, risks and mitigations of each proposal

This section provides details of each of the proposed changes to support the health and care system.

1. Medicine information systems

Proposal summary

Medicines registries provide a valuable resource for assessing and monitoring the safety and effectiveness of medicines. The Independent Medicines and Medical Devices Safety Review[2] (IMMDSR) in 2020 made specific recommendations on the need for a national antiepileptics registry. Following this, the Medicines and Healthcare products Regulatory Agency (MHRA) is seeking regulation making powers to enable NHS Digital to establish and operate UK-wide medicines information systems in order to ensure that comprehensive national registries can be established and built in a sustainable way. This will require powers to be conferred on NHS Digital to enable them to mandate relevant data collection, including from private healthcare providers and devolved administrations, to build one or more comprehensive medicine information system(s). The intention is that the information included in these systems will then be available to the MHRA to enable it to establish and operate UK-wide registries using existing powers contained in the Human Medicines Regulations 2012.

This proposal only seeks the power to make regulations to establish medicine information systems when the need for a registry is identified. As such while there is no direct cost or impact associated with the clauses in this Bill, consideration as to how the regulations are likely to be laid out and their potential impact through an illustrative example is appropriate. A more detailed assessment of costs and impacts can be conducted when the regulations are made and exercised to develop a specific registry.

It is anticipated that, when there exists a need justified on public health grounds, the MHRA will assess the option of introducing a particular national medicines registry when alternative approaches to capturing sufficient data are not feasible. The proposal for establishment for a new registry will be presented to the Commission on Human Medicines (CHM) who would need to issue a formal registry-specific recommendation subject to the following criteria:

i. There are known risks associated with a medicine that can result in serious adverse health outcomes and where adherence to effective risk minimisation measures is critical to ensuring the benefits associated with the medicine outweigh the risks

ii. There is uncertainty about the safety or effectiveness of a medicine in a population in whom prescribing may occur that means that urgent evidence is required to build the evidence base on the benefit risk balance and inform the need for, and feasibility of, risk minimisation measures

The CHM's final advice on the need for a specific registry will be put to the appropriate authorities to propose issue of a joint direction for NHS Digital to collect the appropriate information required by the registry to be captured within the medicine information system.

Once the medicine information system is populated with the required data, a core register of all patients prescribed the specific medicine of interest will form the basis of a bespoke registry. The aim is to use patient-level data already collected within the NHS to form this core register, which should facilitate complete monitoring of patients prescribed specific medicine where necessary. Therefore, powers are also sought to ensure that individual patient-level data can be linked across different national datasets, held by NHS Digital and the devolved administrations, according to the design specification agreed by the Registry Steering Committee for a specific registry. The MHRA will work with the NHS to build and maintain these registries.

[2] *First Do No Harm The report of the Independent Medicines and Medical Devices Safety Review,* (2020). [Online]. Available from: https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

Rationale for intervention

At present, there are no government funded UK wide registries for products that pose potential health risks to certain patients. Either when a license is first granted for a medicinal product to be placed on the market, or at a later stage should the need be identified, the MHRA can require a Marketing Authorisation Holder (MAH) to establish a registry for that specific medicine to, for example, identify or monitor adverse effects. This is an existing legal power of the MHRA acting as the UK national competent authority for the regulation of medicine. The requirement for a registry is defined in the terms of the license granted to the MAH. MAH-led medicine registries have had mixed success in generating the strength of evidence required to make fully robust regulatory decisions regarding the safe and effective use of medicine. This is in part because such stand-alone registries are voluntary for clinicians, and full identification of eligible patients is also often challenging due to a hesitance on the behalf of clinicians and their patients to enrol as part of an MAH-sponsored registry due to data confidentiality concerns. Enrolment may also be affected as registries can place additional burden on healthcare providers (HCPs) to supply data.

Academic led initiatives also exist and have demonstrated the value that evidence generated by high quality registries can have in supporting regulatory, HCPs, and patient decision making. The MHRA are increasingly using data from these larger disease registries led by clinical and academic research groups, although these often have issues with sustainability. In addition, voluntary participation means data is not comprehensive or representative, rarely including data from private providers and with regional and clinical speciality variations in terms of coverage. NHS Digital and the devolved administrations already collate extensive data on the use of medicines in the UK but there are gaps in this which need to be addressed.

The key justification for this proposal is that it will facilitate a better monitoring system of the use, benefits and risks of medicines, leading to improved evidence bases for regulatory and clinical decision-making and overall patient safety outcomes. The proposals brought forward will make this possible as a central UK wide medicine information system run by the NHS, filling existing data gaps and linking data from different sources, and will enable the initiation of high-quality inclusive registries operated independently of industry.

Other policy options considered

This IA only presents the option to introduce statutory powers to enable NHS Digital to establish a medicines information system. This system will enable MHRA to set up a comprehensive UK wide registry for a product when CHM considers the criteria for such a registry is met. The baseline status quo option involves the MHRA setting up registries without a medicine information system – either by requiring MAHs to set up voluntary registries or trying to develop UK wide registries without powers to mandate data collection.

Option 0 - Business as usual (Do nothing)
In the counterfactual, the MHRA would continue using existing powers to set up registries but without statutory medicine information systems to support them. This could be through the licensing process where MAHs could be asked to set up and maintain registries for specific products or, for example, as is the case with antiepileptics, a national registry is being set up to address an urgent safety concern as recommended by the IMMDSR, but this is reliant upon existing data feeds and voluntary provision of additional data. Currently, there are gaps in data from prescriptions in private practice and from the devolved administrations as well as a lack of detail on clinical aspects that are vital in order for the registry to meet its objectives. This option was not deemed feasible because the lack of robust, objective and comprehensive evidence poses high risks for patients. Without a robust and complete medicine information system building a comprehensive medicine registry, including all patients prescribed that medicine, independent from industry, which can be necessary if public confidence is to be maintained, gaps in the data would

still remain meaning that the registry would not be able to support safe and effective use of medicines in all patients.

Key impacts

There are no impacts resulting directly from this primary legislation as it only seeks the power to make regulations to establish medicine information systems when the need for a registry is identified.

If this power was exercised and a registry were to be set up utilising the medicine information system, requirements would be placed on NHS Digital and potentially the devolved administrations to capture and process the required data. Where information for a medicine information system is required from healthcare providers within Scotland or Wales it may be collected via an intermediary organisation within those territories, where appropriate, rather than, for example, collected directly from healthcare providers. The information would then be shared onwards with NHS Digital. It is not considered that there will be an additional cost to the provider of the data when an intermediary organisation is used as we expect that similar or the same processes for providing the data straight to NHS Digital would be used. There may be small costs for the intermediary organisation, likely to be a public body, in collecting this data, though it is expected that this would be minimal as these bodies would already have infrastructure in place to routinely collect, holds and process data in relation to medicines and health. In establishing each new registry MHRA and NHS digital would work with the intermediary body or colleagues in Wales or Scotland to identify who data is needed from and the best route for collection to minimise burden and cost.

Costs of setting up and running a registry benefiting from a medicines information system are unlikely to be very different from one that does not use a medicines information system. This is because the design of a registry, and hence the requirements in terms of the types and volume of data that would need to be captured, would be determined based on the scientific and regulatory need which would be the same regardless of whether the regulations made based on the powers being sought were in place. The purpose of the medicine information systems proposal is to enable the MHRA to make regulations allowing them to direct the Information Centre to collect the required data and to give them a power to require provision of that data from the relevant data holders. Regulations will also lay out the legal basis for collating and sharing this data. The technology and supporting governance and documentation required to deliver a medicines registry designed to meet its scientific and regulatory objectives would be the same regardless of if it being underpinned by a statutory basis or not. However, the potential benefits are likely to be greater as the powers provided to require submission of the requested data will increase participation by HCPs and the availability of more comprehensive and timely information. This added information would likely address risks to patient health and the benefits would potentially extend to all patients treated with the medicine.

The proposals will enable the MHRA to direct NHS Digital to establish and operate UK-wide medicine information system(s), the information from which will then be available to MHRA to establish comprehensive national registries.

A figure for the Equivalent Annual Net Direct Cost to Business (EANDCB) has not been possible to estimate as these proposals are enabling powers. The costs with regards to data provision are largely expected to fall to the NHS and other public organisations. However, dependent on the scope of a specific registry data may be sought from private HCPs for example, the potential impact of data collection on business will depend upon the medicines of interest, remit, scope and duration of the registry and hence the volume and complexity of the data that needs to be made available to the information system. Therefore, at this stage it is not possible to estimate what the potential cost on business may be. Any additional costs to HCPs from contributing to a mandatory medicine registry would be examined as part of the business case process.

Furthermore, and for this same reason, a full small and micro businesses assessment (SaMBA) has not been completed as part of the IA for the primary legislation. This can be included in future assessments when the design of a specific registry, and therefore its impact on SMBs and other potential data holders, is clearer. For context, in 2012 approximately 53% of NHS consultants undertook some private practice, with an estimated 3,000 working entirely in the private sector[3]. There are an estimated 515 private hospitals offering health care services in the UK, which are a mixture of for-profit and non-profit. There are no comprehensive public data on the total number of patients treated in private hospitals, but of the 285 hospitals that submitted data in 2017, 735,522 patients received treatment. By comparison, more than 8.5 million nonurgent patients were treated by the NHS that year[4]. Again in 2012, an estimated 3% of GP consultations were private (~7 million consultations) although this may have increased since. Any impact on SMBs would be around their need to submit data to the information system. This data would only consist of information that they should already be capturing and recording as part of good clinical and healthcare delivery practice to support individual patient management and safety. We believe there may be two key categories of costs: i) familiarisation and training costs and ii) costs associated with the data collection and submission processes. It is plausible that these costs may impact small providers with less IT capacity more disproportionately. However, by working with the NHS to deliver systems that integrate with local systems and capture the data into the information system efficiently we can reduce the burden on businesses. As described earlier, the number and types of HCPs expected to contribute to an information system for a new medicine(s) will be unknown until details of the needs for that medicine are finalised. It is therefore not yet possible to state whether these businesses will be disproportionately affected or whether an exemption would be appropriate. Again, potential costs to small and micro businesses will be considered as part of the individual business case processes. There are no anticipated impacts on competition or international trade.

