HM Government

Review of the Balance of Competences between the United Kingdom and the European Union

Health

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Executive Summary

i. This report examines the balance of competences between the European Union and the United Kingdom in the area of health. It is a reflection and analysis of the evidence submitted by experts, non-governmental organisations, businesspeople, Members of Parliament and other interested parties, either in writing or orally, as well as a literature review of relevant material. Where appropriate, the report sets out the current position agreed within the Coalition Government for handling this policy area in the EU. It does not predetermine or prejudge proposals that either Coalition party may make in the future for changes to the EU or about the appropriate balance of competences.

ii. The report outlines the overall themes of the EU's impact across the whole area of health and describes the EU's role from a legal perspective. It then examines the EU's role in three distinct areas: medicines and medical devices; public health; and the NHS and patient services. Each section examines key areas, looking at both the current impact of the EU as well as the EU's role.

Overall position on competence

iii. As outlined in chapter one of this report, the Articles in the Treaty on the Functioning of the European Union ("TFEU") mean that the definition of health policy, management of health services and medical care and the allocation of resources are all Member State competences. This is the overall context in which this report should be read, and when stakeholders welcome the current balance of competence, they are essentially supporting this position.

iv. It should also be noted that this report does not cover social care, simply because the EU has an extremely limited role in that field.

v. There are areas relating to the single market and public health where the UK Government recognises the benefits of the EU. For example, a system where life science companies seek 28 different licences across Member States would clearly be detrimental for patients and industry. Free trade across the EU has benefited UK based companies in a variety of different sectors including the life sciences. In public health, we would highlight tobacco control as an area where the EU has spread good practice such as on smoke-free environments, building on work already undertaken here and in other Member States. However, recognition of the positive impact of the EU in certain areas does not necessarily mean that there should be more EU influence in health overall.

vi. The following points of concern were highlighted:

- The need to ensure that non-health EU legislation does not have an adverse impact on the NHS, e.g. the Working Time Directive.
- The potential for Court of Justice of the European Union (CJEU) decisions, for example in relation to freedom to obtain services and free movement, to impact on the NHS (see paragraph 4.10.1) or the implications of particular pieces of legislation, such as the Working Time Directive (see paragraph 3.13.6).
- Certain directives have had adverse consequences for the UK such as the Clinical Trials Directive, although we recognise the positive steps that have been taken to resolve this particular issue.

vii. In light of these points, the report highlights areas of concern where change is needed and where we must be cautious in future. Stakeholders were clear that the current balance of competence is broadly right and that this should remain the case but highlighted the potential for taking forward further work where there were specific concerns such as the Working Time Directive's impact on the NHS.

viii. The themes below outline our findings on competence, highlighting both the positive and negative impacts of the EU in health. They are not exhaustive, but give some idea of the views of stakeholders on the EU's impact on health policy in the UK.

Themes on the EU's role in health

The balance of competence

ix. Overall, based on the evidence submitted, **stakeholders felt that the current balance of competence between the EU and the UK was considered to be broadly appropriate**. As outlined above, this is because the EU's role in most parts of health policy is limited to supporting Member States, which have responsibility for their own healthcare systems. Where the EU does have shared competence to legislate in the health field, this is primarily in areas relating to the single market. In addition, it is important to look in more detail at specific points, as we will do later in this report. There were very few areas where it was suggested that competence should lie elsewhere, although a large number of concerns were raised about the need to improve specific pieces of EU legislation.

x. There was **strong agreement that health policy and the organisation and delivery of healthcare services should remain a Member State competence**. The UK should remain alert to the potential for change in the balance of competence (see, for example, at paragraph 4.9.3). This could include the unintended impacts of EU legislation, the implications of case law from the Court of Justice of the European Union (see paragraph 4.10.1), or Joint Actions[1] aimed at information sharing (for example, the potential implications of the future Health Technology Network for the existing UK process – see paragraph 3.2.15).

xi. **Stakeholders strongly supported more input from the EU on public health**, including greater effort on tackling obesity, alcohol misuse, tobacco use and health inequalities at the European level (see, for example, paragraph 3.4.1 on health inequalities and paragraph 3.8.4 and 4.6.3 on alcohol). Some respondents would support an extension of competence to improve public health, but most would prefer to see progress under existing competence. Whilst supportive of EU work on public health in general and certain voluntary initiatives, the UK Government believes that the current balance of competence is broadly appropriate and therefore does not need to extend further.

[1] Joint Actions are voluntary networks of Member States working together on specific issues.

xii. **Industry were generally very supportive of the current position regarding competence**, both in terms of promoting growth in the UK and the benefits of the single market for trade (for example in food – see paragraph 3.6.2). There was support for the EU's work on medicines and medical devices. Industry stressed the advantages of the common regulatory framework for ensuring a high level of patient safety and secure supply (see case study 3A and the quotes at paragraph 3.2.3). Notwithstanding this, many responders commented on the need for improvements to the medical devices framework. Importantly, however, all agreed this did not mean that the balance of competence was in the wrong place, but rather that the system needed to be improved.

xiii. **Evidence suggested that free movement of persons brings benefits for the UK health sector and for patients, but not without risk**. In terms of health professionals, there has been a very positive impact for the NHS as 10% of NHS staff are from European Economic Area (EEA) countries, without whom there could be staff shortages (paragraph 3.14.2). Patient safety is paramount and so it is vital that healthcare professionals meet exacting standards of practice. Negotiations on the recognition of professional qualifications are very important in this regard. For individuals, the benefits of EU membership that enable access to health care for UK citizens living in countries such as Ireland, Spain and France and for UK visitors to other European countries are clear. On the other hand, there are implications for the NHS of EU/EEA patients seeking treatment in the UK (see paragraphs 3.15.2 to 3.15.6). The potential effects of the Cross Border Healthcare Directive,[2] which concerns individuals who wish to purchase a health care treatment from a provider in another Member State, are described in paragraph 3.15.9.

Positive impact of the European Union

xiv. Responses have shown that **the UK has had a positive impact on the EU in terms of public health and vice-versa**. In some areas such as smoke-free legislation, the UK and other Member States have been important in persuading the Commission to take more action to promote public health (see paragraph 3.7.2). EU legislation, Joint Actions and research have also encouraged the UK to take further action in other areas of public health policy.

xv. There was a **great deal of support for EU health research funding**, where the UK receives more funding than any other Member State. Examples of beneficial EU funded research included the work on alcohol described in paragraph 3.8.6, or e-health, at paragraph 3.16.1. However, there was also a belief that outcomes and application from the research could be greatly improved (see paragraph 3.11.4) and that the process of funding research could become more transparent.

xvi. **One of the key benefits of EU membership is the sharing of information**. Examples given included the single market information system, the sharing of data on new and emerging infections (see paragraph 3.5.4). There was strong support for Joint Actions from stakeholders and many felt that other European networks were stronger because of links made through EU membership. In rare diseases, where population numbers are low at national level, this sharing of information is crucial (see paragraph 4.9.2).

xvii. **Many pieces of legislation closely mirror what would have been done at the UK level anyway** i.e. the UK would have introduced similar legislation on professional qualifications in any event. Other examples include tobacco measures and levels of non-ionising radiation (see paragraphs 3.7.3 and 3.10.4). In these areas, stakeholders' main concern was the quality of legislation, whether at the UK or EU level.

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[2] Directive 2011/24/EU on the application of patients' rights in cross border healthcare

xviii. **UK stakeholders have become much more effective at the EU level** and in recent years the Commission has listened more carefully to concerns raised. This issue is discussed further at paragraph 3.13.3. Some stakeholders also pointed to useful dialogue between employers and trade unions as a result of the social chapter. In addition, stakeholders and the UK Government have worked extensively together on different directives, such as the Recognition of Professional Qualifications Directive (paragraph 4.12.3). However, it is important that the UK Government and stakeholders continue to engage effectively at the EU level.

xix. **EU membership assures patients of the quality of services and products across the EU**. This is particularly true where the EU sets standards on safety and quality in the life-sciences sector, for example with rules on monitoring the safety of medicines (paragraph 3.2.2). Respondents have also argued that minimum quality and safety standards on organs, blood, tissues and cells benefit patients by improving practices across the EU (paragraphs 3.5.1 to 3.5.3 and 4.3.4).

Concerns over specific EU action and legislation

xx. There were **significant concerns about certain pieces of legislation**, such as the Clinical Trials Directive. However, there was also **recognition that the Commission has actually greatly improved much of it following feedback from the UK Government and stakeholders**. The recent proposal for a Clinical Trials Regulation to replace the current Directive is an excellent example (see paragraph 3.2.11).

xxi. **Concerns were also raised about various cross-sectoral EU legislation which has a significant impact on the delivery of healthcare in the UK**. Many of these concerns related to proposals around data protection (paragraph 3.17.8) and the Working Time Directive (WTD) (section 3.13) – neither of which were specifically designed with healthcare in mind. There was a strong view that it is important to consult more with health departments and their stakeholders on these areas from the outset. A number of concerns were raised about the negative impact of the WTD on the NHS and this issue is looked at later in the report. As outlined in the coalition agreement, the Government is committed to "limit the application of the Working Time Directive in the United Kingdom".

xxii. A number of **responses stressed the need for increased transparency and a more evidence based approach at the European level**. All recognised the progress that has been made, such as the Commission's system of impact assessments which have a number of similarities to the UK system (see paragraph 4.1.1). However, some stakeholders felt that the Commission did not always look enough at the costs and benefits of a specific policy, could be more transparent, and engage to a greater extent with key parties. In aspects of public health, stakeholders argued there was also a need for a more science or risk based approach (see for example paragraph 3.5.10 and 3.6.8) and across the board, it was agreed that proportionality is key to all EU policy.

xxiii. **It is important that the EU concentrate activity where it can add the most value**. There was an overwhelming view that the Commission should avoid duplicating existing arrangements such as our systems on emergency preparedness. However, EU membership also adds real value in health security, such as the European Centre for Disease Control (ECDC) and the early warning and response system (see paragraph 3.9.2). It is important to ensure that this remains the case and effective systems are not compromised. The UK Government strongly supports these stakeholder views and would urge the Commission to focus on those areas where value can be added, as action is often best taken at Member State level. A number of stakeholders also had comments on the inter-relationship between the EU, World Health Organization Europe, Council of Europe and others, and links between different directorates general in Brussels (see paragraph 3.12.2).

Issues for the UK

xxiv. **Inconsistency in implementation** was raised by many stakeholders. Directives require Member States to achieve a particular result, leaving the means of achieving that result to the discretion of the Member State. In most instances, this flexibility is a distinct advantage of Directives: it is right that Member States have discretion in implementation in the context of different cultures and domestic systems. However, in some cases where consistent implementation across Member States is beneficial, a Regulation can be more appropriate. Clinical trials is an example – a number of stakeholders highlighted the problems associated with its inconsistent implementation between Member States (see paragraph 3.2.11).

xxv. Stakeholders also recognised that problems with particular legislation could be a **result of its interaction with existing systems in the UK**, rather than an inherent problem with the legislation. Examples include the way in which EU legislation on the co-ordination of healthcare provision interacts with our domestic provisions about entitlement to NHS care (see paragraph 4.13.1) or the Working Time Directive with the junior doctors contract and the ability to properly train the next generation of consultants (paragraphs 3.13.5 and 3.13.8). Again, involvement of the right stakeholders from the outset as legislation is developed is the key.

xxvi. Some stakeholders raised the issue of '**gold-plating**'. Some believed that the UK sometimes 'gold-plates' legislation unnecessarily, although opinion is divided and evidence is non-specific. In addition, there is no simple definition of 'gold-plating'. For example, it can be the result of a deliberate policy decision to exceed the minimum requirement required by an EU Directive. In other cases, national transposition may be more detailed than the text of a Directive in order to try to avoid uncertainty about the interaction with domestic systems (see paragraph 3.5.7). Examples of stakeholders' views are given in the sections on clinical trials, tissues and cells and employment policy. This is an issue that the Government is very aware of and the Government has committed to ending 'gold-plating' of EU legislation. Indeed, most examples given were from the past, and much progress has been made in recent years. The Government's Guiding Principles for EU Legislation, finalised in June 2011, were introduced to prevent gold-plating of EU legislation. The Guiding Principles include five transposition principles that Government Departments must abide by, including the principle that Government will always copy out the text of the Directive for transposition where possible, except where doing so would adversely affect UK interests e.g. by putting UK businesses at a competitive disadvantage compared with their European counterparts. The Government has now introduced a new transposition principle that emphasises the importance of minimising regulatory burdens when implementing EU legislation and will ensure that the UK does not go beyond the minimum requirements of EU legislation when transposing it into UK law.

xxvii. **Positive engagement between London and the Devolved Administrations is crucial** whether on different directives or prior to Health Formal and Informal meetings. Stakeholders in the Devolved Administrations highlighted the importance of developing clear UK-wide positions (see paragraph 4.10.3).

xxviii. One other important point to consider is **how action can be taken more swiftly when it is clear that change is required**, particularly for patient safety reasons. This issue is discussed at paragraph 4.1.3. Examples cited include the newspaper reports on the inconsistent quality of notified bodies of medical devices (see paragraph 3.2.13), and the original Clinical Trials Directive, where it became apparent that the Directive was having a negative impact on the attractiveness of the EU as a place to conduct clinical trials. The UK Government believes that the ability to act more swiftly on these points is crucial going forward.

Introduction

This report is part of a Coalition commitment to review the balance of competences between the UK and the European Union (EU). The review will provide an analysis of what membership of the EU means for the UK national interest and deepen public and Parliamentary understanding of our relationship with the EU. It seeks to provide a constructive and serious contribution to the national and wider European debate about modernising, reforming and improving the EU in the face of collective challenges. We have not been tasked to produce specific recommendations or look at alternative models for the UK's overall relationship with the EU.

This account is one of 32 subject-based reports analysing specific areas of EU competence. The reports are divided into four semesters and will be published on a rolling basis until the end of 2014. All reports will be based on evidence gathered during a twelve-week period. More information can be found on the Review at www.gov.uk/review-of-the-balance-of-competences.

Competence has a legal definition set out in the Treaty. A full explanation of competence is available in the Cabinet Office Glossary.[1] However, for the purposes of this review, we are using a broader definition of competence. Put simply, in the context of this review, competence is everything deriving from EU law that affects what happens in the UK.

Health report

The Department of Health is leading this review into competences relating to health. The call for evidence was launched on 27 November 2012 and closed on 28 February 2013. The call for evidence was sent widely to Parliament and its committees; business; the Devolved Administrations; civil society; the European institutions and to EU partners. The Department of Health received 125 written submissions, supported by evidence from a number of workshops, seminars and meetings, including with members of both the House of Lords and House of Commons.

Member States in the EU are facing similar challenges in improving the health of their populations: the demands of an ageing population and increasing rates of chronic diseases, coupled with an economic climate resulting in pressure on budgets available to spend on healthcare systems. Whilst the EU has limited competence in many areas of healthcare – and is required to respect the responsibilities of each Member State to define their own health policy and to organise, deliver and manage health services[2] – there are other areas where the EU does have the competence to get involved in health issues.

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1 https://www.gov.uk/eu-law-and-the-balance-of-competences-a-short-guide-and-glossary

2 Article 168(7) of the Treaty on the Functioning of the European Union – for further detail see chapter 1.

This report examines those areas of competence and their implications for health and healthcare in the UK. It is informed by the evidence we have received, some of which is quoted in the chapters which follow. The constraints of space mean that we have been unable to quote all of the evidence we have received, and we would encourage readers to examine the full body of evidence received.

Chapter 1: Development of Competence

1.1 Within this document, references to Treaty articles are to the Articles in the Treaty on the Functioning of the European Union ("TFEU") unless otherwise indicated. An explanation of the three main types of competence in the Treaties is given in the Cabinet Office Glossary, along with a description of the Treaties themselves.

Public health was introduced as an express area of EU competence for the first time by the Maastricht Treaty and is now found in Article 168 TFEU. The importance of health in the EU is recognised at Article 168(1) "A high level of human health protection is to be ensured in the definition and implementation of all Union polices and activities"

1.2 The protection and improvement of human health is an area in which the EU is generally limited to supporting competence. Article 168(7) expressly recognises that Member States are responsible for their definition of health policy, management of health services and medical care and the allocation of the resources assigned to them. However, in certain aspects relevant to health, the EU shares competence with the Member States. A group of shared competences relating to common safety concerns was introduced in the Treaty of Amsterdam and extended by the Treaty of Lisbon; Article 168(4) makes provision for the Union to adopt measures relating to: the quality and safety of organs and blood; certain measures in the veterinary and phytosanitary fields[1] and medicinal products and medical devices. Similarly, Article 168(5) which was extended in scope by the Treaty of Lisbon, provides an EU competence to adopt certain incentive measures designed to protect and improve human health.

[1] See the Balance of Competences Review: Animal Health and Welfare and Food Safety report, also published in semester one

Case Study 1A: Impact of Treaty Changes on Medicines and Medical Devices

The Treaties set out the EU's competence. There has been EU legislation regulating medicines for almost 50 years and medical devices for the last 20 years on the basis that the EU has the competence to establish a single market of goods which protects the health of the public.

For the first time in 2010, the Treaty of Lisbon clearly set out that the EU has competence to set quality and safety standards for medicinal products and medical devices. In practice, this clarifies the legal basis for the EU's legislation. It does not significantly extend the EU's competence, given that the Treaties still clearly state that Member States are responsible for organising and delivering health services and medical care.

1.3 Article 114 (single market)[2] (formerly Article 95 TEC), is used as the legal base for measures adopted in the areas of medicines and medicinal devices, food safety and labelling, cross-border health care, and tobacco. Article 114(3) states that Commission proposals will take, as a base, a high level of health protection.

1.4 Other treaty articles relevant to this report include: Article 48[3] which is relevant to the coordination of Member States' health care benefits (see paragraph 3.15.2 [Reg 883]); Article 56[4] which has affected patients' rights to obtain health care services abroad (see paragraph 3.15.8), Article 53[5] and Article 153 which have affected health care workers and health service provision (see sections 3.14 and 3.15) and Article 34 (quantitative restrictions) has been used to challenge domestic health measures.

1.5 At an international level Article 168(3) provides that the Union has competence to foster cooperation with third countries and international organisations in the sphere of public health.

1.6 Further detail can be found in the legal annex of the call for evidence.

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2 EU competence on the single market is covered by the report produced by the Department for Business, Innovation and Skills.

3 Article 48 TFEU enables the adoption of measures in the field of social security that are necessary to provide for freedom of movement.

4 Article 56 TFEU makes provision for the free movement of services.

5 Article 53 TFEU relates to the mutual recognition of diplomas, certificates and other evidence of formal qualifications.

Chapter 2:
Current State of Competence

2.1 This section outlines the legal basis for EU action in the specified areas and signposts the key provisions and case law.

2.2 **Medicines** – Measures in this area are under Article 114 on the harmonisation of the single market (which includes the single market in medicines) and Article 168(4) (c). The key legislation in this field includes a regulation establishing the European Medicines Agency and providing for certain medicines to be subject to licensing by the Commission[1], a directive regulating the licensing of medicines by Member States[2], directives regulating the approval of clinical trials and the products used in clinical trials[3], the manufacturing practice of medicinal products[4] and the transparency of measures regulating the pricing of medicinal products.[5]

2.3 **Medical devices** – EU medical devices legislation is currently based on the single market competence Article 114 and includes directives on active implantable medical devices[6], general medical devices[7] and in vitro diagnostic medical devices[8]. The Commission recently adopted two proposals to replace the existing three directives with two regulations. The proposed new regulations would be adopted under Articles 114 and 168(4)(c).

2.4 **Organs, blood, tissue and cells** – Article 168(4) (a) provides the EU with shared competence to set quality and safety standards for organs, substances of human origin, blood and blood derivatives. However, this competence does not affect national provisions on the medical uses of donated organs or blood. Directives set standards that apply to the quality and safety of: human tissues and cells[9]; organs for transplantation[10], and human

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1 Regulation (EC) No 726/2004

2 Directive 2001/83/EC

3 Directive 2001/20/EC

4 Commission Directive 2003/94/EC

5 Council Directive 89/105/EEC

6 90/385/EEC

7 93/42/EEC

8 98/79/EC

9 Directives 2004/23/EC, 2006/17/EC; and 2006/86/EC, implemented into UK law by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (S.I. 2007/1523).

10 Organ Donation and Transplantation Directive 2010/53/EC implemented into UK law by the Quality and Safety of Human Organ intended for Transplantation Regulations 2012 (S.I. 2002/1501)

blood and blood components[11]; Directive 2002/98 allows Member States to set more stringent protective measures than the requirements of the Directive but more stringent Member State requirements must comply with EU competition law[12].

2.5 **Nutrition and labelling** – EU food legislation is based on Article 114 (single market). It covers food labelling[13], presentation[14], advertising[15], nutrition and health claims[16], food supplements[17], fortified foods[18] and foods with particular nutritional uses[19]. EU food legislation has been subject to an unsuccessful competence challenge[20]. Member States have established their competence to make national food law where the Commission has failed to do so although national measures must be consistent with EU law[21].

2.6 **Tobacco** – EU tobacco legislation is based on the single market competence Article 114 and includes the Tobacco Products Directive 2001[22] and the Tobacco Advertising Directive 2003[23], both of which have survived competence challenges[24]. An earlier directive[25] was annulled by the European Court[26] on competence grounds. A revision of the Tobacco Products Directive is currently under negotiation. Tobacco manufacturers have also used Article 34 to challenge UK domestic tobacco control legislation[27].

2.7 **Alcohol** – Article 168(5) TFEU provides the EU with competence to adopt incentive measures which have as their direct objective the protection of public health in relation to abuse of alcohol. Article 168(5) has been used to develop the EU alcohol strategy. The EU traditionally exercises its competence in relation to alcohol through Directives, such as those that set out criteria for the advertising of alcohol[28] and which impact upon the labelling of alcoholic beverages[29]. In 2006, the EU also developed an alcohol strategy aimed at reducing alcohol related harm.

The Scottish Government successfully defended the Scotch Whisky Association's

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11 Directives 2002/98/EC; 2004/33/EC; 2005/61/EC; and 2005/62/EC, implemented into UK law by the Blood Safety and Quality Regulations 2005 (S.I. 2005/50), as amended.

12 Case C-421/09 Humanplasma GmbH v Republik Osterreich.

13 Directives 1990/496/EEC on nutrition labelling and 2000/13/EC on the approximation of laws dealing with labelling, presentation and advertising of foodstuffs (both to be replaced by Regulation (EU) 1169/2011 on the provision of food information in 2014)

14 Directive 2000/13/EC

15 Directive 2000/13/EC

16 Regulation (EC) 1924/2006 on nutrition and health claims in relation to foods

17 Directive 2002/46/EC on the composition and labelling of food supplements

18 Regulation (EC) 1925/2006

19 Directive 2009/39/EC; this Directive is being reviewed and a new replacement text is expect to be adopted in 2013.

20 *Food Supplements* case, C-154/04. Article 95 was upheld as an appropriate legal base as the Directive addressed differing national rules; the fact that health factors were present did not prevent article 95 being relied on.

21 *Solgar Vitamin*s case. Case C-446/08

22 Directive 2001/37/EC

23 Directive 2003/33/EC

24 See cases C-380/03 Germany v Parliament and Council [2006] ECR I-11573, C-491/01 British American Tobacco [2002] ECR I-11453, C-210/03 Swedish Match [2004] ECR I-11893

25 (Directive 98/43/EC)

26 case C-376/98 Germany v Parliament and Council [2000] ECR I-8419

27 See for example Sinclair Collis Ltd and Nacmo v The Secretary of State for Health [2011] EWCA Civ 437

28 Directive 2010/13/EU (the Audiovisual Media Services Directive)

29 2000/13/EC (to be replaced by Regulation (EU) 1169/2011 on the provision of food information in 2014)

challenge to the proposed legislation introducing minimum unit pricing of alcohol and the Court found that although the proposed measure would be a measure equivalent to quantitative restrictions on imports under Article 34 TFEU, it could be justified on the grounds of protecting public health under Article 36. The Court of Session confirmed that a national authority was entitled to a margin of appreciation or discretion when the proportionality of the measure could be objectively justified.

2.8 **Health Security** – EU competence under Article 168(5) permits the adoption of incentive measures and it has been exercised in an EU Decision[30] to establish a network for the surveillance of communicable diseases and to provide an early warning system for the spread of these diseases which has not required any UK legislation to implement it.

2.9 **Radiation** – A Council Recommendation[31] concerning the exposure of the general public to electromagnetic fields was adopted under Article 168. A draft Physical Agents Directive under Article 153 is currently under negotiation which will apply to worker exposures.

2.10 **Public Health Programmes** – Article 168 is the legal base for EU programmes of action on public health aimed at promoting and protecting the health of citizens across the Member States and provides the basis to facilitate work and encourage collaboration across borders[32].

2.11 **Rare Diseases** – Decision 1295/1999/EC provides for a programme of Community action on rare diseases within the framework for action in the field of public health; it provides support through EU Reference Networks for sharing expertise and best practice. Regulation (EC) No.141/2000 provides incentives for the development of "orphan" medicinal products for the treatment of rare diseases.

2.12 **Implications of employment policy** – The Working Time Directive[33] was adopted under Article 153(2) and relates to Article 153(1)(a) which covers the improvement of the working environment to protect workers' health and safety. The Directive lays down minimum requirements for the organisation of working time. Two key Court of Justice of the European Union judgements, "SIMAP"[34] and "Jaeger"[35] have had a significant impact on the scope of the law, with consequences for health service provision. They address (respectively) the issues of actual working time, and time on call and compensatory rest.

2.13 **Free movement of persons: healthcare professionals** – The Professional Qualifications Directive[36] facilitates the mobility of healthcare professionals to work in the EU by imposing a requirement on Member States to recognise where appropriate the workers' qualifications. This requirement is imposed through the harmonisation of qualifications and training[37] or an assessment of qualifications and experience[38] depending on the profession

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30 Decision No 2119/98/EC setting up a network for the epidemiological surveillance and control of communicable diseases in the Community

31 Recommendation 1999/519/EC

32 The first programme from 2003 -08 was established by Decision No. 1786/2002/EC; the present EU health programme from 2008 – 2013 was established by Decision 1350/2007/EC.

33 2003/88/EC (which consolidates the former Council Directive 93/104/EC)

34 C-303/98 Sindicato de Médicos de Asistencia Pública v Conselleria de Sanidad y Consumo de la Generalidad Valenciana.

35 C-151/02 Landeshauptstadt Kiel v Norbert Jaeger

36 The Mutual Recognition of Professional Qualifications Directive 2005/36/EC.

37 This requires the automatic recognition of qualifications relating to the following professions: doctors, dentists, nurses, midwives, pharmacists, veterinary surgeons, and architects;

38 Professions benefiting under the general system where qualifications and experience are assessed and where necessary compensatory measures may be imposed.

in question. The Tennah-Durez[39] case established that it is within the competence of each Member State to take account of relevant prior learning when awarding the relevant qualification under the Directive which may include prior learning undertaken outside the EU.

2.14 **Free movement of persons: coordination of healthcare provision** – Article 48 enables the adoption of measures in the field of social security that are necessary to provide for freedom of movement[40]. Regulation (EC) No. 883/2004[41] provides for the coordination of social security benefits including access to health care. This Regulation together with its implementing regulations[42] contains detailed provisions to identify the Member State responsible for the provision of health care and arrangements for reimbursement of costs between Member States.

2.15 **Free movement of services: cross-border healthcare** – The freedom to provide services under Article 56 extends to those receiving the services[43]. CJEU judgments[44] including the Watts Case[45] established that under certain conditions an individual could purchase health services in another Member State and seek reimbursement from their home system. The CJEU judgments led to domestic legislation[46] and to the Cross Border Healthcare Directive[47]. Member States are required to transpose the Directive by 25 October 2013.

[39] JUDGMENT OF 19. 6. 2003 — CASE C-110/01

[40] Regulation 3 drawn up in 1958 provided for the coordination of social security. It was succeeded by Regulation (EEC) No. 1408/71 which was replaced by Regulation (EC) No. 883/2004.

[41] Regulation (EC) No. 883/2004 is incorporated into Annex IV of the European Economic Area Agreement and thus applies to Iceland, Liechtenstein and Norway. It also applies to Switzerland by virtue of the EU-Switzerland Agreement.

[42] Regulation (EC) 987/2009.

[43] Joined Cases C-286/82 and C-26/83 *Luisi and Carbone*

[44] See C-157/99 *Geraets-Smits v. Stichting Ziekenfonds VGZ and Peerbooms v. Stichting Z Groep Zorgverzekeringen*; C-385/99 *Müller-Fauré/van Riet*; Case C-56/01 *Inizan v Caisse Primaire d'Assurance Maladie des Hauts de Seine* ; Case C -512/08 *Commission v France*.

[45] Case C-372/04 The Queen on the application of Yvonne Watts v Bedford Primary Care Trust and the Secretary of State for Health

[46] the National Health Service (Reimbursement of the Cost of EEA Treatment) Regulations 2010 (S.I. 2010/915) which amended the National Health Service Act 2006

[47] s2011/24/EU

Chapter 3:
Impact on the national interest

Medicines and medical devices

3.1 Introduction

3.1.1 Overall, the majority of stakeholders thought that the balance of competence is appropriate for medicines and medical devices. The EU helps to ensure a high standard of patient safety across the EU, early launch in the UK market of new medicines and medical technologies and the competitiveness of the UK life sciences industry through access to the single market. The Government recognises these benefits as part of its strategy to promote growth in the UK.

3.2 The operation of the EU regulatory framework and the single market

> "The single market operates most strongly and effectively in medicines regulation, including marketing authorisation and other issues focused on ensuring the safety, quality and efficacy of medicines (such as rules governing GMP, GDP and pharmacovigilance)."
>
> British Generic Manufacturers Association

3.2.1 Many respondents across the healthcare sector and industry highlighted the benefits to patients and industry of Member States collaborating at European level on medicines and medical devices. Action at European level can be more effective, which benefits patient safety. For example, the EU is able to:

- effectively tackle and eliminate counterfeit medicines, which involve complex global supply chains;
- share safety information for medicines once they are on the market and quickly detect safety signals; and
- take coordinated European action in the context of the globalised pharmaceutical and medical technology industries.

3.2.2 Secondly, respondents stated that European legislation supports existing national work and helps raise regulatory standards across the EU and raise the bar for patient safety. For example, the Royal Pharmaceutical Society noted that the EU directive on monitoring the safety of medicines (termed 'pharmacovigilance') extended the UK's scheme to

encourage reporting of suspected reactions to new drugs or vaccines across the EU (the Black Triangle Scheme). The Government recognises the important role of the EU in these areas and the resulting benefits for patients.