There are potential impacts on the justice system. In particular, with regards to clauses on new offences related to information disclosure from the medicine information system(s) and potential identification in a specific registry of cases suitable for compensation. A Justice impact test to fully assess the impacts will be completed in conjunction with the Ministry of Justice.

Indicative estimates of costs and benefits of a national registry

This analysis is an illustrative example as the proposal relates to enabling powers to establish medicine information systems rather than the actual establishment of specific registries. It examines the potential impacts of the MHRA using this power to enable NHS Digital to establish an information system to support a specific registry. The overall aim would be to provide data from the system to MHRA to set up and maintain such a national registry, using MHRA's existing pharmacovigilance powers. The intention is to provide an initial high-level assessment of the impact that the use of this power could have in the future. This mirrors the approach used to assess the set-up of national registries for medical devices in the MMD Bill Impact Assessment[5].

Each individual registry is likely to vary in design (size and function) as the specific risks relating to the specific product are likely to be different and as a result so are the potential impacts. To highlight this point, we present cost estimates using data from three existing registries that vary significantly scope and size (Sodium Valproate[6], National Joint Registry, Breast and Cosmetic implants).

[3] The Kings Fund, 'The UK private health market', 2014. [Online]. Available from: https://www.kingsfund.org.uk/sites/default/files/media/commission-appendix-uk-private-health-market.pdf
[4] The private healthcare information network, 'Annual report 2016-17', 2017. [Online]. Available from: https://apicms.phin.org.uk/Content/Resource/158-PHIN_AR_2016-17.pdf
[5] Medicines and Medical Devices Bill - IA No: 9556 - 2020
[6] https://digital.nhs.uk/data-and-information/publications/statistical/mi-medicines-in-pregnancy-registry/valproate-use-in-females-aged-0-to-54-in-england-april-2018-to-september-2020

Also presented are potential benefits of a national medicines' registry using the England-only Sodium Valproate registry example. Estimates of benefits must be treated with caution as they are based on data available so far from the valproate example which is still being developed. These are for illustrative purposes only. Specific costs and benefits of individual registries must be considered as part of the business case process.

Costs

MHRA and NHS Digital – set up and running costs

MHRA would be responsible for establishing and running such national registries, bringing in relevant partners as required. This could be through a Registry Steering Committee to provide operational support and clinical guidance, and oversight of the project's set up, running, and translation of its findings. There are likely to be both one off set up and ongoing opportunity costs of MHRA staff time spent on these activities. It is not anticipated that there will be additional costs to Marketing Authorisation Holders.

NHS Digital would collect the data needed for all medicine registries from various sources and hold this in an information system. Data from the information system would be provided to the MHRA to establish and operate/run medicine specific registries.

Table 1 outlines the cost of setting up three different medicines registries. The table demonstrates that depending on specific circumstances such as size and scope, set up and running costs can vary substantially. Similarly, the benefits of the registry may be expected to scale up according to the size and scope of the registry, as for example a greater number of patients or treatments may be covered, thus benefitting a larger patient population.

Table1: Indicative set up and running costs of national registries per annum

National registry example	Potential annual costs to MHRA and NHS Digital (Set up / annual running cost)
Sodium Valproate	£1.014m / £183,000 (estimated)
Breast and Cosmetic Implant registry	£83,000 / £183,000
National Joint Registry	£1.8m / £4.1m

Sodium Valproate - method to calculate set up and running costs

Based on the Sodium Valproate example, it is estimated that roughly that about 0.5 FTE hours of a SEO, G6 and SCS costing approximately **£164,000** in MHRA staff resources could be spent on a registry annually[7]. This is an estimated average with likely slightly higher costs in the first 2-3 years, due to the need for more senior staff involvement while the registry is being developed, balanced by slightly lower costs once it is established.

Total NHS Digital potential staff and non-staff costs on Sodium Valproate is estimated at about **£950,000per annum** based upon the costs for the delivery of the second phase of development planned for 2021/22. This amounts to a potential total set up of **£1.014million** annually for the Sodium Valproate registry. However, this estimate must be treated as indicative only as the majority of the cost is to develop the registry and once established running costs will be substantially lower. Beyond the initial set up which is likely to last 2-3 years, maintenance costs could be estimated to be similar to the BCIR as described below given the comparative size. For reference, the first year costs for NHS Digital were substantially lower at approximately £20,000.

[7] Based on average salary data from MHRA Finance

National Joint Registry (NJR) and Breast and Cosmetic Implant registry (BCIR) - method to calculate set up and running costs

The potential costs to NHS Digital below have been taken from the Medicines and Medical Devices Bill IA June 2020[8]. The estimates are based on data from the National Joint Registry (NJR) and Breast and Cosmetic Implant registry (BCIR). The size, scope and amount of activity undertaken i.e. amount of information collected and how it is used would impact costs. The below is therefore an indicative range of costs.

One off set up costs:
The MMD IA estimates that a large-scale registry such as the NJR (with over 225,000 procedures reported to it in 2018) could require an initial set up cost of **£1.8m**. The BCIR (with just under 15,600 operations reported over a year July 2018-June2019) could involve set up costs of about **£83,000**. The costs are likely to cover any IT systems set up, and staff resources to design the registry and publish guidance for participating providers.

Ongoing costs:
The MMD IA reports ongoing costs **of £4.1m** per annum for the NJR and **£183,000** per annum for BCIR. Ongoing costs are likely to cover – auditing data collected, analysing and reporting on safety alerts, communicating with HCPs, researchers, government and the public, IT systems development as registry evolves.

Administrative costs to NHS and private healthcare providers

It will be mandatory for all HCPs to contribute to an information system. This could involve clinical staff time spent on undergoing training on the new registry and on an ongoing basis, recording the data. Some providers may already be providing this data voluntarily to existing MAH registries and for them the additional costs are unlikely to be significant. The number of HCPs this will impact is unknown as it will depend on each specific registry and the prescribing trends of each medicine. In general, HCPs can refer to GPs, private and state hospitals but could also include nurses, midwives, pharmacists for some registries. However, it is unlikely that the overall costs to HCPs will be high, as most of the data required are likely to already be collected by HCPs as part of clinical management.

In the case of Sodium Valproate, women should have annual appointments with a neurologist who should review their treatment and ensure patients complete a signed annual risk acknowledgement form (ARAF), which is part of the Pregnancy Prevention Plan. There are currently estimated to be 625 consultant neurologists[9] in England who might review a woman's valproate treatment. Given that they already have to undertake regular reviews with patients on their Sodium Valproate use, the inclusion of an ARAF on the registry is unlikely to increase administrative burdens.

Benefits

More informed patients and greater public confidence in the health system:
Patients can directly report on safety issues and may be more informed on the risks and benefits of their medicines. This is likely to enable patients to take more informed decisions about their health.

Improved regulatory system:

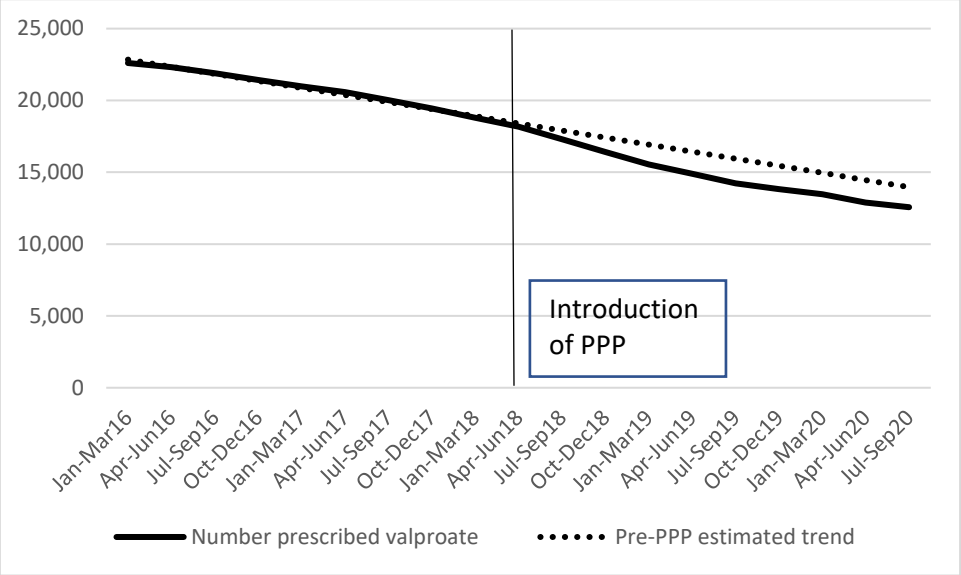
[8] Medicines and Medical Devices Bill - IA No: 9556 - 2020
[9] Association of British Neurologists, Neurology Workforce Survey, 2020. [Online]. Available from: https://cdn.ymaws.com/www.theabn.org/resource/collection/219B4A48-4D25-4726-97AA-0EB6090769BE/2020_ABN_Neurology_Workforce_Survey_2018-19_28_Jan_2020.pdf

Information from medicine information systems will support the establishment of national registries. This would allow the MHRA to use registries to more widely support safe use of a medicine through inclusion of it in regulatory information and prescribing guidelines, and to take swift informed regulatory action, as it is likely to receive timely and more complete data on risks associated with the specific medicines.