3.2.3 There was strong support for the UK's participation in the common framework of regulation protecting patient safety in the single market for medicines and medical devices. Stakeholders, such as the Academy of Medical Royal Colleges, the National Pharmacy Association, the Genetic Alliance UK and the Optical Confederation all identified clear benefits to patient safety and industry competitiveness. The view of industry, including the Association of British Pharmaceutical Industry, the British Association of Healthcare Industries, and the British Generic Manufacturing Association, is that harmonised regulatory requirements and lower administrative burdens confer benefits including lower costs, economies of scale, a level-playing field for competitiveness and higher productivity. This helps the UK to deliver on the Government's growth agenda for the life sciences industry.

Case study 3A: the centralised procedure for authorising medicines

The introduction of the centralised procedure (leading to a pan-European Marketing Authorisation for medicines) for certain medicines, along with the creation of the European Medicines Agency (EMA), means that patients across Europe gain earlier access to new drugs.

The centralised procedure offers a simpler alternative to national licences with less administrative burden for industry. Moreover, it means that medicines information, such as the patient information leaflet, is consistent across all Member States. No longer participating in the centralised procedure would add unnecessary complexity for the UK.

It was noted that the UK regulator, the Medicines and Healthcare products Regulatory Agency, takes the lead on a high proportion of centralised marketing authorisations and has a strong influence on the EMA through its leadership in committees and influence on the Management Board. The UK would lose this influence if it did not participate in the centralised procedure.

> "Prior to the implementation of the centralised procedure, companies either licensed their medicines using national authorisation procedures or by processes coordinated by the Member States. These processes were unnecessarily burdensome as they required individual applications in each Member State, leading to individual authorisations in each country and information provided to patients which could be different in each Member State.
>
> The introduction of the centralised procedure, along with the creation of the EMA, not only greatly simplified the above situation but also resulted in a system where medicines information such as the patient information leaflet are consistent across all EU Member States, which is good for public health protection."
>
> Association of British Pharmaceutical Industry

3.2.4 The single market is particularly important for the UK's medical technology industry, which is dominated by small and medium sized enterprises (SMEs) that produce a

relatively low volume of products and make high investments in technology. Industry stakeholders noted that the single market in devices had improved the competitiveness and exports of the British medical technology industry. The Government recognises these benefits and is fully supportive of work at the EU level, which helps the UK to deliver on the growth agenda.

"Whilst some UK-based generic manufacturers continue to seek authorisation from the MHRA to market their products solely for UK usage, many others benefit from using the centralised and decentralised procedures to access the broader EU market. This is highly beneficial, enabling companies to expand, as well as contributing to a high level of competition in the UK that has delivered some of the lowest generics prices in the western world."

British Generic Manufacturers Association

3.2.5 Membership of the EU also gives the UK a stronger voice in international efforts to collaborate and develop harmonised standards, including international standards of Good Clinical Practice and Good Manufacturing Practice and the Global Harmonisation Task Force for medical devices.

3.2.6 Respondents, including the Scottish Government, the British Medical Association, the Proprietary Association of Great Britain, the Association of the British Pharmaceutical Industry, the Medical Research Council, and the Academy of Medical Research Charities, were concerned that Member States' varied implementation of EU legislation establishing the single market on medicines and medical devices poses risks which reduce the benefits of the single market in three ways:

3.2.7 Firstly, Member States have varying levels of resource and capability to implement EU legislation. One example is the regulatory framework for medical devices. Member States have varying levels of resources to scrutinise notified bodies, which assess the safety and performance of medical devices before manufacturers can sell them on the EU market. As a result, clinical and voluntary sector stakeholders highlighted that a lower quality medical device may be approved by a notified body in one Member State and then sold freely on the EU market and bought in others.

3.2.8 Secondly, Member States implement EU legislation differently and some may choose to impose additional requirements. This may be due to different national approaches to the law or the lack of clear and detailed guidance on how to implement EU legislation from the European Commission. Stakeholders called for Member States to implement EU rules as effectively as possible, to encourage a level playing field and consistently high levels of patient safety. This can also be achieved through changes to legislation. For example, the proposed clinical trials regulation, currently under negotiation, aims to harmonise the currently divergent requirements across the EU. Because a regulation directly applies in national law, it removes the need for Member States to transpose the European rules into national legislation with the concomitant risk of divergence.

3.2.9 Thirdly, a few stakeholders, including the British Generic Manufacturers Association and GlaxoSmithKline, argued that the balance of competence between the EU and the UK in health policy made it difficult for EU legislation to be implemented effectively given that the organisation and delivery of health services remained a national competence. As an example, some industry stakeholders argued that the Falsified Medicines Directive sought to apply constraints to how Member States' supply chains operated without

taking into account the variety of healthcare systems, medicines pricing, and prescribing and dispensing systems across the EU. In this context, it was felt that it would be difficult for the Directive to achieve its policy objectives. The Government is aware of these concerns and is currently in the process of implementing the Directive – including through discussions with the European Commission on forthcoming delegated and implementing acts – at least cost to the UK.

Case study 3B: the Falsified Medicines Directive

The Directive consists of a range of measures designed to strengthen the medicines supply chain from the threat of counterfeits and additional controls on substances used in the manufacture of medicines.

Stakeholder comments on the falsified medicines directive focused mainly on requirement for "safety features" (a tamper proof seal and a unique identifier) to be applied by industry to certain categories of medicines and for industry to establish a system to ensure that medicines protected by the safety feature can be checked for authenticity.

The Government notes that the secondary legislation for safety features – which will set out much of the detail on this aspect of the Directive – is still under preparation and will not come into force until around 2017.

3.2.10 Whilst the responsibility to implement and enforce European legislation rightly remains with the Member States, the European Commission has, in recent years, taken a greater interest in how effectively this is being done. This has been driven by a desire to ensure that the outcomes envisaged are being delivered in a consistent way across the EU. This increased focus has been in part due to increasing pressure on the Commission and Member States from the European Parliament across a number of policy areas, with MEPs taking an active interest in how EU legislation is being implemented and enforced.

Case study 3C: Herbal medicines

Whilst, there were no specific comments from stakeholders on herbal medicines, this is an important area to highlight because it is a good example of inconsistent implementation across the EU. Many herbal products are close to the borderline of medicines and other regulatory categories, such as foods. Herbals are an area where there is evidence among Member States of differing interpretations of their classification and the application of legislation where herbal products are classified as medicines.

In the Government's view, on the one hand, differences of approach to the regulation of herbal medicines make it challenging for companies wishing to market products across the EU. On the other hand, it is not clear that any initiative to achieve greater harmonisation of Member States' regulatory approach to herbal medicines would necessarily result in an effective application of better regulation principles and an appropriate level of public health protection within the UK. Classification of products remains a national competency.

3.2.11 Lastly a number of stakeholders raised concerns about increased bureaucracy as a result of European directives, including the Liberal Democrat MPs on the Parliamentary Committee for Health & Social Care, the Royal College of Physicians, the Medical Research Council, and the NHS European Office. The Clinical Trials Directive (CTD) was identified by a large number of respondents as having been problematic in this regard. Although the recent proposals for the revised regulation (to replace the current Directive) are viewed positively, there are suggestions that the Commission could have paid more attention to these concerns when the original directive was proposed.

"The implementation of the EU Clinical Trials Directive in 2004 was intended to harmonise the standard of clinical research performed in the EU. Unfortunately, different interpretations of the legislation across the Member States, different national laws and a general increase in the number of requirements greatly increased the administrative burden associated with performing clinical research. This increased the time taken to obtain key documents such as Clinical Trial Approvals (CTAs). This steep increase in complexity is considered to have contributed, along with other factors, to the steady decline in the number of clinical trials performed in the EU since 2004."

Association of British Pharmaceutical Industry

3.2.12 This does not mean that the balance of competence was thought to be incorrect – a large majority of responses backed the CTD as extremely important for patient safety in the UK and across Europe.

"The patient populations for clinical trials relating to the diseases into which Anthony Nolan conducts research are typically very small in the UK alone. Therefore almost all clinical trials relating diseases require participation from patients in multiple countries. The Clinical Trials Directive, while in need of improvement, is a good mechanism by which to ease the bureaucracy involved in established cross-border clinical trials and ensures consistency in standards of research provided into central studies from EU Member States."

Anthony Nolan

3.2.13 In relation to medical devices, although overall the view of respondents was positive, several identified concerns about the implementation of the current regulatory framework that were highlighted by recent safety concerns relating to fraudulent breast implants and certain metal on metal hip replacements. These issues are discussed further in chapter four.

"We have concerns that a device failing to meet the approval criteria of one notified body may gain approval from another, less stringent, notified body elsewhere. We see this as a public protection risk, and one which is a barrier to increasing public confidence in the system."

Royal College of Surgeons

"The medical device industry is a global industry with a profile of (relatively) low volume and high technology/investment; consequently it is better, particularly for the relatively substantial UK based medical device industry, that there is as little variation between markets as possible. ABHI is therefore in favour of competency existing at EU Level where possible."

Association of British Healthcare Industries

3.2.14 As illustrated by some of the examples set out in this section, stakeholders' responses highlighted a number of areas where existing EU action might be strengthened. The Government shares the concerns expressed, for instance on the Clinical Trials Directive and the framework for medical devices, and is actively engaged in the negotiations revising both legislative areas. Overall, however, the evidence supported the current balance of competence in these areas.

> "The future voluntary Health Technology Network proposed via the implementing acts of the patients' rights in cross border health care directive should be monitored closely to ensure that the UK's well functioning process is continued and not detrimentally affected by the outcomes of the proposed network. In particular, the modalities for stakeholder engagement at the EU level must be open, transparent and fully accountable."
>
> North of England EU Partnership

3.2.15 Whilst most submissions focused on the EU legislative framework for medicines and medical devices and related work, some stakeholders also discussed the role of voluntary collaboration activities, for example, the forthcoming EU voluntary network on research into the effectiveness of different healthcare treatments (termed 'Health Technology Assessment'). It is important to recognise that competence remains with Member States but such activities can offer useful opportunities to share information, experience, and learning.

3.2.16 There were also some suggestions from stakeholders that the EU should take more action on Health Technology Assessments and relative effectiveness, but others were more sceptical on this point and the Government view is that any change to the status quo would be problematic. In addition, some stakeholders voiced concern at the potential adverse impact of this work in future and the Government agrees it is important that any network does not have any adverse impact on the UK.

3.3 Stakeholder engagement with the EU

3.3.1 Stakeholders, such as the Academy of Medical Research Charities, the National Pharmacy Association and the Royal Pharmaceutical Society described how EU competence can bring greater benefits to both patients and industry where there is more stakeholder collaboration at EU level. In particular, there are calls for a joint approach from regulators, industry, clinicians and patients to improve the quality of the new European medical devices regulatory framework. The Government is very supportive of many of these initiatives, with the Medicines and Healthcare products Regulatory Agency (MHRA), National Institute for Health and Care Excellence (NICE) and others playing a leading role in different projects.

3.3.2 A broad range of stakeholders, including the Association of the British Pharmaceutical Industry and the British Generic Manufacturing Association, gave examples where better consultation could help to improve EU legislative outcomes and the transposition of EU directives into UK law. One such example was the Falsified Medicines Directive which is currently being implemented. The Government believes that stakeholder engagement is essential throughout the EU legislative process, both at national and European level and key to effective implementation of EU legislation in the UK. In the case of the Falsified Medicines Directive, public consultations were held both during the negotiation phase

and on the draft statutory instrument that will implement the Directive, in addition to other stakeholder engagement activity.

Public Health

3.4 Introduction

3.4.1 Overall, respondents were of the view that competence in public health is broadly in the right place, although some argued for more action to promote public health in areas such as tackling health inequalities. The overarching question is whether an action is justified in light of the potential public health benefit.

> "The EU has a potential to narrow the gradient in health inequalities within Member States and across the EU area. Its current redistributive policies serve to enhance this matter, and the EU may be able to influence the social determinants of health in a manner that would increase overall levels of health across populations."
>
> Royal College of Physicians of Edinburgh

3.4.2 Support was strong for the single market, particularly from industry in the area of alcohol and food, although recent developments around horsemeat show that there are also potential risks. This area will be looked at in more detail in the animal health, welfare and food safety report. One extremely positive impact of the EU has been to ensure a consistent minimum quality of service, as outlined in the sections on organs, blood, tissues and cells, and nutrition.

3.5 Organs, blood, tissues and cells

3.5.1 There are EU directives in place for Blood, Tissues and Cells, and Organs. The directives set minimum quality and safety standards, which respondents generally welcome.

> "The introduction of common standards across the EU enables a culture of mutual recognition between Member States, which in turn should facilitate and ease the movement of tissues, cells and organs across Member States. For example, if tissues or cells are imported to the UK from another member state an import licence is not required as the tissues/cells will already have been assessed as meeting the regulatory requirements by the Competent Authority (CA) of another member state."
>
> Human Tissue Authority

3.5.2 Whilst many indicated that the UK had excellent practices in place before the Directives, respondents, such as NHS Blood and Transplant (NHSBT), Advisory Committee on the Safety Blood, Tissues and Organs (SaBTO), National Blood Transfusion Committee and the British Medical Association, believed that overall, EU competence has brought improvements across Member States, such as reduced variation in practice, particularly in tissues and cells, and improved traceability of blood and blood components.

3.5.3 The focus on safety has been beneficial, and stakeholders, such as NHSBT and the Health Protection Agency, have welcomed the introduction of reporting systems for serious adverse events and reactions, where these did not exist.

"The EU Directives have been the impetus for the establishment of national reporting systems for errors and serious complications of blood transfusion, tissues and most recently organ transplantation."

NHS Blood and Transplant

3.5.4 NHSBT and SaBTO have welcomed the increased working and co-operation with European colleagues facilitated by the Directives, and the sharing of information, which tend to improve clinical practice. The Government strongly supports this. Similarly, NHSBT welcomed the ease with which young scientists from across the EU can contribute to UK health research.

"Up to date information is also shared between European countries on the incidence of new and emerging infections, supporting the surveillance role of UK organisations such as the Health Protection Agency and strengthening the evidence base for measures to combat potential infection risks such as donor deferral or the testing of donations"

Advisory Committee of the Safety of Blood, Tissues and Organs

3.5.5 The free movement of tissues, cells, blood and organs between Member States, facilitated by EU wide minimum standards, are considered by respondents, such as Anthony Nolan, Genetic Alliance UK and SaBTO, to benefit patients and the Government recognises these benefits. For example, cell based treatments not available in the UK can be imported for named patients and UK citizens can receive suitable organs from across Europe. However, it is important to note that there were already existing arrangements in place in the UK and some stakeholders, such as BMA, point out the complexities and costs around introducing European legislation in place of existing national arrangements, whilst recognising the benefits outlined above.

"Any assessment of the EUTCD must be a balanced one. On the one hand it can be argued that the Directive adds little to previous UK law in this area and is more cumbersome or prescriptive than is ideal. The UK was arguably the first country to introduce a regulatory regime for ART and human embryo research (in 1990) and the EUTCD merely codifies much of what was already in place in the UK; although it should be noted that the Directive did bring previously unregulated services (IUI centres which only carried out insemination of husband/partner sperm) into the scheme of regulation."

Human Fertilisation and Embryology Authority

3.5.6 SaBTO also said that variations in the way Member States interpret the Directives' requirements or transpose them into national law has created barriers which hamper the free movement of some tissues and cells. Some Member States have service level agreements with common standards, which works well for 'standard tissues', but problems remain for bespoke tissues and cells.

3.5.7 NHSBT and others consider that the requirements of UK law are sometimes more onerous, or more bureaucratic, than those in the Directives. Others questioned whether the Tissues and Cells Directive (EUTCD) was an example of 'gold-plating'. It was noted that the interaction between the Directives and other domestic legislation made implementation of the Directives complex.

3.5.8 The Government view is that the Directives were implemented in a proportionate manner, such as the decision to licence tissue storage facilities rather than require each donating hospital to be licensed as part of the implementation of the EUTCD. As well as public consultations on proposals for implementation including a draft of the proposed implementing legislation the Department worked closely with key stakeholders such as NHSBT and HTA in working groups developing the detail of the implementation including the legislation. The Government's view is that the implementation of the Directive was proportionate and appropriate in relation to our domestic system. This is part of a broader debate on how to implement European legislation (see paragraph xxiii in the executive summary), which is also outlined in other sections of the report.

3.5.9 SaBTO and NHSBT were also exercised about the costs of complying with the Directives and the regulatory oversight arrangements, and suggested this could benefit operators in other Member States where costs are lower. Others though, believed that meeting higher standards could give the UK a competitive advantage (for example in tissue exportation). Anthony Nolan thought that the information required for stem cells, for example, informs clinical decision making and they supported the retention of the regulatory regime. This view is shared by the Government.

> "Taking responsibility for setting detailed blood transfusion specifications nationally rather than at EU level will mean that these can be made appropriate for the UK, and be up to date and evidence based. New evidence can be reviewed more promptly and translated into revised guidelines/standards. This will ultimately have benefits for the safety of donor and recipient and security of the blood supply, as the UK requirements will be taken into account when considering revisions. This would also be true for tissues, cells and organs"
>
> NHS Blood and Transplant

3.5.10 As decisions on EU Directives are reached by Member State negotiation, amending them in light of changing evidence or circumstances can be difficult and slow. Because NHSBT and SaBTO argue that technical detail would be better set nationally the Government would be supportive of setting higher quality and safety standards nationally where it was thought appropriate. Where scientific advances mean Directive technical detail is no longer appropriate, the introduction of a fast track system of amendment would be welcome.

3.5.11 The application to blood for transfusion of Directive 85/374/ EEC on Product Liability (through the UK Consumer Protection Act 1987) has benefitted patients, for example by obliging Blood Services to investigate all new technologies which might improve blood safety, and allowing compensation for patients harmed by a transfusion without the need to prove negligence. There is also concern that proposed changes to the In Vitro Diagnostics Directive, affecting the use of tests used on blood, organs etc. developed 'in house,' often specialist tests not available commercially, could damage patient care.

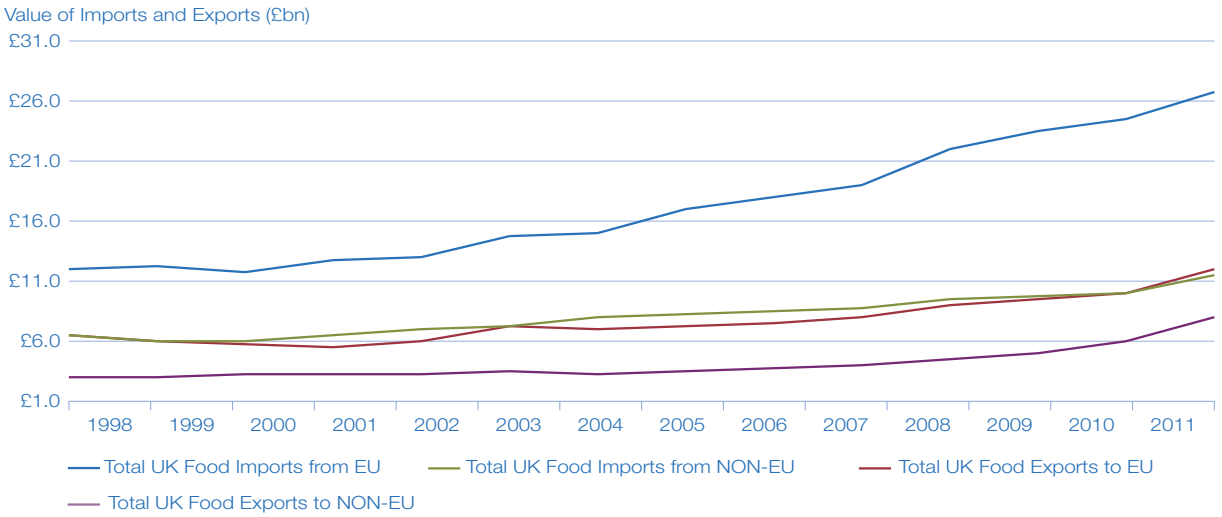
3.5.12 Overall, it is clear that EU competence in this area has advantages for patients, who benefit from minimum standards of quality and safety. The Directives build on existing good practice in the UK, and the Government welcomes their impact.

3.6 Nutrition and food labelling

3.6.1 This report covers EU action in relation to nutrition and food labelling; other aspects of food law are dealt with in the Animal Health, Welfare and Food Safety Report.

3.6.2 Nutrition and labelling legislation has been harmonised at EU level for over 30 years. While food law is an area of shared competence, a large body of legislation has been introduced which effectively precludes the UK and other Member States from introducing national rules, except where harmonisation has not been agreed or specific derogations are provided for in Union rules. Due to the long history of Union rules in this area, evidence from interested parties focuses mainly on the advantages and disadvantages of trading in the single market. Trade and the creation of the single market was a major driver of EU food law. Figure 3D shows the importance of the single market to UK businesses and consumers.

Figure 3D – Value of UK Trade with EU and Non-EU regions – Food and Drink Sector (current prices) (Source: UK ONS)



3.6.3 The reliance on EU imports to maintain the variety of foods available to consumers is compelling evidence of the value to the UK of the single market in the food sector. On balance, interested parties (including public health, industry and consumer groups) felt there is an overall advantage to EU competence in food law, including nutrition legislation. The functioning of a single market justifies action in this area, and generally provides a high level of consumer protection.

3.6.4 Harmonisation of standards, not only of food, but also food production, i.e. food hygiene and food safety, ensures that consumers can have confidence that the food they purchase is of the same high standard, regardless of the country of origin. Common standards also make it easier to import foods from the EU, ensuring the quality of a wide choice of products.

"National rules would be likely to create trade barriers, so restricting the range of foods on offer. Having common standards can also give UK consumers confidence when they travel within the EU."

Food Standards Agency

3.6.5 Although there is general acceptance that EU competence is of benefit to the UK, there are examples of where the single market is not fully working, despite the best intentions of the regulator. Inconsistent interpretation and enforcement are most commonly cited by stakeholders (Health Food Manufacturers' Association, Proprietary Association of Great Britain, Provision Trade Federation, Very Low Calorie Diet (VLCD) Industry Group) as the reasons for distortion of the market. The move away from the use of Directives to directly applicable Regulations has to some extent removed differences in interpretation, but there remain some areas of uncertainty.

3.6.6 Where the EU has sole competence, this prescriptive legislation can also create a barrier to innovation and market development, and can place disproportionate burdens on small and medium enterprises (SMEs). Prescriptive legislation does not always take account of the different cultures and unique nature of Member States' markets and this is of concern to the UK Government.

"Basing EU food legislation on science has been a cornerstone of UK policy under successive Governments. Such an approach ensures consumer safety, encourages innovation and (combined with appropriate labelling rules) maximises consumer choice. The UK has frequently been successful in negotiating science based EU rules, to the benefit of UK consumers and businesses. Implicit in such rules are judgements about what levels of risk are appropriate and in the main EU safety levels are (rightly) cautious. But in some areas, especially at the forefront of technological development, science has been set aside in favour of overly restrictive measures, ostensibly designed to respond to "social" considerations."

Senior European Experts Group

3.6.7 For instance, EU Regulation 1169/2011 on Food Information to Consumers requires energy information to be expressed in both kilojoules (kJ) and kilocalories (kcal) wherever it is given. This has implications for UK policy on the voluntary labelling of energy – for example, in restaurants – under the Government's Public Health Responsibility Deal, where energy information has been provided in calories only, as this is more easily understood by UK consumers. It is possible that this Regulation will have an adverse impact on the UK Government's ability to promote and extend this voluntary initiative with UK businesses, particularly on menus in the catering sector, therefore reducing the availability of information to consumers to help them balance their calorie intake.

3.6.8 Another issue of concern for some stakeholders (CHC, PTF, Seafish, VLCD Industry Group) is that sometimes the European legislative process does not take a sufficiently science based or a risk based approach. For example, the late stage introduction of delegated acts to update the 'Union list' of permitted substances for the revised framework on dietetic foods. The Government believes that such decisions should be based on science and evidence and are better done by implementing acts, more specifically with the examination procedure, with input from a Committee of member state experts.

3.6.9 Broadly the view of both Government and respondents is that, despite some of the concerns above, the EU work on food law and other initiatives is generally the most appropriate level of regulation and serves the UK well, allowing free exports and good quality imports, whilst effectively protecting consumers, and this shows the benefit of the single market.

3.7 Tobacco

3.7.1 EU tobacco directives are based on the single market treaty base, with the objective of improving the functioning of the single market, while aiming for a high level of health protection.

3.7.2 There is evidence of mutual benefit between the UK Government and EU action on tobacco control.

3.7.3 EU level measures have prompted the UK to take further action in this area, some of it legally required, but equally, the UK's own actions have impacted on other EU Member States as the EU has looked to play catch up with European leaders in tobacco control. A clear example of where EU and domestic legislation align is the introduction of smoke free environments in the UK before the Council Recommendation on Smoke Free Environments in 2009.

3.7.4 Another example of legislation aligning is the 2002 Tobacco Advertising and Promotion Act, which prohibited most tobacco advertising. In 2003, The EU introduced the Tobacco Advertising Directive (see Chapter 2) which addresses tobacco advertising at EU level. This, together with other tobacco control policies, is considered to have reduced smoking prevalence rates since its introduction.

3.7.5 Public health and medical respondents, such as Action on Smoking and Health (ASH) and the Association of Directors of Public Health, welcomed the shared EU competence on tobacco related matters because they felt that EU competence on tobacco control has set a useful baseline, which Member States can supplement with additional tobacco control measures in areas not regulated by the EU. ASH referred to the prevention of the sale of tobacco from vending machines in 2011 as an example where the UK has done this. These respondents supported this flexibility to implement domestic tobacco control measures which complement EU legislation, a position with which the Government is in agreement.

> "The EU has previously passed Directives on tobacco packaging, labelling and advertising and promotion, all of which supported the UK's own legislative and non-legislative approaches in these areas. Including flexibility into the implementation of Directives has allowed the UK to provide a higher level of protection in one of those areas such as introducing picture warnings on pack"
>
> Royal College of Physicians

3.7.6 The WHO Framework Convention on Tobacco Control (FCTC) (the world's first public health treaty), to which the UK and the other 27 EU Member States are signatories, provides a framework for tobacco control measures to be implemented by the Parties in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke. The FCTC and the EU tobacco directives complement each other – the Directives align well with the FCTC and its implementing guidelines. In signing up to the FCTC, the EU and its Member States have undertaken to protect health policies from commercial and vested interests of the tobacco industry.

3.7.7 Aside from their role in proposing and agreeing legislation, EU actions include co-ordination of cooperation between Member States, active participation in international tobacco control initiatives (i.e. FCTC); supporting tobacco control networks and projects, and tobacco prevention campaigns.

3.7.8 Tobacco manufacturers operating in the UK, for example Imperial Tobacco, British American Tobacco and ECITA, who responded to the call for evidence, would prefer tobacco regulated at Member State rather than at EU level, and would prefer less strict tobacco control legislation in general. Tobacco manufacturers, such as Japan Tobacco International, would prefer the single market treaty base not to be used for tobacco control measures. They noted the series of legal challenges to tobacco control directives and expressed disappointment at the CJEU's interpretation of the single market treaty base.

3.7.9 In summary, most of the responses we received suggested that the current balance of competence appears to be working well, resulting in complementary UK and EU action to reduce the harm from tobacco in the UK. Some respondents also noted that it has helped to strengthen the functioning of the single market. The Government recognises the positive joint working between Member States and the Commission, and that this work has been instrumental in reducing smoking rates across the EU. Those against legislation in the area of tobacco would appear to prefer a less regulatory approach to tobacco control more generally, regardless of whether that legislation emanates from the EU or is domestic legislation.

3.8 Alcohol

3.8.1 The UK faces a particular challenge, as levels of harmful drinking, deaths and crime due to alcohol are high and have been rising for 50 years. The UK has reached European average levels of alcohol consumption, which are high in global terms. UK levels of harm from alcohol are higher than the European average, as parts of our population practise North European styles of 'binge' drinking, which cause additional harm to health and result in harm to people other than the drinker. UK consumption per head has doubled since 1960 and liver disease is now one of the few major causes of death rising in the UK – this contrasts sharply with similar European countries where rates are falling.[1]

3.8.2 In England, there were over 1.2 million alcohol-related hospital admissions in 2011/12 and over 15,000 alcohol-related deaths in 2011. The UK Government has committed to tackle the range of alcohol related harms. Governments have struggled to deliver a sustained reduction in harm, including failing to reverse rising deaths from alcohol and reduce alcohol-related violent crime, showing the depth of the challenge.

> "Alcohol is the world's number one risk factor for ill health and premature death among the 25-59 year old age group and Europe is the heaviest drinking region in the world. Due to the scale and pervasive nature of alcohol misuse across the UK and Europe, it is essential that there is a comprehensive, coordinated response at the local, national and European level."
>
> Royal College of Physicians

[1] CMO annual report: Volume One, 2011 'On the state of the public's health'

3.8.3 EU competence on alcohol exists to complement the actions of Member States to reduce harmful alcohol use. It has largely exercised this competence through the EU Alcohol Strategy, which has supported Member States by raising awareness of the impacts of hazardous alcohol consumption, and developing an evidence base. This has had some impact, for example, in convergence between most Member States on minimum purchase ages for alcohol and on blood alcohol limits for drink driving. The British Medical Association argued in favour of further action on this issue at both the national and European level.

3.8.4 A number of public health respondents, such as the Alcohol Health Alliance and the National Heart Forum, argued that public health should be given appropriate weight when considering action in all appropriate areas, for example consideration of public health gains made through requiring labelling on alcoholic drinks. This would be in line with the "Health in All Policies" approach, enshrined in the EU Health Strategy and official guidelines for impact assessments. Several of these, including the Royal College of Physicians, the Institute of Alcohol Studies, the Royal College of Physicians of Edinburgh and Alcohol Health Alliance UK, argued that EU law must prioritise effective public health measures over commercial interests and that a ruling in favour of minimum unit pricing (MUP) would set an important precedent that could encourage Member States to introduce further public health legislation.

3.8.5 Following notification to the European Commission in June 2012 of the intention to introduce minimum unit pricing, the Scottish Government received a detailed opinion from the Commission in September 2012, concluding that minimum pricing is disproportionate as taxation would be less intrusive in trade within the EU. The Scottish Government responded in December 2012, reiterating that minimum unit pricing is more effective as it targets cheap alcohol relative to its strength and it has more of a progressive effect on those that drink the most and suffer the most alcohol-related harm. Taxation could not achieve this targeted impact.

"EU funding from the Seventh Framework Programme for research FP7 supported our members` project AMPHORA (Alcohol Measures for Public Health Research Alliance). This work, collaborating with 35 partners across the North West, enabled creation of the European Alcohol Policy Research Alliance, evaluation of cost effectiveness of policy measures, and the conduct of longitudinal studies on alcohol policy and pricing. All of these activities have contributed to the development of alcohol reduction policies within the UK, translating science into policy. NEEHP supports opportunities for continued funding of such projects to enable further collaboration and successful health outcomes."