Improved service provision to patients:
Information from medicine information system and the resulting medicines registry should allow HCPs to analyse reports on data to evaluate outcomes. HCPs could recall/amend patient treatment if necessary and offer more efficient and effective services.

Avoided patient harm:
Most importantly, information from medicine information systems and the resulting medicines registry is likely to give healthcare professionals timely access to more complete information – including at the individual patient level. This would enable them to take rapid action and avert potential risks to patient health from adverse effects.

> ***Illustrative example – avoided patient harm from Sodium Valproate registry:***
> Currently the Sodium Valproate registry, which is the basis of the planned antiepileptics registry is not mandatory and coverage may not be comprehensive, particularly for women treated in the private sector. One of the aims of introducing a comprehensive mandatory Sodium Valproate registry is to increase coverage which should in turn further accelerate the decline in prescribing and reduce the number of exposed pregnancies. Reducing the number of exposed pregnancies was a key aim of the 2018 Pregnancy Prevention Plan (2018). The proposed power would enable NHS Digital to collect data, subject to a Direction, from private prescribers and from devolved administrations, which would then be provided to MHRA to establish a comprehensive valproate/anti-epileptic drugs registry. Therefore, the data illustrated below is a useful example of the possible impact of enactment of the proposed enabling power.
>
> Figure 1 presents data published by the NHS Business Services Authority on the number of women aged 14-45 in England prescribed Sodium Valproate over time. Figure 1 shows that in the two years prior to the introduction of the PPP prescribing in women aged 14-45 was falling by approximately 15%. Following the PPP, prescribing fell approximately by an additional 10%.
>
> **Figure 1: The number of female patients aged 14-45 prescribed valproate over time before and after introduction of the Pregnancy Prevention Plan**



The first retrospective data from the non-mandatory Sodium Valproate registry suggest that between April 2018 and Sept 2020, 181 pregnancies have been exposed to Sodium Valproate (or approximately 70 per year). One hypothesis is that if a mandatory comprehensive drug registry were in place, some of these exposures may have been avoided as there would be more complete data on adherence by prescribers to best prescribing practices and implementation of the Pregnancy Prevention Programme. Using an arbitrary assumption of a further 20% reduction in the exposure to Sodium Valproate following the introduction of a mandatory registry, it is estimated that this would reduce the number of pregnancies exposed by a further 11 in the year September 2020-21.

Net benefits of the Sodium Valproate registry
This simple analysis examines what Quality Adjusted Life Year (QALY) gains are required to compensate for the cost of setting up and running the Sodium Valproate registry. The estimated cost for setting up and running the registry in the second year is £1.014million. The best estimate for the value society places on a QALY is £60,000[10]. Therefore, it is estimated that approximately 16.9 QALYs would have to be generated per annum through development to account for the initial annual cost of the registry. If a 20% reduction in exposure is achieved this would equate to 1.5 QALY per exposed pregnancy avoided. However, in future years this would be lower at approximately 3 QALYS generated per annum and a 0.3 QALY per exposed pregnancy avoided. Given valproate exposure during pregnancy is associated with an approximately 50% risk of severe and lifelong physical and neurological disorders this threshold would be reached. This demonstrates that with a very modest reduction in exposure, only limited QALY gains are required for the net benefits of the registry to break-even once the initial set up is complete.

Avoided costs to NHS from compensation / litigation and additional treatment:

[10] HM Treasury: The Green Book: appraisal and evaluation in central government, (2020). [Online]. Available from: https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent

Through early identification of risks and reducing scope for error (outlined above), harm to patients could be prevented. This might in turn avoid potential claims and litigation costs against the NHS. Costs to NHS of providing additional treatment to affected patients could also be avoided[11].

Risks and Mitigations

The purpose of a medicine registry is to generate evidence. This evidence will be used by MHRA and other organisations to inform regulations and guidance and to drive changes in clinical practice. However, the economic benefits will only be fully realised if those changes actually happen, and patient safety is improved. MHRA have an established role in leading within this area. This is highlighted in the MHRA 2018-2023 Corporate plan[12] and the 2020/21 Business plan[13], which lay out the strategy to reshape post-market vigilance to run proactive life-cycle monitoring, of which this policy is a component, and to increase MHRA influence on clinical practice through further engagement with patients and key strategic healthcare partners.

2. Professional regulation

Proposal summary

The powers proposed in this Bill form part of a wider programme to create a more flexible and proportionate professional regulatory framework that is better able to protect patients and the public. These powers will make it easier to ensure that professions protected in law are the right ones and that the level of regulatory oversight is proportionate to the risks to the public.

Section 60 of the Health Act 1999 already provides powers to make changes to the professional regulatory landscape through secondary legislation. The Bill provisions will widen the scope of section 60 and enable us to, where necessary, make further changes in secondary legislation to ensure the professional regulation system delivers public protection in a modern and effective way, and, ensure professions are regulated in the most appropriate manner.

The new powers will enable:

i. the abolition of an individual health and care professional regulatory body where the professions concerned have been deregulated or are being regulated by another body;
ii. the removal of health care professions from regulation where regulation is no longer required for the protection of the public;
iii. the delegation of certain functions to other regulatory bodies through legislation (which was previously prohibited); and
iv. the regulation of groups of workers concerned with physical or mental health of individuals, whether or not they are generally regarded as a profession i.e. senior managers and leaders.

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[11] The literature review carried out by NICE estimates the percentage of hospital admissions due to ADRs in the UK to be 6-7%. Of these ADRs, it is estimated that 1.6-3.7% were to be preventable. One review estimated that the overall impact of ADRs in England was 4 out of 100 hospital bed stays with an equivalent cost of about £380 million a year to the NHS in England. https://cks.nice.org.uk/topics/adverse-drug-reactions/background-information/health-financial-implications-of-adrs/

[12] Medicines and Healthcare products Regulatory Agency (MHRA), 'Corporate plan 2018-23', 2018. [Online]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/702075/Corporate_Plan.pdf

[13] Medicines and Healthcare products Regulatory Agency (MHRA), 'Business plan 2021-21', 2020. [Online]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/889864/MHRA_Business_Plan_2020_to_2021.pdf

The use of these additional powers will be subject to public consultation and the resulting secondary legislation would be subject to the affirmative Parliamentary process. DHSC will work with the regulatory bodies, the Professional Standards Authority and devolved administrations on proposals to make further improvements to professional regulation through secondary legislation if these amendments are successful. Wider stakeholder engagement will also be undertaken including with patient safety groups and the public.

The measures form part of a larger project to modernise the legislation of the UK health and care professional regulators. The programme is commencing with reforms to the Medical Act 1983 which provides the legislative framework for the General Medical Council by means of an Order in Council using powers in the Health Act 1999. It is envisaged that changes to the other health and care regulators legislation will follow shortly after. The powers in the Bill complement this work to support the move to a modern and effective professional regulatory system, including considering whether there should be a reduction in the number of healthcare professional regulators.

Rationale for intervention

The UK model of professional regulation for healthcare professionals has become increasingly rigid and complex and needs to change to better protect patients, support the provision of health services, and help the workforce better meet current and future challenges.

In 2017, the four UK governments consulted on high-level principles for reform of professional regulation and set out their five objectives, to:

- improve the protection of the public from the risk of harm from poor professional practice;
- support the development of a flexible workforce that is better able to meet the challenges of delivering healthcare in the future;
- deal with concerns about the performance of professionals in a more proportionate and responsive fashion;
- provide greater support to regulated professionals in delivering high quality care; and
- increase the efficiency of the system.

The consultation *Promoting professionalism, reforming regulation* included questions relating to the provisions in the Bill. The link to the consultation can be found here. The consultation set out the proposals that were welcomed by key stakeholders, including professional organisations, regulators and employers. The link to the consultation response can be found here.

The consultation response also highlighted the case for broader changes to the regulatory landscape including reducing the number of regulators. The Secretary of State for Health and Social Care further committed to reviewing the number of health and care professional regulators in the November 2020 *Busting Bureaucracy* policy paper and DHSC has commissioned an independent review, led by KPMG, which is due to report by the end of the year.

A further consultation *Regulating healthcare professionals, protecting the public* was published in May 2021 which sets out reform proposals for all of the regulators. The implementation process will start with changes to the Medical Act 1983 which is the legislative basis underpinning the General Medical Council. Changes for the other regulators will follow. A response to the consultation will be published in the next few months.

Additional wider reforms have also been considered such as the government response to the Law Commission's review of UK law relating to the regulation of healthcare professionals, and, the recent review of the fit and proper persons test (further details are included in the fourth power below).

The powers proposed in the Bill are:

> i) the abolition of an individual health and care professional regulatory body where the professions concerned have been deregulated or are being regulated by another body

There is the inevitable duplication in having nine regulatory bodies (10 including Social Work England) that perform similar functions in relation to different professions. A reduction in the number of regulators would deliver public protection in a more consistent way, while also delivering financial and efficiency savings. Powers under section 60 already allow for the creation of new regulators through secondary legislation. However, similar powers are not currently available to close a regulator, and this can only be done via primary legislation.