North of England EU Health Partnership

3.8.6 Several respondents, including the Association of Directors of Public Health, the Institute for Alcohol Studies and the North of England EU Health Partnership, noted that EU funding for research and collaborative projects has been essential in helping to build the evidence base and improve health outcomes in Member States. They also highlighted the benefit of EU research funding in this area. The UK particularly welcomes the work to develop an evidence base, done in collaboration with the World Health Organization (WHO). This should support Member States to implement well-evidenced, effective policies suited to their needs and circumstances.

3.8.7 The Scotch Whisky Association (SWA), whilst welcoming the role of the single market, were clear that they did not believe that competence should be extended in this area. SWA supports the status quo in terms of the current balance of competences between the EU and UK.

> "The trade environment within the EU single market, in which one set of common rules applies, is immeasurably simpler than the alternative in which 27[2] different regulatory regimes would operate… If the EU was to be given more powers in this area we believe that could be contrary to the UK interest as it may lead to the imposition of measures which may not be relevant to the UK context."
>
> Scotch Whisky Association

3.8.8 The Government is supportive of the current position with regard to competence, and recognises the valuable contribution of the EU alcohol strategy.

3.9 Health security

3.9.1 EU competence in this area is exercised by a Decision which establishes systems for the surveillance and early warning of communicable diseases. A proposal for a new Decision is being negotiated which will extend its scope to cover other cross-border health threats, and this is covered in chapter four. Overall, this is a crucially important role for the EU, which could not be effectively fulfilled by national governments independently.

3.9.2 The existing communications networks at European level are an important and valued component of regional cooperation mechanisms for cross-border health threats. In particular, the formal alert and communications systems, such as the Early Warning and Response System and the systems managed by the European Centre for Disease Prevention and Control, have considerably improved the degree of information sharing and coordination of response at the EU level.

> "The establishment of ECDC provides a source of technical expertise and capacity that the UK is able to, and has often, called upon in dealing with infectious disease threats."
>
> Health Protection Agency (now Public Health England)

3.9.3 Communications systems operated by the EU/European Centre for Disease Prevention and Control (ECDC) and WHO, such as the Early Warning Response Systems (EWRS) and the International Health Regulations (IHR) Events systems, were used during the swine flu pandemic. These agencies also facilitate coordination of communication by providing a 'directory' function that enables the relevant experts or authorities in Member States to be identified rapidly during a crisis.

3.9.4 This is an example of an area where the EU adds real value, particularly in the formal alert and communications systems for communicable diseases. The Government fully recognises this and is supportive of the extension of these systems to include other cross-border health threats.

3.9.5 In today's world where there is increasing travel and free movement of persons, global cooperation is vital and the EU and other bodies including the World Health Organization (WHO) play a key role. The UK is a key contributor to international work in a variety of

[2] There are now 28 Member States since the accession of Croatia to the European Union on the 1st July 2013.

areas and whilst this report cannot highlight every area, work on pandemic influenza and anti-microbial resistance are excellent examples of the UK's impact on the world-stage but also of how the EU works together with other international bodies. Current cases of corona virus highlight the importance of this work at the present time.

3.9.6 With regard to influenza, collaboration on a global scale is well established for detection of influenza viruses with pandemic potential and responding to protect the health of the population, should a pandemic occur. The Department of Health works closely, through Public Health England, with the European Centre for Disease Control (ECDC). There is an expectation that any country identifying a new influenza virus with the potential to transmit easily from one person to another will report this to WHO. This information, and if relevant, samples are then shared throughout the WHO regions and collaborating centres. The UK hosts the European WHO influenza collaborating centre and is therefore a key player in responding to a pandemic. WHO commends the UK for the quality of its pandemic influenza response plan.

Case Study 3E: Pandemic Flu

A recent example of such collaboration was the H1N1 pandemic in 2009. The Global Outbreak and Alert Response Network (GOARN) was established in 2000 to strengthen the coordination of international outbreak response. Throughout the pandemic, GOARN supported collaboration and engagement of international technical institutions and linked to partners at all levels. GOARN partners from the UK included the then HPA Centre for Infections, Imperial College, London, and the London School of Hygiene and Tropical Medicine, as well as ECDC representing Europe as a whole.

Part of the Commission's (DG SANCO) core role in the crisis was to provide coordination for all Member States. This coordination was provided throughout the crisis, through large numbers of audio-conferences both formal and informal. In some cases, participating Member States believed that audio-conferences had been well practiced prior to the crisis and this helped them structure their response. UK officials were involved in these teleconferences. Joint Health Security Committee/European Early Warning and Response System audio-conferences were also carried out with EU Member States, including the UK.

By 30 April Health Ministers had adopted EU Health Council conclusions on the H1N1 infection which called Member States to: take all necessary measures for public health protection; to share information on evolution of the virus between Member States and to facilitate risk management; to provide accurate, timely and consistent information to citizens; and to promote the funding of measures for cooperation on preparedness, and response to health threats under existing Community programmes.

A European Union case definition was agreed, which included both clinical and laboratory criteria. All but one participating Member States used the services of reference laboratories for pandemic influenza confirmation. Many participating Member States used their own national reference laboratories, with four participating Member States utilising the services of the WHO Collaborating centre in the UK, until their own systems were operational.

3.9.7 Another key issue is Anti-Microbial Resistance (AMR), which is a rapidly evolving health issue which extends far beyond the human health sector. The dynamic and interrelated nature of AMR requires better control in all sectors: environmental, agricultural, food production, animal health and human health. Much good work has been done at the UK and international level, but, despite these efforts, AMR has continued to escalate.

3.9.8 The case for further action to tackle the AMR threat is clearly set out in Volume II of the Chief Medical Officer's (CMO) annual report. The UK will shortly be publishing a new AMR Strategy which addresses the challenges raised in the CMO annual report and identifies priorities areas for action, including strengthening international collaboration. The case study below outlines the on-going work being carried out at the EU and international level.

Case study 3F: EU initiatives on AMR (antimicrobial resistance)

The need to accelerate progress on AMR has been recognised by the WHO and European Commission. The 2011 EU AMR Action plan and the 2012 EU Council Conclusions have helped provide a renewed focus on the area. These documents provide a mechanism to get Member States to develop national strategies and action plans to tackle AMR as well as work to strengthen the legislative framework on the animal health side.

In addition, new work is being carried out to strengthen global health security and develop ideas to help inform WHO, EU and others such as Food and Agricultural Organisation of the United Nations (FAO) and World Organisation for Animal Health (OIE) to develop a framework and coordinated programme of collaborative action for the future.

The European Commission has also put in place a wide range of work in recent years to develop closer links with the USA, through the Trans-Atlantic Task Force on AMR, establish an annual European Antibiotic Awareness Day (EAAD), improve AMR surveillance aspects, fund research and establish the Innovative Medicines Initiative (IMI) which encourages public private partnership drug development programmes. These are all important strands of work which must continue, but the speed of this work needs to be accelerated if it is to have a significant impact. These EU activities supplement work being carried out in the UK and provide a useful means to share data and experience and actively contribute to EU research and other initiatives.

There are three pressing areas where collective international action is urgently needed:

- Incentivising the development of new antibiotics by stimulating collaborative funding mechanisms (including public private partnerships) to pump prime the drug pipeline, and addressing regulatory and economic barriers that hinder investment and innovation.
- Improving the knowledge and understanding of AMR through better information, intelligence, supporting data and developing more effective early warning systems to improve global health security.
- Conserving existing treatments by improving antimicrobial stewardship and developing resources to facilitate more rational and optimal use of antibiotics.

These issues are being actively discussed at a national and international level.

> "The EU have promoted and written a number of important council recommendations on Healthcare Associated Infections (HCAI) and AMR….These have influenced England's surveillance strategies and the implementation of these."
>
> Health Protection Agency (now Public Health England)

3.10 Non-ionising radiation

3.10.1 This report covers non-ionising radiation, such as power lines; ionising radiation will be dealt with in a future balance of competence review to be run by the Department for Energy and Climate Change.

3.10.2 EU competency in non-ionising radiation is represented by a Recommendation, which states that the International Commission on Non-Ionising Radiation Protection (ICNIRP) guideline levels are adopted by Member States. The UK adopts these and they are enforced under Health and Safety at Work regulations. If injury to a member of the public or a worker occurs, it is the responsibility of the employer controlling the non-ionising radiation source. ICNIRP Guidelines are endorsed by the World Health Organization (WHO). As outlined above, this is an area that would require national legislation anyway and any legislation would be likely to be very similar whether at the national or EU level.

3.10.3 The Health Protection Agency (HPA) noted that the Recommendation has been helpful in providing evidence that there is a broad consensus between Member States on the health implications of exposures to electromagnetic fields (EMFs) and on the measures that should be undertaken to protect public health from such exposures. By stating EU policy on EMF exposure, it helps Member States put into context resolutions from other EU bodies when they advocate risk management measures that go further.

3.10.4 The National Grid argued that if there were no EU competence, the UK would almost certainly have adopted similar guidelines; however, they are supportive of consistent controls across the EU rather than national competence because it reassures citizens across the continent that the level of protection is universal.

3.10.5 As in other areas of public health, respondents argued for the importance of an evidence-based approach. They noted that exposure limits (or any other health measures) should be scientifically based. In the EU, the process allows for a more political approach and there is a need to ensure that the scientific basis and recommendations are not lost.

3.10.6 This is an area that would require national legislation anyway. In practical terms, the outcome would be similar whether the competence for setting limits for non-ionising radiation lay with the EU, the UK or the WHO. There are benefits in principle from the standardisation of health protection measures across Europe, but in practice, these are quite limited.

3.11 Public health programmes and rare diseases

3.11.1 The EU's competence on public health provides for incentive measures to protect and improve human health. EU action complements national policies and facilitates the development of best practice and internationally recognised standards. For example, while quality standards and guidelines for the prevention of drug related health damage are available in some Member States, their quality is variable. This was addressed by the development of new European standards, with significant input from the UK. This is the first European framework on the prevention of drug related health damage and the standards have been used as an example of best practice in EU Accession States, as well as coming to the attention of other countries such as Canada, who have shown a strong interest in their application. It is clear that the EU's efforts to support national policies in this area add real value.

3.11.2 The current public health programme is intended to fund projects that provide European added value, including providing learning and examples of good practice that can be shared with other countries. European collaborative activity on rare diseases can be valuable in terms of diagnosis and treatment due to the low numbers of patients in individual Member States.

3.11.3 Benchmarking between EU Member States can be invaluable for stimulating positive change. The European Community Health Indicators projects have proved to be extremely useful initiatives, the value of which was highlighted by the Welsh Government.

> "Short scale projects charged with more immediate outcomes [e.g. production of guidelines] should have a significant and distinct role in the programme in relation to broader medium/long term priorities."
>
> North of England EU Health Partnership

3.11.4 However, there have also been concerns about the public health programmes. A 2009 Court of Auditors report on the 2003-2007 programme found that, whilst the programme had facilitated the sharing of experiences and mutual learning between Member States, the broad and ambitious objectives contrasted sharply with the limited budget.[3] Clearly, it is important that work carried out through the public health programme is outcome focused and in line with the available resource. In addition, the UK Government has in the past expressed some concerns about dissemination of the outputs from public health programmes, and the need for increased transparency. In response, the Commission now regularly provides details of projects in an electronic newsletter, showing willingness from the Commission to engage and make changes where necessary.

3.11.5 EU action on rare diseases complements and supports activity in Member States. For example, following an EU Recommendation asking Member States to develop a National Plan on Rare Diseases, work is underway to deliver a UK Plan for Rare Diseases by the end of 2013. The Plan is intended to benefit patients by outlining a strategic vision for the treatment of people with rare diseases and aims to improve diagnosis, treatment and care management. The UK has a history of supporting genetics research and its application for patient benefit and we continue to so. This can be seen in our approach to whole genome sequencing, where rare diseases are identified as a priority area.

3.11.6 Respondents also welcomed other work by the Commission across public health such as health care associated infection (HCAI) and health inequalities. Examples are shown in text boxes below.

> "An example here is the EU Joint Action on Health Inequalities (2011-2013), which aims to identify good practice, share learning and develop a multi-level approach to tackling health inequalities. The Welsh Government is a national partner in two work streams: 'tools' and 'regions'."
>
> Welsh Government

[3] *The European Union's Public health Programme (2003-2007): an effective way to improve health?* Available at: http://ec.europa.eu/health/programme/docs/php2003-2007_an_effective_way_to_improve_health.pdf

"The initiative around rare diseases will benefit from the establishment of Academic Health Science Networks in England and from the effective collaborations and partnerships already established in Scotland."

Medical Schools Council

The RCN supported the adoption of an EU recommendation on patient safety, including healthcare associated infection (HCAI), as well as ECDC's role in supporting Member States and evaluating the recommendation's impact. Although non-legislative, the recommendation is viewed as a positive step in raising and maintaining the profile of HCAIs and the impact of their burden from both a healthcare and public health perspective for current Member States and accession countries alike. It has also focused interest on exchange of good practice, including the development of link nurses in infection control."

Royal College of Nursing

3.11.7 Overall, the EU action taken through the public health programmes in a wide range of areas of public health has added considerable value, from benchmarking between Member States to the work outlined above on rare diseases.

NHS and Patient Services

3.12 Introduction

3.12.1 As outlined in the executive summary and legal chapters, Articles in the Treaty on the Functioning of the European Union ("TFEU") mean that the definition of health policy, management of health services and medical care and the allocation of resources are all Member State competences and stakeholders were supportive of this position.

"The economic value of health and social care is now increasingly understood at national member state level. Despite this the specific health competence at EU level is not always reflected in the approaches of the other European Commission Directorates General (DG). We would like to see more coordination at EU level between the respective DGs in the Commission in ensuring the health aspects of a policy have been taken into account in the formulation of their work programmes."

NHS European Office

3.12.2 With regard to the NHS and patient services, very few stakeholders advocated a change to the current position on competence, although a large number of concerns were raised about specific pieces of legislation that have a significant impact upon the delivery of healthcare in the UK. This includes employment policy, particularly the Working Time Directive and measures to enable the free movement of persons, such as the Professional Qualifications Directive. There was also a concern that there should be more coordination between the Directorates General in Brussels on these points, although the recent example of the European Innovation Partnership on Active and Healthy Ageing shows this can be done effectively.

> "A number of different European Commission Directorate Generals (DGs) have competence over matters that affect patient safety and may not always work jointly to consider the specific requirements and implications for the health of those living in the EU. For example, DG Single market and Services is responsible for freedom of movement initiatives, rather than DG Health and Consumers, despite the fact that the movement of health professionals has significant implications for the health and safety of the public."
>
> General Medical Council

3.12.3 This section of the report does not cover social care, simply because the EU has an extremely limited role in that field, and respondents did not address social care as an issue in the call for evidence, although there is some important work being taken forward on mental health by WHO Europe, as well as work coordinated by the European Commission (see case study 3G), and there is also work on dementia being taken forward by the European Commission (see case study 3H).

Case Study 3G: European Mental Health Strategy

At the 65th World Health Assembly in Geneva (May 2012) Member States adopted resolution 65.4 which acknowledged the need for "a comprehensive, coordinated response to addressing mental disorders from health and social sectors at the country level" which was to include approaches such as:

- programmes to reduce stigma and discrimination;
- reintegration of service users into workplace and society;
- support for care providers and families; and
- investment in mental health from the health budget.

As a consequence, the UK is contributing to the development of a European Mental Health Strategy which, as well as being an important element of the European policy for health, Health 2020, will feed into the Global Mental Health Action Plan which was considered at the 66th World Health Assembly meeting in May 2013.