This change would enable Parliament to use secondary legislation to abolish a regulator where its regulatory functions have been merged or subsumed into another body or bodies, or where the professions that it regulates have been removed from regulation.

The July 2019 Government response to the *Promoting professionalism, reforming regulation* consultation set out the Government's intention to consider reducing the number of regulators. The Secretary of State for Health and Social Care further committed to reviewing the number of health and care professional regulators in the November 2020 *Busting Bureaucracy* policy paper and DHSC has commissioned an independent review, led by KPG, which is due to report in the coming months. Use of these powers would be subject to consultation and the affirmative parliamentary procedure.

> ii) the removal of health care professions from regulation where regulation is no longer required for the protection of the public

Statutory regulation should only be used where it is necessary for public protection. The level of regulatory oversight for each profession should be proportionate to the activity carried out and the risks to patients, service users and the public.

The landscape of the health and social care workforce is not static, meaning that the risks to the public will change over time as practices, technology and roles develop. While statutory regulation may be necessary now for a certain profession, over time the risk profile may change, such that statutory regulation is no longer necessary. Clearly, in order to protect the public, professionals such as doctors, nurses, dentists and paramedics will always be subject to statutory regulation.

A provision to enable the removal of a profession from statutory regulation through secondary legislation will make it easier to ensure that the protections and regulatory barriers that are in place remain proportionate for all health and care professions. Any use of these powers would be subject to consultation and parliamentary approval using the affirmative procedure.

> iii) the delegation of certain functions to other regulatory bodies through legislation (which was previously prohibited)

Currently, there are legal restrictions in place which limit the functions that professional regulators can delegate to another body. This prohibits regulators from delegating the functions of the keeping of a register of persons permitted to practise; determining standards of education and training for admission to practice; giving advice about standards of conduct and performance; and administering procedures relating to misconduct and unfitness to practise.

The removal of these restrictions would enable further collaboration in how regulation is delivered, which could drive up quality, reduce costs and provide greater consistency. This would enable a single regulator to take on the role of providing a regulatory function, such as the holding of a register, the assessment of international applicants or the adjudication process for fitness to

practice, across some or all regulators. This will help to deliver public protection in a more consistent fashion and may also increase efficiency. Where a function is delegated, a regulator would retain responsibility for that function.

> iv) the regulation of groups of workers concerned with physical or mental health of individuals, whether or not they are generally regarded as a profession i.e. senior managers and leaders

While the definition of those groups which can be included in regulation using the powers in Section 60 of the Health Act 1999 is broad in relation to healthcare professionals, the proposed changes allows for the regulation of groups of workers concerned with physical or mental health of individuals, whether or not they are generally regarded as a profession, to be regulated. .For example, those in senior management and leadership roles and other groups of workers are within the scope of future regulation.

The 2019 Kark review of the fit and proper persons test recommended putting in place stronger measures to ensure that NHS senior managers and leaders have the right skills, behaviours and competencies. While it stopped short of recommending full statutory regulation, NHS England/Improvement is currently considering how best to take forward the recommendations.

Extending the scope of professions who can be regulated using the powers in Section 60 of the Health Act 1999 would provide additional flexibility to extend statutory regulation to, for example NHS managers and leaders in the future, if further measures are needed.

Other policy options considered

Option 0 - Business as usual (Do nothing)
Not being able to expand the scope of Section 60 of the Health Act 1999 will restrict the extent of reform can be made. Proposals are currently being developed using the powers available to reform professional regulation in the areas of fitness to practise, governance and operating framework, and the registration and education and training functions. However, the aim is to go further to modernise professional regulation and the new powers will support this.

Option 1 - Seek fewer powers
If fewer powers were established through the Bill, then it would be expected that primary legislation would be pursued for the remaining powers in the near future. This is because all of the powers proposed are expected to be required as part of our reform programme. This will delay completion of our reform programme.

Costs

These provisions seek new powers to be taken forward through secondary legislation. There are therefore no costs associated with these powers coming into force. An impact assessment which calculates associated costs will be completed if the powers are put into effect.

Benefits

As mentioned above, these provisions seek new powers to be taken forward through secondary legislation. Therefore, the benefits from all proposals are indirect and depend on the actions of the Secretary of State. The potential benefits of these enabling powers, if put into effect through secondary legislation, are outlined in the Rationale for Intervention section. An impact assessment which calculates associated benefits will be completed if the powers are put into effect.

Important note

We are currently engaging with the devolved administrations, Treasury, Cabinet Office, Department for Education and the Department for Business, Energy and Industrial Strategy regarding the reform proposals.

3. Medical examiners

Proposal summary

The Department of Health and Social Care (DHSC) has developed policy over the past several years which aims to ensure that a reformed system for certifying non-coronial deaths improves the quality and accuracy of Medical Certificate of Cause of Deaths (MCCDs), and, provides adequate scrutiny to identify and deter criminal activity or poor practice. The legal framework of this system was set out in Part 1 of the Coroners and Justice Act 2009, but not commenced at this time.

As part of this work, DHSC ran a consultation from March to June 2016, seeking views on the detail of the operation of the proposed reforms to the death certification process, and draft regulations setting out the system within which the services would operate. The consultation document proposed the introduction of a unified system of scrutiny by independent medical examiners, hosted by local authorities, of all deaths in England and Wales that are not investigated by a coroner as set out in the Coroners and Justice Act 2009 and described how the Government saw the new system working in practice. The Department's preferred option for funding this scheme in England was described as a nationally set fee. The consultation documents and assumptions suggested this fee would be between £80 and £100 for England.

The Department's consultation response was published in June 2018 and set out an approach to introduce a non-statutory medical examiner system by April 2019, where medical examiners were to be appointed within the NHS, without the introduction of a new fee at that time. An Impact Assessment was published on the gov.uk website alongside the June 2018 consultation response, outlining three policy options and associated costings for England. Option 3 outlined the impact of introducing a ME system hosted within the NHS. Since the publication of the 2018 consultation response and impact assessment, a non-statutory medical examiner system has been set up within the NHS in England. To date, all NHS Trusts which require a medical examiner office (based on number of deaths) under a statutory system have done so on a non-statutory basis. In terms of the impacts of the amendment on Wales, an impact assessment has been published and can be found here: Introduction of the medical examiner role and reforms to death certification | GOV.WALES

The consultation response also outlined the intention to commence sections 18 and 21 of the Coroners and Justice Act 2009, to provide for regulations to require medical practitioners to report deaths to the coroner which the coroner has a duty to investigate, and, for the appointment of a National Medical Examiner.

The Government committed to amending the Coroners and Justice Act 2009 when an opportunity arose, to put the medical examiner system on a statutory footing. It also committed to further considering legislative requirements post-April 2019 (based on the non-statutory medical examiner system).

The Health and Care Bill includes provisions to amend the Coroners and Justice Act 2009 to allow NHS bodies to appoint medical examiners instead of local authorities in England and Welsh NHS bodies rather than only local health board, in Wales. The Secretary of State and Welsh Ministers will have a duty to ensure that there are sufficient medical examiners and that they are adequately funded, and a power to issue directions to ensure that the duty is met.

After these amendments have been made, we intend to commence the statutory provisions underpinning the medical examiner system set out in the Coroners and Justice Act 2009. The

necessary secondary legislation will also be made in respect of key aspects of the system including the payment of a fee in respect of medical examiner services. The fee regulations will apply in relation to England only, the Welsh ministers may make regulations in relation to Wales.

Policy work on setting an appropriate public fee is on-going (to be informed by the non-statutory system since 2019) and will be addressed when making the secondary legislation following the commencement of the primary legislation. We do not envisage introducing secondary legislation to provide for a fee to be payable in respect of medical examiner services before April 2022. This will follow the passage of the Health and Care Bill.

Rationale for intervention

The arrangements for scrutinising MCCDs have remained largely unchanged for over 50 years yet there are concerns about their efficacy and efficiency, particularly for those cases which are not referred to a coroner. For cremation there is currently a degree of scrutiny but the system for burials does not include any additional scrutiny of the quality or accuracy of the MCCD. The statutory system was set up in the Coroners and Justice Act 2009 after the Shipman Inquiry concluded that it was no longer suitable to have a different certification processes for cremations and burials, and that all MCCDs should be subject to independent medical scrutiny. The rationale behind the provisions in this Bill allowing NHS bodies in England and Welsh NHS bodies in Wales to appoint medical examiners instead of local authorities and local health board respectively, is that medical examiners employed in the NHS system will have access to information in the sensitive and urgent timescales required to register a death.

Other policy options considered

An Impact Assessment was published on the gov.uk website alongside the June 2018 consultation response, outlining three policy options and associated costings for England. This IA was cleared across all departments (including HM Treasury) via write-round. The IA outlined in this paragraph is England specific.

The preferred option (and that consistent with the consultation response) was option 3:

"Reform the current system for cremations and burials by introducing a new universal check by a Medical Examiner (ME) applicable to all non-coronial deaths. The system will initially be funded through cremation form fee revenues sourced from efficiencies in the system and DHSC. Following the interim period, the ME system would be primarily funded through a fee for cremations and burials."

This option was preferred as it would improve the assurance and crime deterrence aspects of death certification and provide the same level of scrutiny for both burial and cremation cases.

The published IA describes a two-stage process for implementing the Medical Examiner (ME) system. Initially, the non-statutory ME system would be funded through revenues from cremation form 5, with DHSC funding any deficit. However, once underpinned by statute, the system would be primarily funded through a fee for all adult non-coronial deaths that are certified by an ME. DHSC would fund ME costs related to child deaths and any other costs to the service not covered by the fee. DHSC will also fund the set-up costs of the system. The Welsh Impact Assessment also bases costs on option 3 and the two-stage process using the same methodology as the English impact assessment.

Costs and benefits

The Health and Care Bill makes a change to the existing statutory framework set out in the Coroners and Justice Act 2009, so that NHS bodies in England and Welsh NHS bodies in Wales may appoint medical examiners, instead of local authorities and local health boards respectively.

This change would come into effect once statutory system in the Coroners and Justice Act 2009 is commenced, and we have exercised the powers to make relevant secondary legislation. An updated impact assessment, which includes an EANDCB and SaMBA will be produced alongside that secondary legislation as appropriate.

The impacts of the full statutory system for England are set out in the June 2018 impact assessment, and for Wales in a separate impact assessment which uses the same methodology, where policy Option 3 set out the estimated costs and benefits of introducing a national statutory system of medical examiners based in the NHS. As the June 2018 (England) IA sets out in para 77-79, we anticipate that any new net cost to business from implementing the statutory system would be minimal or zero. These included the risk of familiarisation costs for doctors employed in both the NHS and private sector to understand new procedures and establish contacts with new MEs, although that risk ought to be mitigated to a large extent as DHSC is not proposing significant changes to the MCCD itself. There may have been the potential for increased costs to funeral directors who must collect cremation fees from the bereaved on the behalf of doctors, but the IA states that this is likely to be mitigated as no changes are proposed to the mechanism for the collection of cremation fees. Minimal or zero costs to businesses are also expected in Wales from policy option 3.

DHSC have further confidence that will be no additional costs to businesses stemming from this proposal, as since 2018 a non-statutory national system of medical examiners has almost completely been established within the NHS in England. This means that the ME system has moved away from the 'Do Nothing' option which was the baseline for the 2018 IA, and towards the ME system hosted in the NHS that was analysed in Option 3 of the 2018 IA. Importantly, to date, all NHS Trusts which require a medical examiner office under a statutory system have done so on a non-statutory basis. Hence moving from the non-statutory system to the statutory system is unlikely to result in further ME offices being established, thus resulting in minimal set up costs. DHSC will re-assess the assertation that there are unlikely to be impacts on businesses of the proposals at secondary legislation stage: the intention is to update the 2018 IA with supplementary information informed by the non-statutory system set up in the NHS before making the secondary regulations and once the primary legislation is implemented. An EANDCB and SaMBA will be produced at that point as appropriate.

The June 2018 IA for England outlines that the set up and running costs of the statutory system will not fall on private businesses. The non-statutory arrangements currently in place in trusts reflect the arrangements which would be in place in the statutory scheme. For clarity, the June 2018 IA gave an estimated running cost (to DHSC and the public) of approx. £34-£41 million per annum[14] in England (using 2018 prices). Initial internal analysis, drawing on cost data from the non-statutory system provides confidence that the estimated costs and benefits to DHSC and the public outlined in the 2018 IA (for England) are likely to be similar to the statutory arrangements in the Coroners and Justice Act 2009, once these are commenced. One risk is that introducing the statutory system leads to a requirement of more medical examiners. Analysis on the number of medical examiners required in the system is provided in the June 2018 IA (pages 20-22), though these costs would be covered by DHSC or the public and the mechanism by which this occurs is outlined in the 2018 IA. These cost estimates will be updated before the secondary legislation is made (see below). Economic costs for Wales are outlined in the Welsh IA.

Furthermore, given that the transition to a non-statutory system is almost complete, many of the costs outlined in the 2018 impact assessment, which compared to a 'Do Nothing' option, are sunk costs which have already been incurred by the health system.

[14] Introduction of medical examiners and death certification reform in England: impact assessment (publishing.service.gov.uk) p28

In summary, DHSC are content that our previous estimates published in the 2018 English impact assessment, and Welsh impact assessment, remain sufficiently accurate for the purposes of estimating the costs and benefits of establishing a statutory scheme. As such, readers are referred to the aforementioned impact assessments for the purpose of understanding the impact of the statutory scheme, once it is commenced.

Important note

The intention is to update the 2018 IA with supplementary information informed by the non-statutory system set up in the NHS before making the secondary regulations once the primary legislation is implemented.

As described above, the costs of medical examiner services will only have effect once we have commenced the statutory medical examiner system and exercised powers to make relevant regulations. It will be appropriate to review the financial implications of the medical examiners system as part of that process. This will enable us to calculate a more accurate figure, incorporating actual quarterly costs, as well as maximum learning around operational points, all gathered via the existing non-statutory ME system.

4. Hospital food standards

Proposal summary

This proposal introduces a Statutory Instrument (SI) to grant the Secretary of State for Health and Social Care powers to adopt secondary legislation to make NHS Hospital Food Standards mandatory across the NHS in England. If introduced, these would be enforced by the Care Quality Commission.

The Independent Review of NHS Hospital Food[15] made eight recommendations to improve the standard of food across the NHS estate. NHSEI are leading on implementing recommendations from the Food Review and are establishing an expert group to facilitate this. The proposals will allow the Secretary of State to make Food Standards mandatory. Granting this power will allow the Government to deliver swiftly on its ambition to improve hospital food through secondary legislation, and, will send a clear message that improving hospital food is a priority for the Government.

Rationale for intervention

The Food Review published on the 26th October 2020 highlights that there is clear scope for improvement in the provision of food in the NHS estate. Overall, patients in NHS hospitals are satisfied with the quality of hospital food, with a 2019 survey[16] finding that 22% of NHS hospital patients rated the food they received as very good, whilst 36% rated it as good. However, the report also states that the public perception of hospital food is poor, and that 39% of NHS staff felt that food and catering facilities offered in their workplaces were poor. The Food Review outlines also detailed justification for the improvement of hospital foods. These include the role of food and nutrition in the treatment of patients (“food as medicine”), the importance of food safety, and the role of the food supply chain with respect to sustainability.

[15] Department of Health and Social Care, “Report of the Independent Review of NHS Hospital Food.”, October 2020. [Online] Available: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/929234/independent-review-of-nhs-hospital-food-report.pdf

[16] Care Quality Commission, “Adult inpatient survey 2019,” July 2020. [Online]. Available: https://www.cqc.org.uk/publications/surveys/adult-inpatient-survey-2019

The Food Review recommended for improved NHS food and drink standards for patients, staff and visitors to be put on a statutory footing. By granting the Secretary of State for Health and Social Care powers to adopt secondary legislation, this will allow Ministers to deliver swiftly on the Government's ambitions to improve hospital food standards via secondary legislation.

Other policy options considered

Option 0 - Business as usual (Do nothing)
Under the business as usual (do nothing) option, this statutory instrument would not be introduced. At present, without the proposed reform, changes to food standards would be challenging to implement and measure. Monitoring methods for food targets are already in place but do not go far enough to ensure the highest quality of food standards are carried out by all organisations. Given the recommendations from the Food Review, this was not deemed a viable option as it which would restrict the extent of reform that can be made.

Costs

The proposal brings forward a statutory instrument which in itself has no direct impact, An Equivalent Annual Net Direct Cost to Business (EANDCB) has not been estimated, as any costs would not be incurred until these powers are exercised. However, it is acknowledged that this primary legislation does grant powers, if exercised, which could entail costs to businesses who provide catering services in hospitals. This may be increased costs to adhere to higher food standards, through for example, requirements to serve more fresh produce in hospital meals. The true extent of these costs or savings cannot be estimated until the use of the power is finalised. In particular, there are additional steps to be completed, such as Public Consultation, which will inform the food standards which may be put in place. A full examination of costs to businesses will be completed at that stage.

Similarly, a Small and Micro Business Assessment (SaMBA) which quantifies the costs to SMBs is not possible at this stage. Current high-level data suggests that 659 contracts across 48 companies associated with the 216 NHS Trusts would be impacted by legislation; however, at this point that impact cannot be clearly defined as the mechanism of secondary legislation that has not been agreed. Any secondary legislation would take into account views and needs of small and micro businesses, and potentially nutritional standards would not impact any organisation, small, medium, or large. Any exemption for small or micro businesses from the regulations would be investigated at the time of secondary legislation being developed, and at that point a SaMBA will be produced.

If the Secretary of State uses the powers granted to him as part of the statutory instrument, then there may be costs for trusts to train staff or to buy equipment to meet the food standards. These costs will be considered as part of an impact assessment if these enabling powers are exercised and secondary legislation is enacted.

Benefits

The benefits of this proposal are indirect and will depend upon how the enabling powers are exercised. Granting the Secretary of State for Health and Social Care powers to adopt secondary legislation that will implement the national standards for food across the NHS will enable the government to move more swiftly in acting on the recommendations outlined in the Food Review.

Risks

It should be noted that this proposal introduces enabling powers with a duty to consult stakeholders prior to introducing legislation and does not contain substantive provisions. It is therefore difficult to assess with any certainty what the impact of the measures will be. Any policy that will be implemented using the regulation-making powers provided in this proposal in future will

be required to develop an impact assessment for the settled policy at the point at which the government is ready to legislate.

Important note
Any future regulatory policies that intend to introduce secondary legislation via the enabling provision in the Bill will need to be consulted upon and will need to be accompanied by an impact assessment.