In consultation with European Member States, NGOs and key partners, WHO Europe is developing a strategy which is intended to guide the work for mental health in the European Region for the next decade.

With regard to work led by the European Commission, the Commission published a green paper in 2005 on Promoting the Mental Health of the Population, which was followed by the launch of the European Pact for Mental Health and Well-being in 2008, which led to Council conclusions in 2011, which committed to "make mental health and well-being a priority of their health policies and to develop strategies and/or action plans on mental health including depression and suicide prevention."

Case Study 3H: Dementia

In July 2009 the European Commission issued a formal communication to the Council and the European Parliament on a European initiative on Alzheimer's disease and other dementias. This committed the Commission to use its different programmes (including Health and Disability) in an integrated way, with the Commission supporting Member States in addressing the issue of dementia. As part of this process, the Commission has funded a pan-European dementia project called 'Alcove', to allow the exchange of experiences and knowledge at the health care institutions level in order to improve the quality of care and services, as well as other objectives. The Department of Health leads on a project on dementia diagnosis on behalf of the UK as part of this work.

3.13 Implications of employment policy

3.13.1 The Working Time Directive (WTD) derives from Treaty of Lisbon (TFEU) article(s) on workplace health and safety. The WTD sets down minimum EU standards for working time, including minimum holiday and rest break requirements and the maximum average hours for a working week. The UK Government is committed to "limit the application of the Working Time Directive in the United Kingdom" as stated in 'The Coalition: our plan for government'.

> "Greater clinician involvement in EU legislation reviews and developments – specifically within health legislation and within areas impacting on health – could improve the level of benefit the UK obtains from EU action in health."
>
> Academy of Medical Royal Colleges

3.13.2 The WTD will also be considered as part of the Social and Employment Balance of Competences Review and, therefore, this section simply looks at the implications it has for the NHS.

3.13.3 There was recognition from the Royal College of Physicians (RCP) that the voice of the UK medical community in raising concerns about the WTD is now being better heard in Brussels. However, the Academy of Medical Royal Colleges (AoMRC) highlighted that further interaction at national level would be beneficial.

3.13.4 Respondents, including the RCP, RCP (Edin), Royal College of Radiologists, the British Medical Association (BMA) and Health Education England (HEE), mentioned that the WTD can provide benefits for staff and patients. This is because in some circumstances it can afford NHS staff a work-life balance and safety is improved as patients are less likely to be treated by tired staff (in most cases doctors were directly referred to). However, whilst a work-life balance is crucial for NHS staff and there is evidence that working excessively long hours can lead to patient safety issues arising, the question raised by other stakeholders, including the Fresh Start Project, General Medical Council (GMC) and several medical Royal Colleges, was whether the WTD delivers a work life balance for all staff and what impact it has on continuity of patient care as well as the departmental effect it has upon as junior doctors' training and other adverse consequences for the NHS.

3.13.5 Respondents expressed concerns over the impact of the WTD on training specifically and that the WTD limits the time available for training. The Royal College of Physicians and Surgeons of Glasgow and the Association of Surgeons in Training further added that, therefore, there has been a reduction in the total hours of experience gained by those attaining consultant status today, as compared with predecessors ten years

ago. Other stakeholders, including the Royal College of Surgeons (RCS) and Fresh Start Project were concerned that an increased number of handovers of patients and a reliance on locums, owing to the various rules governing working time[4] constraining staff capacity, are impacting on safe and continuous care as well as driving-up temporary staff costs for NHS trusts. In contrast, Sir John Temple's report *Time for Training* (2010) highlighted that handovers present an excellent opportunity for training and they allow continuity of care and enhance patient safety, although as handovers take place at the end of often lengthy work shifts, theory and practice may well diverge. However, the Care Quality Commission (CQC) mentioned that, although good practice guidance for handovers does exist, there is some variability in its implementation.

3.13.6 Additionally seven of our stakeholders, including the Royal College of Physicians (RCP), HEE and the GMC, felt that there is a lack of operational flexibility, particularly around the on-call time and compensatory rest requirements caused by the CJEU judgements SiMap (which stated that all time when a worker was required to be present on site whilst on call counted as actual working hours) and Jaeger (which confirmed that time on call at a place of work counted as working hours even if workers could sleep and that compensatory rest must be taken immediately after the end of the working period). Some stakeholders believed more needs to be done to ensure rules governing working time allow suitable training opportunities for doctors to deliver a health service that operates on a 24-hour basis.

3.13.7 There were comments from three Royal Colleges, the AoMRC and the European Society of Radiology that the impact of a cross-sectoral one-size fits all approach is not helpful because it does not take into account the difference between the operating environment in the health sector and other sectors or between different medical specialties. Similarly, some stakeholders expressed that the WTD does not take into account that Member States have different approaches to training their health professionals.

> "Where there are problems in balancing full implementation of the Directive with the demands of achieving a high level of training for junior doctors, the BMA believes that the problem lies with the design of training programmes and hospital rotas rather than with the Directive itself."
>
> British Medical Association

3.13.8 The RCP, Royal College of Physicians of Edinburgh and the RCS pointed out that even with the individual opt-out from the WTD; the junior doctors' contract still imposed significant restrictions on their hours. However, the BMA concurred that the reforms proposed by Sir John Temple in Time for Training (2010)[5] can provide solutions to difficulties that are being experienced with regard to designing and delivering training for junior doctors and the RCS welcomed the fact that the Government is reappraising the junior doctors' contract.

3.13.9 Particular concerns were raised by the Fresh Start Project and the RCS about the consequences for specialisms, such as surgery which noticed deterioration in training[6] and exhausted surgical staff owing to full-shift rotas including surgical training and in maternity and paediatric units.

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[4] Junior doctors' hours are governed by the Juniors Doctors Contract and the Working Time Directive.

[5] "Time for Training, A Review of the impact of the European Working Time Directive on the quality of training", Sir John Temple. 2010. http://www.mee.nhs.uk/PDF/14274%20Bookmark%20Web%20Version.pdf

[6] A survey of over 1,600 surgeons in training, by Association of Surgeons in Training, reported that two-thirds reported a deterioration in their training

> "The College expressed reservations about the application of the European Working Time Directive in medicine even prior to its phased introduction in the UK. We continue to be concerned about its impact on patient care in the NHS and the training of the workforce."
>
> Royal College of Surgeons

3.13.10 Although the WTD sets out the working time rules that must apply in all Member States, it is for individual Member States to implement the WTD with national legislation (which is by the Working Time Regulations 1998 in Great Britain). The CQC mentioned that Member States have interpreted and implemented the WTD differently, noting that "in some EU countries they 'bypass' the regulations by treating service delivery and education via separate contracts that are merged and work flexibly so that 48 hours service + 12 hours education = a 60 hour week."

3.13.11 Implementation of the Directive was also a major theme at a seminar on 24 April 2013, hosted by the Secretary of State for Health as part of the Balance of Competences Review, with concerns over whether the Directive was implemented consistently or in the correct manner. There was a lack of evidence on this point in the rest of the review but there was agreement at the seminar that it was important to think through these issues further.

3.13.12 We received a few responses that commented on competence: the Royal College of Midwives, Royal College of Nursing, BMA and The Royal College of Paediatrics and Child Health are content with current competence and the RCS is indifferent. However, respondents' views broadly seemed to suggest that it was not where the competence lay that was at issue but rather that it is important to get the legislation right, both at national and EU-level, and, separately, to address the other constraints mentioned above (for example within the junior doctors' contract).

3.13.13 This does not mean that stakeholders felt that the impact of the WTD was positive, and a number of problems were outlined in relation to the directive. The main point of disagreement was whether the problems are due to the directive itself or due to associated points such as the interaction with domestic arrangements or problems with implementation.

3.13.14 Overall, the Government is concerned about issues raised above about the WTD in the NHS, and in particular those raised by stakeholders including the RCS on the detrimental impact of the directive on training and on continuity of care and this issue is looked at further in chapter four.

3.14 Implications of free movement of persons: healthcare professionals

3.14.1 The Professional Qualifications Directive is concerned with removing barriers to the free movement of persons throughout the EU, and is therefore considered to be an important part of the single market. This Directive will be considered as part of the review on free movement of persons and this section considers the impact of the directive on the health sector. Health professionals make up around half of the total number of the UK's regulated professionals affected by the Directive.

3.14.2 Barriers to free movement are removed by Member States agreeing recognition through minimum training requirements. This is so that qualifications can be recognised and accepted, by one of two routes: 'automatic' recognition or 'general' recognition which may require compensatory measures.

3.14.3 Free movement of health professionals benefits health professionals individually, and the UK generally as a net importer of health professionals. This ensures that skills gaps in the UK workforce are filled quickly, and is particularly important in the NHS and for medical specialisms. The process of automatic recognition, based on harmonised minimum training standards, speeds up registration for doctors promoting speedier access to posts. Some respondents, including the Royal College of Nursing and Health Education England, highlighted the increase in the number of nurses recently from other EU Member States.

> "Freedom of movement within the EU means that there are generally no restrictions for EU nationals to move within the wider labour market and EU nurses now comprise the majority of nurses in a position to seek work in the UK. Indeed increases in inflows from EU countries experiencing economic difficulties (for example of the number of nurses gaining admittance to the NMC UK register from Portugal rose from 20 in 2006/7 to 550 in 2011/12) combined with the addition of EU 'accession countries' (who joined in 2004 and 2007) has contributed to a more recent increase in new international registrants (double that of 2010)."

Health Education England

> "The European Union (EU) has an important role to play in social and employment law. Health professionals benefits from EU health and safety legislation which in turn benefit patients in the form of increased patient safety. The European single market guarantees that professionals can move and work freely throughout the EU by virtue of having their professional qualifications recognised in other EU Member States."

British Medical Association

3.14.4 The table below illustrates the number of healthcare professionals working in the UK who qualified in other European countries:

All doctors by country of primary qualification group

England as at 30 September each year						numbers (headcount)
	2010			2011		
	All Doctors[1]	Medical staff[1]	GPs	All Doctors[1]	Medical staff[1]	GPs
All Countries of Qualification	141,326	101,917	39,409	143,836	104,056	39,780
Qualified in the United Kingdom	91,821	61,576	30,245	94,537	64,099	30,438
Qualified in the remaining European Economic Area	8,12 [2]	6,336	1,786	8,460	6,667	1,793
Qualified outside the European Economic Area	35,381	28,041	7,340	35,340	27,858	7,482
All Unknown staff with a Dental specialty[2]	4,035	4,035	–	4,030	4,030	_
Other Unknown	1,994	1,956	38	1,493	1,426	67

3.14.5 The Directive on the Mutual Recognition of Professional Qualifications (MRPQ) (2005/36/EC) is currently undergoing revision following the European Commission's proposals published in December 2011. Key elements of the Commission's proposal included: the introduction of a European Professional Card, better access to information, the updating of minimum training requirements, the introduction of an alert mechanism for health professionals; and a mutual evaluation exercise on regulated professions.

3.14.6 None of the responses to our call for evidence suggested that the current balance of competence was wrong. Respondents, including the British Medical Association and the General Medical Council, supported the underlying principle of freedom of movement for professionals, and recognised the benefit to the UK as a net importer of health professionals. However concerns were raised by the British Medical Association, the General Medical Council, the Royal College of Nursing, the Alliance of UK Health Regulators on Europe, the Nursing and Midwifery Council and others on matters that impact on patient safety, namely medical training and language testing.

> "In the past, the College has expressed concerns that this Directive would usher in a new degree of standardisation which would lower standards in Member States where the existing standards exceed Europe-wide proposals. We did not want to see a reduction in the UK's ability to develop or maintain standards and training curricula that best align with its health services."
>
> Royal College of Surgeons

> "The BMA supports the move to clarify the current wording of the Directive from 6 years *or* 5500 hours to five years *and* 5500 hours. The move to 5 years *and* 5500 hours recognises that training practices are changing and that the length of training is far from the only factor that determines quality."
>
> British Medical Association

3.14.7 In terms of basic training, concerns centred on the current Directive's minimum duration approach, rather than an approach based on training outcomes. For specialist training, there were concerns by the British Medical Association and others about whether there is sufficient consistency of quality between Member States to provide adequate reassurance on standards.

3.14.8 Stakeholders, including the Royal College of General Practitioners Scotland, wanted greater transparency on what is included in specialist training in other Member States – they felt they had more information on doctors from outside the EU than inside the EU.

3.14.9 Another issue of concern for responders was that of language testing:

> "The ability to communicate effectively with UK patients and colleagues is integral to the safe practice of all healthcare professionals and as such should be a prerequisite for access to the profession."
>
> The Alliance of UK Health Regulators on Europe (AURE)

> "From a patient perspective, communication is key to building trust in the patient-practitioner relationship. It also goes without saying that clinical information and advice must be communicated clearly and accurately to patients. Robert Francis QC, in his report of the Mid Staffordshire NHS Foundation Trust Public Inquiry included at recommendation 172, a recommendation that 'Government should consider urgently the introduction of a common requirement of proficiency in communication in the English language with patients and other persons providing healthcare to the standard required for a registered medical practitioner to assume professional responsibility for medical treatment of an English-speaking patient."
>
> General Pharmaceutical Council

3.14.10 Discussions on the MRPQ review are on-going and the issue of patient safety is a key consideration of those negotiations. Accordingly, the outcome of the negotiations may address some of the stakeholders' concerns around patient safety issues, in particular, issues including language controls and to some extent modernisation of the minimum training standards are likely to be addressed in the directive.

3.14.11 Furthermore, the Government announced earlier this year that in pursuit of the Government's objective to strengthen the arrangements to ensure that all doctors practising in England have sufficient knowledge of English, options are being explored to amend the Medical Act 1983. This would be to strengthen the General Medical Council's (GMC's) powers so that where legitimate concerns arise about a doctor's ability to communicate effectively during the registration process, the GMC can undertake checks on language knowledge before a doctor is authorised to practise in a medical setting; and also to enable language deficiency to be investigated as a fitness to practise issue under the Act.

3.14.12 Overall responses were positive about the existence of a European system of qualification recognition, although specific concerns were also raised, as outlined above. However, as the Royal College of Surgeons stated, Member States "must retain the right to develop and evolve their own competency requirements, as determined by the health systems and needs of their country". Therefore, the Government would not support complete harmonisation as this could have the effect of transferring the educational competency to the Commission.

3.15 Implications of free movement of persons: healthcare provision

3.15.1 The free movement of persons will be the subject of a separate balance of competence review in the second semester. This section only considers the implications in terms of the co-ordination of healthcare and cross-border healthcare provision. An EU citizen has the right to freedom of movement and the freedom to obtain services across the EU.

Regulation EC No. 883/2004

3.15.2 EEA countries are required to reimburse the cost of healthcare which is provided to some categories of people for whom they are responsible when they are travelling or residing in another EEA country. For the UK these people are most often UK residents who are temporary visitors to another EEA country who use a European Health Insurance Card (EHIC) issued by the UK for medically necessary treatment where the need arises during their visit, as well as UK state pensioners and their dependents who reside elsewhere in the EEA.

3.15.3 The EHIC card, which every EEA country issues, entitles the holder to receive state provided healthcare whilst on a temporary visit to another EEA country on the same basis that it is provided by the host state to its own residents. This enables the holder of an EHIC to receive free or reduced cost health care depending on the health care system operating in the host state. Many UK citizens go on holiday within the EEA with the peace of mind that should they fall ill, their health needs will be taken care of via the EHIC.

3.15.4 In 2012/13 the UK paid a net £805 million to other EEA countries to cover the healthcare costs of those for whom it is responsible, the majority of whom were for UK state pensioners living in other EEA countries. That the UK pays out such a large sum shows just how many UK citizens benefit from these provisions. The Regulations also give the NHS the ability to seek reimbursement for the cost of health care provided to state pensioners from other EEA countries that choose to live in the UK and temporary visitors using EHICs issued by other countries.