5. Water fluoridation

Proposal Summary
The policy intention is to transfer the current Local Authority (LA) responsibilities for water fluoridation schemes to the Secretary of State. The changes proposed will transfer the current powers and duties of LAs in respect of water fluoridation to the Secretary of State, including the power to propose new, variations or terminations to fluoridation schemes, as well as the responsibility for ensuring that schemes are operable and efficient and the duties to consult.

The Secretary of State is already responsible for capital funding, and LAs' current responsibility for revenue funding will, following a period of transition, transfer to the Secretary of State. The Bill will introduce a future flexibility to seek contributions in respect of water fluoridation costs. At present, capital funding responsibilities lie with DHSC and it is not currently intended to change this position. Arrangements will continue to be held and managed by central Government. Water companies are funded under these contracts to install and maintain fluoridation arrangements and their role is unchanged. They are refunded for the revenue and capital costs they incur. Any proposed changes to this arrangement will be subject to regulations, consultation, engagement and assessment of impacts.

There will be a requirement for the Secretary of State to consult on water fluoridation schemes, except in certain circumstances, and the Secretary of State will continue to be responsible, as now, for directly entering into arrangements with water undertakers. Central Government will continue to be responsible for managing contracts with water undertakers and publishing reports monitoring the effects of water fluoridation schemes on the population.

For existing schemes, arrangements with water companies will continue to be held as now by central Government. There will be no significant operational changes to existing schemes. The duty to monitor the effects of water fluoridation schemes on the health of people living in the areas covered by these arrangements, and to produce reports at no greater than four-yearly intervals will remain. This will include the monitoring of health outcomes.

This policy proposal is to reform only the fluoridation regime in relation to England and the effect of the amendments is that the status quo is maintained for Wales, however, the relevant clauses in the Bill will extend and apply to England and Wales - the English Votes for English Laws (EVEL) policy will apply to the provisions. This is a standalone policy and is not dependent on other Bill policies, but it feeds into wider Bill objectives around improving public health via increased integration to drive better outcomes for residents of areas across the nation.

Rationale for intervention

Fluoride is widely agreed to be a clinically effective intervention for oral health[17]. Around 70% of five-year-old children live in areas with naturally low levels of fluoride. If they were to drink fluoridated water, then there would be between 17-28% fewer children with tooth decay. Research has shown that drinking fluoridated water benefits children and adults so there could be a significant public health benefit.

Fluoride mitigates the impact of poor diet and/or poor oral hygiene. It can be applied directly to teeth via toothpaste (most toothpastes now contain fluoride) and mouthwash, or professionally applied through varnishes and gels or added to the water supply (water fluoridation). All methods of delivery are effective, but water fluoridation has the strong advantage that no action or change in behaviour is required by the individual or dentist and it has a greater impact on reducing oral health inequalities.

Fluoride is naturally present in drinking water, but apart from a few areas in England, is at too low a level to be effective against tooth decay. A community water fluoridation scheme involves raising the level of fluoride in water to 1mg of fluoride per litre of water (mg/L), the level accepted in the UK to be most effective in reducing tooth decay whilst minimising unwanted effects.

Current community water fluoridation schemes in England serve around 6 million people, resident in 28 upper tier and unitary local authorities, including large areas of the North East and the Midlands. This means about 10% of the population in England currently receive fluoridated water. Whilst fluoride is naturally present in most water supplies, it is only present at an optimum level for dental health in a small number of areas such as Hartlepool and Braintree.

Since 2013 LAs have been responsible for proposing new fluoridation schemes, and for variations and terminations to existing schemes. However, the Secretary of State has the final decision on whether these proposals go ahead. LAs are also responsible for carrying out and funding the actions needed to take forward a proposal. This includes feasibility studies and public consultations. However, in the last 7 years no new schemes have been successfully implemented.

The intended transfer of responsibility for proposing schemes to the Secretary of State recognises that LAs face a number of specific barriers to proposing and leading discussion of new schemes:

- Water flows usually cross LA boundaries and all LAs affected must be invited to take part in the decision-making process. Everyone who is affected by the proposal must be consulted- even if their LA chooses not to take part in the decision-making process. Where multiple LAs are involved in the process this adds procedural complexity and the challenge of establishing consensus across multiple organisations.
- The structure of LAs can add further time and complexity. LAs coordinating the process across more than one decision-making body will face multiple committee stages which creates problems of coordination, particularly if the LAs have different election cycles.
- Cost is another barrier. For an individual LA the cost of feasibility studies and public consultations may be a significant deterrent particularly as LAs have no guarantees that the proposal will be agreed and result in an operational scheme.
- Overall, the existing framework has multiple complex processes built in which, taken together, present a significant barrier for LAs.

Other policy options considered

[17] Public Health England, “Water Fluoridation: Health Monitoring Report for England 2018”, 2018. [Online]. Available: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/692754/Water_Fluoridation_Health_monitoring_report_for_England_2018_final.pdf

The prevention green paper *Advancing our Health: Prevention in the 2020s*, published in July 2019, set out the Government's initial intention to explore the funding barriers to water fluoridation expansion. Transferring LAs' existing responsibilities to the centre was decided following consideration by Ministers as the only way to effectively remove the entirety of barriers facing LAs. The responsibilities of all current parties with a role in water fluoridation are set out in the WIA 1991 and these powers and duties can only be altered by primary legislation. The existing legislation requires amendment to allow:

- The Secretary of State to directly initiate, vary or terminate water fluoridation schemes.
- LAs' powers to be removed.
- A duty for the Secretary of State to consult, the form of which will be open to debate during passage of the Bill.
- Transitional arrangements to require water undertakers currently providing existing fluoridation schemes to transition onto new contracts to enable them to comply with the new legislative regime.
- To enable possible future cost sharing between the Secretary of State and other entities.

Costs

The costs of existing schemes will not be affected by these proposals, as the proposals simply transfer responsibility for revenue costs (currently estimated to be £3.7m for 2021/22) from LAs to DHSC. This will mean a transfer of costs for existing schemes but no overall increase in costs. Capital costs are already borne by central government (DHSC). The changes include flexibility to allow for future cost sharing with water companies and/or public sector bodies, however, any firm proposals will be subject to regulations, engagement, consultation and assessment of impacts.

The Water Industry Act 1991 places a duty on the Secretary of State for Health to reimburse water companies any costs incurred that are associated with water fluoridation. Therefore, the transfer of responsibilities for existing water fluoridation schemes to the Secretary of State has no direct costs for water companies, and so the Equivalent Annual Net Direct Cost to Business (EANDCB) is zero for this particular aspect of the proposal. However, the proposals would allow for possible future cost sharing with water companies which if exercised, may introduce costs on water companies to fluoridate water. It is not possible to estimate what this cost would be until details of how the power will be exercised are known. Any proposal will be subject to an impact assessment and an EANDCB will be calculated at that stage.

There are 16 statutory water undertakers (i.e. regional monopolies) in England that provide either water services, or both water and sewerage services[18]. There are a number of other regulated companies, including: local companies providing either water or sewerage services or both; water supply and sewerage licensees that offer water and sewerage retail services to business customers; and infrastructure providers delivering large infrastructure projects. However, there are currently no small or micro businesses which would be responsible or in the future for fluoridating water supplies. There is no current intention to exempt any small or micro businesses who may provide water fluoridation from possible future cost sharing. However, were the enabling powers to be exercised, any secondary legislation would take into account views and needs of small and micro businesses, and, any exemption for small or micro businesses from the regulations would be investigated at the time of secondary legislation being developed. At that stage a SaMBA would be produced, and as mentioned at the end of this section, DHSC will continue to engage, as appropriate, with DEFRA and water companies as the proposals develop.

The transfer of responsibilities is intended to streamline and make the process of proposing and consulting on new schemes less burdensome. Decisions on any future schemes will be taken in

[18] Drinking water 2020, The Chief Inspector's report for drinking water in England, 2020, p13. [Online]. Available from: Drinking water 2020 - The Chief Inspector's report for drinking water in England (dwi.gov.uk) and confirmed by internal analysis from PHE.

the context of wider financial decisions on health and care, including through Spending Reviews. Any transitional costs for LAs will be worked through and identified as part of the new/reverse burdens process led by MHCLG.

Benefits

The proposals will transfer the power to propose new schemes, variations or terminations to central government and as part of this LAs will no longer be required to undertake consultations or feasibility studies which may generate some savings in terms of reduced resourcing costs. This is in order to reduce the burdens on local authorities and allow for the process to be streamlined. The legislation will preserve the duty to consult on any proposed new schemes or changes to schemes, except in certain circumstances.

Risks and mitigations

There is a potential risk that, in transferring these powers to the centre, the benefits of greater autonomy are forgone. However, the barriers LAs face in effectively proposing new fluoridation schemes, or in varying or terminating existing ones mean that no new schemes have been established in the past seven years. Transferring these powers to the centre aims to break down these barriers to implementing fluoridation schemes which will have positive public health benefits.

Important note

The changes remove responsibilities and costs from LAs and will therefore go through MHCLG's reverse burdens process. The officials who lead on this are sighted and the process can run in parallel to legislation.

DEFRA is the other government department with a direct interest (through the role of water companies). The department has, and will continue to engage, the water companies and DEFRA on the proposals as they develop. They are content that the current proposals do not substantively affect the current relationship with the water companies and the Secretary of State for Health and Social Care. However, any decisions to alter the duty to reimburse water companies will alter the relationship between water companies and the Secretary of State and will be subject to regulations, engagement, consultation and assessment of impacts.

6. Food information for consumers: power to amend retained EU Law

Proposal Summary

The retained Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers ('Regulation (EU) No. 1169/2011') was incorporated into domestic law, carried forward and modified according to the EU (Withdrawal) Act 2018. It sets out requirements on the provision of food information to consumers which includes the labelling of prepacked food and drink in the UK. Due to its status as retained direct principal EU legislation, primary legislation is often required to amend or otherwise, modify the provisions contained within Regulation (EU) No. 1169/2011.

The proposals confers a power on the Secretary of State and Ministers of Scotland and Wales to amend and modify by regulations parts of retained direct principal EU legislation, set out in Regulation (EU) No. 1169/2011. The intention of the power is to broaden the reach for any modifications to Regulation (EU) No. 1169/2011 to those matters that fall within the scope of section 16 (1) (e) of the Food Safety Act 1990. Regulations made under the new power are subject to the affirmative process. This clause therefore allows the Secretary of State and Ministers in

Scotland and Wales to implement new policies regarding food information and labelling applicable to their relevant territories.

The new power to amend retained direct principal EU legislation, Regulation (EU) No. 1169/2011 will enable the Secretary of State and Ministers in Scotland and Wales to amend food labelling requirements so they meet the needs of their respective nations. For example, the Government's obesity strategy: 'Tackling obesity: empowering adults and children to live healthier lives'[19] included a commitment to consult on front of pack nutrition labelling and whether to mandate alcohol calorie labelling to help support consumers make healthier choices. If consultations indicate that changes to food and drink labelling and/or presentation is required, this provision will enable Ministers to introduce key policies, whilst retaining a level of scrutiny on any proposed changes. It will also support the alignment of labelling policies across the three nations, by allowing each nation to make changes applicable to their relevant territories.

Other policy options considered

Option 0 - Business as usual (Do nothing)
Not taking forward these powers would restrict the extent that reform can be made if consultations indicate that changes to food and drink labelling and/or presentation is required.

Costs

This proposal provides enabling powers; no immediate impacts are expected as the exercise of powers in the proposals are subject to any secondary legislation which may or may not be implemented in future.

Costs of any future secondary legislation using this power will likely be the costs associated with businesses having to implement changes to labelling requirements, as well as burden placed on local authorities and the justice system for enforcing it. DHSC will look to align its work on labelling with other government departments, namely DEFRA, where possible.

An EANDCB figure has not been provided as the impact of the proposal will depend upon whether and how the powers are exercised. Any exercising of this power is likely to affect a large number of manufacturers and / or retailers. Depending on how the power is used, there may be familiarisation costs to manufacturers who need to put the new labelling practices into place, as well as greater administrative costs as companies are required to provide more information on their products. This may disproportionately affect smaller businesses where administration costs may account for a larger proportion of their overheads.

DEFRA report that "There were approximately 7,130 micro, small and medium sized enterprises (SMEs) in the food and drink sector with turnover of around £21 billion and 135,000 employees in 2019. In the food sector (excluding beverages) SMEs accounted for 79% of businesses, 27% of employment and 17% of turnover."[20] This suggests that small and micro businesses, along with medium sized enterprises, account for a significant proportion of food and drink market share. At this stage it is not possible to state whether and the extent to which small and micro businesses will be impacted by any secondary legislation introduced using these powers, as these proposals have not yet been brought forward or finalised. Any secondary legislation would take into account views and needs of small and micro businesses, and by extension any exemption for small or micro businesses from the regulations would be investigated at the time of secondary legislation being developed. At the secondary legislation stage an EANDCB will be calculated as part of an impact assessment, and, a SaMBA will be produced.

[19] DHSC, 'Tackling obesity government strategy', 2020. [Online]. Available from: https://www.gov.uk/government/publications/tackling-obesity-government-strategy/tackling-obesity-empowering-adults-and-children-to-live-healthier-lives
[20] DEFRA, Foot statistics in your pocket: Food chain, 2020. Food Statistics in your pocket: Food Chain - GOV.UK (www.gov.uk)

Costs may be further influenced by factors such as the extent of the labelling change (major or minor) and length of implementation period. These costs are illustrative and would depend upon if and how the enabling power is used. Any potential wider costs and benefits (such as those on the environment) of future secondary legislation would be covered in an impact assessment.

Benefits

The Health and Care Bill will grant the flexibility to act on the evidence, once final policy proposals have been fully consulted on. Scientific evidence and consumer needs continue to evolve, and DHSC does not currently have the legislative ability to respond to those changes as and when they occur. Having left the European Union, the Health and Care Bill will allow us to continue to meet consumers' needs in the future.

When secondary legislation is enacted using the enabling powers in this Bill then this will be done in circumstances where the government considers that there is sufficient evidence to support such measures as necessary to improve food information for consumers, potentially resulting in consumers making better informed dietary choices. This may have the spill-over effect of preventing ill health, such as illnesses linked to poor diet such as diabetes or coronary heath failure[21], and by extension reduce cost to the NHS and public services further down the line[22]. This may not be applicable for all possible regulations introduced using the power, and because the details of possible secondary legislation have not yet been finalised, it is not possible to give greater detail on the possible benefits of the regulations which may be enacted using this enabling power.

Risks

It should be noted that this proposal introduces enabling powers and does not contain substantive provisions. At this stage, it is therefore difficult to assess with any certainty what the impact of the measures will be. For example, the government is consulting on whether to introduce changes to its front of pack nutrition labelling scheme and introducing calorie labelling requirements on alcoholic drinks, but the detail of those final proposals is not yet settled, and hence it is not possible to assess their impacts. At the point the government is ready to legislate using the regulation-making powers provided in this proposal, industry will be consulted, and a detailed impact assessment will be produced for the settled proposals.

Important note

Any future regulatory policies that intend to introduce secondary legislation via the enabling provision in the Bill, will need to be consulted upon and will need to be accompanied by an impact assessment. Since changes to Regulation (EU) No. 1169/2011 will require an affirmative process, any policies using this power will be scrutinised and approved by both Houses of Parliament.

7. Reciprocal healthcare arrangements with Rest of World countries

Proposal summary

This legislation will provide the UK government with the powers to fund and arrange for healthcare abroad and to implement reciprocal healthcare arrangements with countries outside the EEA and Switzerland ('Rest of World countries'). Under the current legislation, the UK is limited to

[21] NHS, Obesity (web page). Available from: https://www.nhs.uk/conditions/obesity/
[22] DHSC, *Advancing our health: prevention in the 2020s – consultation document*, (2019). [Online]. Available from: https://www.gov.uk/government/consultations/advancing-our-health-prevention-in-the-2020s/advancing-our-health-prevention-in-the-2020s-consultation-document

implementing comprehensive reciprocal healthcare arrangements with the EU, EEA, EFTA blocs or their Member States.

The UK has multiple reciprocal healthcare agreements outside of the EU, EEA and EFTA, with countries such as Australia and New Zealand. However, without financial reimbursement or data sharing mechanisms, these agreements are limited in scope and reach and take the form of simple equal treatment or waiver agreements. The proposal will enable the government to strengthen existing agreements and to implement new comprehensive reciprocal healthcare agreements with Rest of World countries, subject to negotiations.

We are proposing to amend the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 to extend its territorial scope to Rest of World countries.

This proposal has no immediate impacts as the exercise of powers are subject to the negotiation of future reciprocal healthcare arrangements with Rest of World countries.

Rationale for intervention

Establishing reciprocal healthcare agreements with Rest of World countries is in line with the government's Global Britain strategy, looking to invest and strengthen the UK's relationships with countries across the globe and strengthen international healthcare cooperation.

Comprehensive reciprocal healthcare agreements with Rest of World countries could offer benefits for UK residents when they travel abroad for tourism or short-term business purposes. Such agreements make healthcare in other countries more accessible and can support individuals with long-term conditions who usually pay higher travel insurance premia or face difficulties in getting comprehensive insurance cover. They can also foster closer collaboration on healthcare with our international partners, supporting improved health outcomes for all.

Other policy options considered

Option 0 - Business as usual (Do nothing)

Not taking forward these powers would mean that the UK is limited to implementing comprehensive reciprocal healthcare arrangements with the EU, EEA, EFTA blocs or their Member States. This would restrict the government's ability to strengthen existing agreements and to implement new comprehensive reciprocal healthcare agreements with Rest of World countries, subject to negotiations. Agreements with other countries would be limited to either: i)waiver agreements, where any fees associated with accessing the healthcare system are waived at the point of access and there is no provision made for the costs incurred to be reimbursed or ii) an agreement for equal treatment, whereby visitors to a country have the same access to healthcare as the residents of that country, facing the same fees and/or exemptions as regular users of the system.

Costs

As this proposal introduces enabling powers, there are no costs associated with its introduction. Any policy using the regulation-making powers provided in this proposal as well as future agreements which will be implemented under the proposed powers will be subject to a new impact assessment as appropriate.

While the expected costs of implementing new Rest of World reciprocal healthcare agreements are currently unknown, the following types of costs could occur depending on the content of future agreements:

- Costs to the UK government to reimburse other countries' governments for healthcare provided to UK residents while travelling abroad and to administer the system.
- Costs to the NHS in terms of forgone income where the agreements result in lower tariff charges in England for Rest of World residents receiving NHS treatment than currently.

There may also be increased demand for NHS services if visitors are entitled to treatment when visiting the UK. This is because the likelihood may increase of visitors using the NHS for needs-arising treatment during their visit compared to if they were directly charged for treatment, although the impact is expected to be minimal.