3.15.5 Many more UK pensioners choose to live in other EEA countries than pensioners from those EEA countries who live here. Using Spain as an example, approximately 400,000 British pensioners reside there at any one time. For a great majority of these, the fact that the UK covers their healthcare is of great benefit. It should also be noted that, had those citizens remained in this country, the UK would be meeting the costs of their NHS care in the usual way and in some Member States the average cost of healthcare can be lower.

> "The Trust sees this as an opportunity to promote its specialist services to a wider market and attract additional referrals to its specialist services to enhance the sustainability of its specialist services."
>
> Guys and St Thomas NHS Foundation Trust

> "The number of EU/EEA patients to the hospital has dramatically increased and far overtaken those patients who are subject to immigration control… Robust measures need to be put in place to secure the financial future of the NHS."
>
> Southend University Hospital NHS Trust

3.15.6 A number of NHS stakeholders raised concerns about the large number of EU/EEA patients seeking treatment in the UK as this may place capacity and funding pressures on the NHS. They also expressed concern about the difficulty in establishing if EEA nationals accessing the NHS are visitors or newly resident in the UK as this affects responsibility for funding the treatment. These issues were raised by West Hertfordshire Hospitals NHS Trust, Oxford University Hospitals NHS Trust, Portsmouth Hospitals NHS Trust, Brighton & Sussex University Hospital NHS Trust, North West London Hospitals NHS Trust, Royal Surrey Country Hospital NHS Foundation Trust, and Southend

University Hospital NHS Foundation Trust. Guy's & St Thomas NHS Foundation Trust referred to the issue but also pointed to the commercial opportunities through treating more patients from abroad.

3.15.7 Most stakeholders recognised that EU legislation actually provides additional safeguards for patients who are treated in other Member States or by doctors or medical staff from other Member States.

Directive 2011/24/EU on the application of patients' rights in cross-border healthcare

3.15.8 The Directive clarifies citizens' rights to purchase healthcare in another Member State and to claim reimbursement from their home state subject to certain conditions. The purpose of the Directive is to assist those patients who choose to purchase healthcare in another Member State and to ensure that it is safe and of high quality when citizens decide to use its provisions. The Directive also aims to help patients benefit from improved information and better clarity on the rules that apply to reimbursement. Decisions by the CJEU in cases including the Watts case[7] have had a direct impact on the NHS and patients and resulted in the introduction of the Directive.

3.15.9 The Directive does the following:

- It requires Member States to make information on rights and entitlements publicly available and easily accessible, including the conditions that apply to reimbursement and procedures for appeal and redress.
- It offers more opportunities for Member States and individual citizens. National authorities will need to work closely together in order to ensure that continuous improvements in the quality and safety of their infrastructure are made. Health experts across Europe will be able to share best practices on healthcare and potentially develop standards of excellence.
- It will allow NHS trusts and other healthcare providers to widen their sources of income by attracting European patients and using spare capacity in the system. In particular, there are real opportunities for those providers with specialist expertise – especially in the diagnosis and treatment of rare diseases – that will emerge from the establishment of European reference networks.

3.15.10 Stakeholders were broadly supportive of the Directive although some were more cautious in commenting on its potential implications.

> "A further aspect of equity is that, under current NHS arrangements in the UK, patients in one part of the country are not free to seek treatment, as a matter of right, in another part where waiting times are shorter. Yet they would be able to seek treatment in another EU country. This is not only an anomaly, but also inequitable to those who might consider treatment elsewhere in the UK but who are denied that option by UK rules, and who for whatever reason will not contemplate seeking treatment abroad."
>
> British Medical Association

[7] Case C-372/04 The Queen on the application of Yvonne Watts v Bedford Primary Care Trust and the Secretary of State for Health

"NEEHP supports the cross border healthcare directive and believes that increased competency in health at EU level is required in order for Member States to be supported and guided adequately as to how best to implement policies related to cross border healthcare provision. This is vital in order to protect UK citizens and to ensure that health care provided is delivered to high standards so as to meet agreed European recommendations."

North of England EU Health Partnership

"Given that the overwhelming majority of UK citizens choose to access healthcare in this country, the RCN is clear that arrangements to implement the cross border care directive should not undermine domestic planning, provision and financing of health services."

Royal College of Nursing

3.15.11 The implementation of the Cross-Border Healthcare Directive was subject to a separate consultation which outlines some of these issues in greater detail. This ended on 24 May 2013.

3.16 E-health

3.16.1 EU action supports the development of Information and Communications Technology (ICT) usage in health and social care (known as e-health) through voluntary programmes. The organisation and delivery of health care is the responsibility of each Member State. Matters such as the ICT infrastructure of the health service and measures such as electronic records are part of the organisation of healthcare. However, the challenges involved are common to other Member States.

"The NHS has fed into the EU's learning of e-health developments and reciprocally, has benefited from the EU's supporting and financing role in particular. For example, the various EU funding programmes (such as the Seventh Framework Programme and the Competitiveness and Innovation Programme) have enabled on many occasions UK actors to engage in collaborative work with colleagues from other EU countries, which have contributed to a better understanding of e-health deployment and integration into service delivery. The UK should certainly look to continue to play a significant role in future EU-funding in this area in future."

NHS European Office

3.16.2 To support Member States in implementing e-health, the Commission has:

- produced non-legally binding e-health action plans;
- dedicated funding to research and projects to help facilitate e-health uptake; and
- set up a voluntary network connecting national authorities responsible for e-health designated by the Member States through Article 14 on e-health of the Directive (2011/24/EU) on the application of patients' rights in cross-border healthcare.

3.16.3 The call for evidence indicated support for voluntary co-operation in e-health. Organisations across the UK, including in Scotland, were highlighted as benefiting from European e-health activities.

3.16.4 There were some calls for the Commission to go further and consider regulation in e-health. The European Society of Radiology, Royal College of Radiologists and CQC raised patient safety concerns about the use of telemedicine services, where it was suggested that standards of use and assurance differ between Member States. Currently, the Commission has published guidance for organisations involved in the provision of telemedicine services.

3.16.5 However, the overall message was that e-health should remain a matter for voluntary co-operation between Member States. The UK Government is supportive of the voluntary co-operation in this area.

3.17 Health research

3.17.1 This review considers EU action in the field of health research; the review on research, development and innovation will consider EU competence on research more broadly during semester two.

> "Medical research is an area in which the UK is a leading player. A disproportionate amount of EU health research funding comes to the UK. This is hugely important to the Russell Group universities and must be retained."
>
> Liberal Democrat Health and Social Care Parliamentary Party Committee

3.17.2 The Framework Programme for research and technological development is the main mechanism used by the European Commission to fund research across Europe. The 7th Framework Programme (FP7) was launched in 2007 and its successor, Horizon 2020, will fund EU research and innovation from 2014 to 2020.

3.17.3 The UK is the largest EU Member State beneficiary of EU funding for health research. Data released in October 2012 shows that, in the health theme of the FP7 Cooperation Pillar, the UK had attracted over €570 million in EU funding, 17 per cent of the whole EU contribution and €30 million more than Germany, the second highest beneficiary.

> "EU-funded projects and partnerships provide great opportunities for a broad range [of] UK partners, including universities, NGOs and NHS organisations, to share knowledge and ideas with colleagues in other Member States. They bring funding to the UK and promote British expertise, for example the adaptation of community nursing model from Northern Ireland, which won the RCN's innovation award, for collaborative projects with France, Lithuania and Greece on developing cost effective integrated institutional to community care."
>
> Royal College of Nursing

3.17.4 Respondents provided a number of examples of funding, which have brought a number of benefits to the UK.

3.17.5 EU Framework Programmes act as a significant driver for the formation of health-related partnerships across Europe and the development of platforms for the dissemination of information. In addition to the direct funding support provided by the EU, actions taken at the European level can add significant value to actions taken by individual Member States.

> "Coordination of research programmes across Europe to address key societal challenges which could not be addressed by one country alone is also welcomed, as such a joint approach to challenges enables Member States to maximise their use of resource for the advancement of science and to compete on a global scale in key research areas. It is difficult to imagine such collaborative efforts taking place without the coordination role of the Commission and joint ambitions towards a wider European Strategy."
>
> Medical Research Council

3.17.6 It is the Government's view that it is important that steps are taken across the whole of Europe to harmonise the research environment, remove barriers to transnational research, and ensure quality of conduct and protection of participants in clinical trials and studies. In addition, European legislation and policy in this field must be proportionate and risk-based, avoiding administrative burden where possible, and providing clear and detailed guidance in order to ensure successful consistent implementation across Member States. The importance of these points is clearly demonstrated by the Clinical Trials Directive. There was also a strong call from stakeholders for a more transparent process in the awarding of research grants.

3.17.7 The Government believes that where European legislation is developed which does not principally concern research; it is vital that potential impacts on health research are fully considered and understood.

3.17.8 There are widespread concerns within the UK health research community about the European Commission proposal for a new legal framework for data protection. Proposals around obtaining consent and the use of sensitive data may have implications for medical research. Negotiations are still live and the UK is seeking to ensure that processing for the purposes of medical research is not subject to additional limitations or onerous burdens.

> "There are concerns about current moves in Europe around data protection and it will be important to ensure that the use of anonymised patient data for health research continues to be permissible."
>
> Medical Schools Council

3.17.9 Research highlights some of the most positive aspects of the European Union's work, and much of the investment in research and work to harmonise clinical trials is supported by the Government. However, sometimes these benefits are threatened by legislation that, however well intentioned, has a negative impact on research in the UK.

Chapter 4:
Future options and challenges

Medicines and medical devices

4.1 EU processes

4.1.1 A theme running through much of the stakeholder evidence relates to how the EU can further apply the principles of better regulation. In the Government's view, the Commission is making progress towards drafting proportionate legislative proposals, supported by impact assessments, in part thanks to the UK's promotion of its own better regulation efforts. However, more progress can be made and the Government will continue to press for a thorough consideration of the costs and benefits of any proposed action at EU level.

4.1.2 The recent experiences around Active Pharmaceutical Ingredients in the context of the Falsified Medicines Directive also highlight the importance of the EU understanding the impact of legislation and working to avoid unintended adverse consequences, and it is vital that the UK Government continues to input strongly on these points.

4.1.3 It is also important for the EU to think through how best to act when changes to EU legislation are required. The Commission has, in the past, been reluctant to review and propose revision of existing legislation. This suggests that it may be important for review clauses to be built into all EU legislation as an opportunity to review implementation after a few years of entry into force.

4.1.4 There were calls, for example from the British Generic Manufacturers Association, for the Commission to develop more expertise and capacity so that they are able to conduct thorough impact assessments and consult a wider range of stakeholders.

4.1.5 As regards implementation, Member States can better enforce EU legislation and the Commission could more effectively resolve issues relating to the implementation of EU legislation by issuing prompt guidance and taking swift action where problems arise.

4.1.6 For example, there are concerns about Member States not implementing the Falsified Medicines Directive on time, which has implications for patient safety. As outlined above, stakeholders felt that the Commission could better assist Member States to implement the directive, especially the provisions on Active Pharmaceutical Ingredients, which may otherwise have a detrimental effect on the supply of medicines to the UK.

4.1.7 The UK Government shares a number of these concerns, whilst recognising the progress that has been made by the Commission in recent years on some of these points.

Case study 4A: European rules on monitoring the safety of medicines

The recent 'pharmacovigilance' legislation was given as an example to illustrate deficiencies in EU decision making processes. Whilst stakeholders supported the legislation, they commented on what were seen as poorly thought through compromises reached behind closed doors during final negotiations between Council, European Parliament and the Commission. The pressure to reach an agreement was seen by some as resulting in legislation of poorer quality.

Industry also commented that the implementation process was not well thought through by the European Medicines Agency (EMA), which de-prioritised implementation of many provisions which would have reduced the administrative burden on industry. In addition, although new tasks were given to the EMA in the pharmacovigilance directive, the Commission failed to provide the necessary budget for these tasks for both the EMA and Member States that contribute to the work of the EMA. The Government has been pressing the Commission to find a solution for pharmacovigilance work undertaken by Member States without reimbursement.

4.2 Opportunities for further European action

4.2.1 Stakeholders mentioned a broad range of areas where there might be possible opportunities for further European action, but there was no consensus around specific proposals. Nevertheless, as highlighted earlier in this report, many responders including the Royal College of Physicians, Royal College of Surgeons, NICE, the British Medical Association, North of England EU Health Partnership, British Dental Association and the NHS European Office commented on the need for improvements in the regulation of medical devices (see case study 4B). The need for continuing work to address problems with the Clinical Trials Directive was also mentioned frequently (see case study 4C).

Case study 4B: revising the medical devices regulatory framework

Drawing on lessons learnt from recent safety concerns relating to fraudulent breast implants and certain metal on metal hip replacements, it is imperative to improve the quality of the regulatory framework on medical devices, even before new European legislation comes into force. As such, Member States are taking action now to tighten up the rules on notified bodies and collaborate more effectively to share and act upon safety information. The Government, through the MHRA, are playing a leading role in these discussions.

New legislation for general medical devices and *in vitro* diagnostic medical devices is also on the table for negotiation between the European Parliament and Council, which industry and clinical stakeholders consider substantially improves the current regulatory framework by placing stricter requirements on the organisations which assess the safety of medical devices before they can be placed on the market, putting in place an electronic traceability system, establishing a centralised registration database of manufacturers and devices, which will reduce the burden on industry to register with different national systems, and introduce better collaboration between Member States to share safety and market surveillance data, which will help to improve the patient safety of medical devices by identifying problems earlier. The MHRA is leading the Government's input.

There is a debate in the EU on whether there should be more or less EU action in the pre-market scrutiny of medical devices. The Government and the majority of stakeholders argued that centralised European checks of the safety and performance of devices would be expensive and bureaucratic, would delay placing devices on the market and would not benefit patient safety. On the other hand, some stakeholders argued that central scrutiny would help to ensure that a consistent level of control was applied to high risk medical devices which would therefore improve patient safety.

Case study 4C: opportunities to improve EU rules on clinical trials

The Commission's proposal for a new regulation on clinical trials seeks to streamline the application process for clinical trial approval by replacing multiple national applications with a single European application process. This is an opportunity to revise the current legislation, which made it difficult to conduct cross-border trials and expensive to get approval for a clinical trial in the EU. As a result, many researchers have started conducting research outside of the EU.

The Government considers it important that the EU becomes a more attractive place for conducting clinical trials. The new regulation will decrease the burden on researchers whilst patients are protected appropriately. As a result, it will become less burdensome and easier to conduct multi-state trials across the EU.

The Government, through the MHRA, played an active role in pressing the Commission to review the current directive and many of the proposed improvements in the Commission proposal reflect UK practice. The Commission's proposal has received a lot of support from stakeholders and the new regulation was cited as an example of an area where the Commission had recognised that the existing legislation was flawed and had actively proposed to repair this.

In addition, all stakeholders called for the new regulation to ensure ethical conduct and foster innovation. A minority of stakeholders called for EU competence to expand to include ethics approval, which would mean consistent high standards of ethics approval and more efficiency and innovation.

Public Health

4.3 Organs, blood, tissues and cells

4.3.1 There is a tension between health priorities and other EU policies, and respondents are concerned about the potential impact in their field. For example, EU competition rules are potentially problematic for the stability of the blood supply under the UK's system of voluntary blood donation. In another Member State a commercial provider of blood took donors and hospital contracts away from the voluntary system, then withdrew its service, leaving the voluntary system to supply hospitals again at short notice.