- Until the details of the reciprocal healthcare agreements are finalised, it is not possible to produce an Equivalent Annual Net Direct Cost to Business figure, nor is it possible to identify whether small or micro businesses would be disproportionately affected. An EANDCB and SaMBA will be completed when reciprocal healthcare arrangements are introduced via secondary legislation.
- Were a reciprocal healthcare arrangement to be introduced, the types of businesses impacted may be travel insurance companies as lower premiums and reduced income from excess payments may result in forgone profit for insurance companies. Furthermore, businesses who have staff that travel abroad may be affected, although the impact on these firms is expected to be small as savings stem from cheaper travel insurance premia.
- There is the potential for reciprocal healthcare agreements to affect trade in goods and services. The nature of these impacts will not be fully understood until details of the reciprocal healthcare agreements are finalised. DHSC will engage with the Department for International Trade when reciprocal healthcare arrangements are being agreed with rest of world countries to fully examine these impacts in line with Better Regulation guidance.

Benefits

As noted above, as an enabling measure, there are no direct benefits arising from the power coming into force. Any benefits associated with the power being used will be subject to future analysis. As an indication, the types of benefits that could arise from reciprocal healthcare agreements are:

- Cost recovery rates for the NHS may be improved due to the introduction of a reimbursement mechanism which means that healthcare costs could be covered by governments instead of direct charging. The UK government will therefore receive income for the treatment of residents from other countries (though this may be offset against the NHS costs of providing the treatment depending on the agreements).
- Incorporating reimbursement/data exchange mechanisms to facilitate reimbursement into new or updated existing agreements will allow for improved monitoring and evaluation of the cost-effectiveness of these agreements over time. Existing waiver agreements do not routinely include accurate data exchange, limiting our ability to evaluate the effectiveness of these arrangements.
- There may also be operational savings to the NHS from reduced administration costs required to administer the current system of directly charging patients.
- Savings to individuals, including avoided costs of paying directly for healthcare treatment abroad, lower travel insurance premiums and increased ease and convenience of travel.
- If agreements cover treatment for certain long-term conditions, it will be easier for these groups of people to travel, improving equality of opportunity. Treatments such as kidney dialysis, oxygen and antenatal care have been covered by the UK's reciprocal agreement with the EU.
- UK businesses, charities and the UK government may benefit from reduced costs when providing travel insurance for business trips due to the likelihood that insurance premiums might be reduced.
- Revisiting existing agreements would also support broader healthcare cooperation and diplomacy, especially with our closest allies (e.g. British Overseas Territories, Crown Dependencies, Commonwealth countries).
- Widening the scope of agreements could encompass other areas of strategic interest, including on wider healthcare cooperation. This could build on existing relationships and dialogues, including on COVID-19.

Risks

It should be noted that this proposal is an enabling measure and does not contain substantive provisions in relation to the content of future reciprocal healthcare agreements with Rest of World countries which will be subject to negotiations. It is therefore difficult to assess with any certainty what the impact of the measures will be.

Important note

An impact assessment will also be conducted for any new reciprocal healthcare agreement with Rest of World countries.

Ahead of future agreements there would also be extensive engagement with stakeholders as appropriate on the feasibility and impact of any proposed arrangements.

8. Powers allowing further products to be centrally stocked and supplied free of charge to community pharmacies without the need to reimburse them under the standard NHS arrangements

Proposal Summary

This amendment adds to Section 164 of the NHS Act 2006 and Section 88 of the NHS (Wales) Act 2006 enabling regulations to be made that would allow no reimbursement under the standard NHS arrangements for certain products centrally stocked and supplied free of charge to community pharmacies. This adds to the pre-existing exemption introduced in 2017 for unlicensed medicines, more commonly known as ‘specials’.

Rationale for Intervention

Without this provision, the only practical way to achieve this on a secure legal footing would be to for the NHS to sell stock to wholesalers. These wholesalers would in turn sell to community pharmacies who are reimbursed by the NHS. Such an approach would be inefficient compared to supplying the products directly, as there is an additional step in the supply chain which may entail costs (such as resource costs to community pharmacies purchasing products from wholesalers). Therefore, where it is deemed appropriate this amendment proposes to allow further exemptions from the obligation to reimburse pharmacies for products to centrally stocked and supplied free of charge to community pharmacies This proposal is enabling, and the exact circumstances of when the powers may be used (if any) have not been finalised.

Other policy options considered

Option 0 - Business as usual (Do nothing)
Not taking forward these powers would restrict the extent that reform can be made if it is identified that changes to the provision of certain medical products is required.

Costs

This proposal provides enabling powers; no immediate impacts are expected as the exercise of powers in the proposals are subject to any secondary legislation which may or may not be implemented in future. Were the powers to be exercised, we anticipate that the main costs would fall on actors within the medicines supply chain, for example, if the role of wholesalers in the supply chain changed from the role of a purchaser to a purely logistical role. Due to the limited cases where these powers are likely to be exercised, any potential costs are also likely to be limited.

To provide some additional context with a simplified model of the medicines supply chain, medicines flow from manufacturers to pharmaceutical wholesalers to end points, such as hospitals and pharmacies, who in turn supply to patients. There are approximately 1,500 registered pharmaceutical wholesalers, but only a very small number are considered a ‘full line wholesaler’

(i.e. they sell nearly all medicines). There are also specialist wholesalers, for example those who deal with hospital only medicines, unlicensed medicines, generics or appliances. Additionally, some have a wholesaler dealer's license because they are, for example, a pharmacy or a hospital but do a small amount of wholesaling as part of their business. To give an idea of the size of the market, in primary care alone, one of the main 'full-line' wholesalers will normally make two deliveries a day to each of the 11,200 community pharmacies, and the total spend in primary care is approximately £5.2 billion of branded medicines, £3.2 billion of generic medicines and £1.2 billion of appliances annually. When the wholesalers sell to pharmacies, they sell at more than the price they purchased them at to pay for the distribution and a profit margin. However, there are some medicines (mainly brands) where the manufacturer sells directly to the pharmacy/hospital and procure a logistic service from the pharmaceutical wholesalers.

This amendment is an addition to a pre-existing exemption with a legal precedent. The changes are restricted to vaccinations and immunisations, medicinal products used for the prevention or treatment of disease in a pandemic, and associated products such as diluents and syringes. Although it is not possible to predict the future scenarios where we may consider this option, we do not anticipate that this will be a significant number of products when compared to the total number of products delivered by wholesalers (there are over 10,000 products listed in the NHS Business Service Authority's Dictionary of Medicines and Devices). The aim of the provision is not to radically change NHS pharmaceutical service provision or payment mechanisms to community pharmacies or the pharmaceutical supply chain that they use. The aim is to strengthen the legal basis for scenarios when the usual supply routes are bypassed. As a result, the specific products for which this power may be used have not been decided, meaning estimating a quantified impact of the proposal is not possible. For example, without knowing the particular medicine (or the level of margin associated with it), it is not possible to state how many units of the product may be provided centrally, and hence the scale of impacts on the wholesaler sector.

The impact on pharmaceutical wholesalers would vary according to the proposed scenario, in the case of a new vaccine or treatment such as COVID vaccinations the stock, supply and associated business is entirely new and therefore does not deprive or interfere with pre-existing market conditions in the sector. In the case of an existing vaccine or treatment, depending on the exact nature of the alternative arrangements, distributors will still be needed to deliver the product to pharmacies. Pharmaceutical wholesalers may undertake this function although this will be under the terms of contracts performing the role of logistics suppliers rather than purchasers. While pharmaceutical wholesalers in general might not lose out, particular pharmaceutical wholesalers may potentially lose out while others may benefit, dependant on which pharmaceutical wholesalers might have bought the stock under the traditional model and which pharmaceutical wholesalers perform the role of logistic suppliers for centrally secured stock.

To take a counterfactual example, one such approach could see DHSC putting out to tender to a number of vaccine suppliers as a direct contract to supply seasonal influenza vaccines. The vaccine would be paid for centrally by the government as a split agreement award with either a small number of manufacturers or all manufacturers, according to the tendering process. The annual NIC for flu vaccinations is valued at £27.9 million (2020/2021 flu season) wholesalers would currently earn a margin out of this when they sell it to pharmacies. As outlined above, rather than denying wholesalers the business this would be recalibrated as per the contracts agreed with the government with the additional benefit to wholesalers of reduced risk due to wastage of expired stock, particularly applicable to this example due to the seasonal nature of flu vaccinations.

Although it is not possible to determine at this stage the specific circumstances and therefore number of products when this exemption may be used, it is anticipated that this would be small, and a full impact assessment, including an assessment of costs to businesses (EANDCB) and small and micro businesses (SaMBA), would be conducted to accompany each regulatory change as they are required.

Benefits
Overall, it is anticipated that the proposed amendment would result in benefits to the NHS, as an efficient alternative option to distribute vaccinations or treatments connected to a pandemic when the usual supply routes need to be bypassed.

Risks
This amendment is enabling only and as such would require regulations to be made to allow any of the proposed products to be supplied in this way. Therefore, aside from counterfactual examples it is not possible to accurately predict what the impacts will be.

Glossary

CHM	Commission on Human Medicines
EANDCB	Equivalent Annual Net Direct Cost to Business
IMMDSR	Independent Medicines and Medical Devices Safety Review
LA	Local Authority
MAH	Marketing Authorisation Holders
MHRA	Medicines and Healthcare products Regulatory Agency
NHSEI	NHS England and NHS Improvement
SaMBA	Small and Micro Business Assessment

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