4.3.2 With regard to blood donor selection criteria, a move to increasingly evidence-based criteria would be welcomed. However, it is important that Member States are able to introduce more stringent measures where appropriate.

4.3.3 Respondents, such as NHSBT, would welcome the EU taking a more proactive role in monitoring emerging infections relevant to blood transfusion, and informing Member States. This role is currently filled by a sub-group of the European Blood Alliance. They would also like to see greater consistency in testing, given the use of imported blood and tissue and the variation in infection risks between different Member States.

4.3.4 Overall, the view of stakeholders is that the benefits of EU action in this area outweigh any disadvantages and they would back the retention of the current position, as having different systems in every Member State would have clear disadvantages.

> "Should we need to navigate 27[1] diverging regulatory regimes across Europe, there would be significant cost implications for our provision of imported cells. More importantly, however, time is critical in Hematopoietic stem cell transplantations. There is potential that if our organisation sat outside the EU common regulatory standards by virtue of our UK location, our stem cell import or export activity would be subject to delay caused by additional bureaucracy or lack of international trust in our 'product' caused by the absence of a recognised European 'kite-mark'. Such delays would undoubtedly have a significant impact on patient survival in the UK and for patients who require UK-sourced stem cells in other Member States."
>
> Anthony Nolan

4.4 Nutrition and food labelling

4.4.1 While most food legislation is harmonised across the EU, there are areas of nutrition-related legislation that have not yet been harmonised. The UK Government supports harmonisation where there is scope to improve consumer protection and/or the operation of the single market, but each issue needs to be considered carefully to avoid unnecessary burden. Member States can have very different ways of managing some of these issues and achieving harmonisation with strongly held opposing views is problematic. There are barriers to trade where rules are not harmonised, which reduce the opportunity for UK businesses to trade in the EU. Lack of harmonisation may also result in imports from other Member States to the UK market that are of varying quality and have safety implications for consumers.

[1] There are now 28 Member States since the accession of Croatia to the European Union on the 1st July 2013.

4.4.2 An example is the setting of maximum permitted levels for vitamins and minerals in food supplements and fortified foods. The absence of harmonised EU rules in this area and the subsequent application of national provisions in some Member States have led to a fragmentation of the single market, adding significant costs for manufacturers. Consumers for Health Choice (CHC) and Health Food Manufacturers' Association (HFMA) have strongly opposed such harmonisation measures that they consider will restrict the unique nature of the UK national market. The Government believes that any future decisions on vitamins and mineral food supplements need to be proportionate and based on evidence, so that consumers have confidence in what they buy, while maintaining a wide choice of safe products.

4.4.3 The Government would welcome greater transparency regarding the Commission's work programme and wider consultation of stakeholders, a common theme with other areas. Better (Smarter) Regulation approaches could be further considered to reduce the regulatory burden. However, attempts to do this, for example with the review and simplification of the dietetic foods legislation, met with a degree of resistance from a number of Member States wanting to increase the number of categories of regulated products.

4.4.4 Whilst this report does not cover obesity policy in detail, this is an area of increasing focus at EU level, and further voluntary co-operation on this issue is likely in future.

4.4.5 The main on-going challenge will be to continue to resist pressure for protectionist or anti-innovation measures, by insisting on maintaining a science-based approach. Strengthening the quality and credibility of scientific support to the Commission and to the Member States in this area would be in the UK's interest.

4.5 Tobacco

4.5.1 NGOs, including the Optical Confederation, the Royal College of Nurses, BMA and the National Heart Forum, felt that the EU has and will continue to have a role to play in tobacco control and many would welcome more legislation at EU level to achieve a more appropriate and higher level of health protection for the public. They also consider that this would be of benefit to the single market and create a level playing field for manufacturers, including those from the UK.

4.5.2 Without legislation at the EU level, the UK would need to legislate domestically to ensure comprehensive tobacco control remained in place in the UK, affording the public with the same levels of protection from the harms from tobacco that they enjoy now.

4.5.3 Legislation – both EU and domestic – has been shown to be an important tool in comprehensive tobacco control and has helped the UK comply with its obligations under the WHO Framework Convention on Tobacco Control.

4.5.4 Many respondents expressed their views on the European Commission's recent proposal to revise the Tobacco Products Directive and what they felt might be the possible impact of the extension of the scope of this Directive. This proposal is still in the relatively early stages of negotiation.

4.6 Alcohol

4.6.1 The UK Government will seek to ensure that the EU Alcohol Strategy supports Member States in applying the most effective and proportionate national policies to tackle issue of alcohol misuse in Europe, and uphold the principle that it is for the State to decide on the degree of protection which it wishes to afford to public health and on the way in which that protection is to be achieved. The Government would see value in helping to promote greater coherence in EU legislation and policies so that they enable Member States to support health improvement better, for example, in the EU Directive on the structures of alcohol taxation so that it might allow duty on wine and other products to rise in line with alcoholic strength. This is known as targeted alcohol taxation and was supported by a number of respondents, including the Royal College of Physicians, the North of England EU Health Partnership, the Alcohol Health Alliance and the Association of Directors of Public Health.

> "The EU alcohol strategy, which came to an end in 2012, was designed to help national governments and other stakeholders coordinate their action to reduce alcohol related harm in the EU. The strategy is an example of how the EU can have a positive role without the burden of legislation. Consideration is currently being given to what should replace the strategy and whether a new strategy should be established; the BMA would view the establishment of a new strategy as a positive step for all Member States in reducing alcohol-related harm. Any new strategy needs to have strong emphasis on regulatory action to reduce accessibility and availability, eliminate all promotional activities and limit industry involvement."
>
> British Medical Association

4.6.2 The Commission has recently proposed a Joint Action on alcohol and health to run from 2014 to 2016. This will include work on common approaches to the development of alcohol guidelines for the public and health professionals. The UK will support this as an associated partner, contributing from our own review of alcohol guidelines now under way. We believe it should be a good example of collaboration, with benefits for the UK and others.

4.6.3 The British Medical Association argued strongly that the EU should be taking a stronger role in supporting Member States' actions to reduce alcohol-related harm.

4.6.4 The UK Government would have reservations if a new EU alcohol strategy were to impose regulatory action across all Member States, especially in areas such as availability of alcohol (licensing), which should be matters for Member States. On the other hand, we would not wish EU policies, or the emphasis on free trade within the EU, to imply a lowest common denominator approach to national alcohol policies. Where the needs of a population justify specific policies, including innovative policies like the alcohol minimum unit price legislation passed by the Scottish Parliament, we believe EU institutions should be flexible enough to accommodate these where a clear case is made.

4.6.5 Article 34 of the TFEU prohibits all quantitative restrictions on imports (or measures having an equivalent effect). Article 34 has been used to challenge national measures on tobacco and alcohol control. Article 36 permits public health measures that impose quantitative restrictions (or the equivalent), provided these are proportionate and non-discriminatory. It is important that there is a sensible balance between these two requirements and that Member States are not unreasonably prevented from bringing in proportionate public health measures.

4.6.6 Some researchers have argued that EU law and policy has focused too much on the removal of trade distorting policies, even at the expense of Member States' ability to set policies that protect public health[2]. While the UK Government does not believe this anxiety is justified, we believe that the institutional balance within the Commission and having the right expertise on public health as well as trade within the Commission can be important in helping to ensure a balanced approach.

4.7 Health security

4.7.1 A proposal on cross-border health threats is currently in negotiation. It aims to streamline and strengthen EU capacities and structures for responding to serious cross-border health threats (such as pandemic flu) building on the existing structures to coordinate surveillance and control of communicable diseases. Under this proposal, the Commission seeks to extend the scope of the procedures to include cross-border health threats from biological, chemical, environmental and unknown origins.

4.7.2 The UK Government welcomes the proposal particularly the legal mandate given to the Health Security Committee and supports the recognition of subsidiarity meaning that Member States retain the freedom to protect their citizens in the way that they see fit. The Commission's original text included an article which was supported by the European Parliament that would have allowed the Commission to use urgent delegated acts to adopt common temporary public health measures across the EU. This provision has always been a concern of the UK Government and the majority of other Member States.

4.7.3 An agreement is currently being negotiated on the joint procurement of medical countermeasures across Europe. It is possible that this could present efficiencies and economies of scale in future procurements. The UK has indicated that it would be willing to be involved, providing the agreement remains voluntary. The actual decision to participate in procurement would need to be taken on a case-by-case basis at the appropriate time.

4.8 Non-ionising radiation

4.8.1 Respondents were content with the EU competence in this area, not least because action at international, European or national level would have the same effect. The current EU position seems proportionate and based on best scientific evidence. Some respondents felt a more restrictive level of exposure should be adopted by both the EU and UK. However, the current available evidence does not support a more restrictive level. Going forward, the key concern is that the EU seek to ensure that decisions taken in this area reflect scientific analysis.

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[2] Health, alcohol and EU law: understanding the impact of European single market law on alcohol policies, B. Baumberg and P. Anderson; *European Journal of Public Health*, Vol 18, No 4, 392-8 (2008)

4.9 Public health programmes and rare diseases

4.9.1 There was support from stakeholders for further work on benchmarking, whether in tackling Health Care Associated Infections (HCAIs) or in improving cancer survival rates. The Government view is that this work should be supported at the voluntary level.

4.9.2 It is anticipated that the UK Plan for Rare Diseases will refer to a number of European initiatives as supporting the UK's national strategy. For example, the European Reference Networks (ERNs) – a proposed network of expert centres for the diagnosis and treatment of individual rare diseases – could play a beneficial role in supporting access to timely diagnosis and treatment for patients with a rare disease in the UK. It should be noted that the discussion on ERNs is one area of the UK Plan where there is also overlap with work on the Cross-Border Healthcare Directive. The UK Government sees the proposal to establish ERNs as an opportunity to focus on rare diseases and act as a EU-wide network to improve knowledge and awareness of rare diseases and share best practice on possible treatment options.

> "The Commission's original proposal for the third community programme in health – Health for Growth programme – illustrates an increasing tendency for EU action to be focused on matters related to healthcare organisation and delivery. This can potentially extend beyond the current EU competence in health, which is primarily concerned with public health issues (health promotion and health protection in particular) and legislation stemming from completion of the single market. However, concerted UK national action was effective in reorienting the Health for Growth proposal towards public health."
>
> North of England EU Health Partnership

4.9.3 It is also important that the Government monitors the potential for certain voluntary initiatives to lead on to arguments in future that harmonisation at EU level is needed. One example given was that of the Health for Growth programme, as noted by the North of England EU Partnership.

NHS and Patient Services

4.10 Overall competence

4.10.1 Whilst the current position on EU competence as it affects the NHS may be generally acceptable to stakeholders, this does not mean there are no risks ahead. A number of general concerns were raised by stakeholders on areas that could have a potential impact on healthcare in the UK in future:

- Concerns were expressed about the role of the courts – in particular, the potential for CJEU decisions to impact on the NHS.

> "A point of concern is that the competence of the EU is not extended in unexpected or burdensome ways. For example, decisions of the European Court of Justice leading to the development of the directive allowing patients to receive health care elsewhere in Europe at the cost of their home country, have gone against the understanding that management of health services is the prerogative of the Member States."
>
> Welsh Government

- Other stakeholders questioned the potential implications of EU competition law for the NHS. However, the UK Government is clear that the Health and Social Care Act 2012 did not change the position with regard to the application of competition law to the NHS.
- Stakeholders also flagged the European Semester process and the involvement of the Troika in discussing national reforms in Member States. Their involvement in health is increasing, particularly in Member States requiring bailouts in recent years. There were questions on whether there are competence implications in health from this work. This is an important point to keep under review. HMT will be considering issues related to the European Semester as part of their Economic and Monetary Union review in the fourth semester.

4.10.2 The Department of Health must therefore continue to scrutinise proposals for European legislation at an early stage to identify the full range of implications for the NHS.

4.10.3 Another suggestion was the need to involve the Devolved Administrations more effectively on European issues and this point was made by the RCN and other respondents.

> "The document rightly states that representation in the EU and in international organisations such as WHO is at UK level. As the healthcare systems in the UK increasingly diverge, the practicalities of a single 'voice' from the UK are an area which would benefit from discussion. Stronger arrangements for devolved administrations to contribute to the single UK voice could be beneficial in more accurately representing the needs of the four nations of the UK."
>
> Royal College of Physicians in Edinburgh

4.10.4 Several stakeholders commented on the implications of the Francis recommendations on areas such as language testing and minimum standards of training.

> "It is important to note the challenge of defining minimum standards (agreeable across all countries) whilst we strive for the highest standards here in the UK and the obvious dislocation between the EU defined minimum standards and the acceptable/desirable minimum standards across the UK (for example, a degree level qualification in nursing)."
>
> Health Education England

4.10.5 This section once again does not mention social care in detail as the EU has such a limited role in this area. However, it is worth noting in this regard given possible future implications for social and long-term care (see paragraph 4.13.4).

4.11 Implications of employment policy

4.11.1 As discussed in chapter three, this section only considers the implications of employment policy for the health sector; social and employment policy in general will be the subject of a separate Balance of Competences Review in semester three.

4.11.2 During 2012, the European social partners were negotiating the Working Time Directive (WTD). However, these negotiations did not lead to an agreement and so the initiative for producing a new proposal reverted to the European Commission.

4.11.3 This Government remains committed to limiting the application of the WTD in the UK and, in order to ensure that the NHS has the flexibility it needs, the Department of Health and the Department for Business, Innovation and Skills (BIS) are working closely together on the application of the WTD to the UK health sector. Whilst stakeholders noted a perceived failure of the UK to effectively influence the original discussions on the WTD, it appears they now feel their voices on this topic are better heard in Brussels.

> "More recently, discussions in Brussels to revise the WTD have demonstrated a higher degree of engagement from the UK medical community and consequently a greater responsiveness to our concerns from the European Commission."
>
> Royal College of Physicians

4.11.4 It is clear from the responses that there are concerns with regard to the WTD and its impact on the NHS. As part of the Government's commitment to limit the application of the WTD in the UK, the Department of Health is taking the following steps:

a. working with BIS to seek greater flexibility in the areas of on-call time and compensatory rest: as highlighted by many of the respondents this requires a solution to the problems posed by the SiMap and Jaeger CJEU rulings. These rulings have meant that employers have had to implement shift systems which, in turn, have made it difficult to get internal cover for absences at short notice;

b. maintaining the facility of individual doctors and other health workers to opt-out of the Directive: the UK Government considers this an important element and that the loss of this would pose significant problems for the NHS;

c. considering the interaction between the WTD and other current contractual provisions (such as the junior doctors' contract) and how the WTD is implemented in the UK in the health sector;

d. undertaking a survey to gather junior doctors' opinions of the WTD so that the underlying principle of any future reform produces regulations that are fit for purpose and meet the needs of the service; and

e. continuing to work with BIS and with partners in Europe, on any renegotiation of the WTD with the aim of providing the flexibility the UK needs.

4.12 Implications of free movement of persons: healthcare professionals

4.12.1 As discussed in chapter three, the free movement of persons more broadly will be considered by a separate Balance of Competences Review in semester two; this section considers the situation for healthcare professionals.

4.12.2 Respondents have not directly called for a change in the current balance of competence on professional qualifications. The UK is a net importer of EEA health professionals, and gains significantly from free movement. This is recognised by most respondents, and accords with the view of the Government. From the evidence most stakeholders appear to have specific issues with the impact of the different parts of the legislation and not where the competence lies.

4.12.3 Respondents felt that in the Directive review, the European Commission has proposed additional safeguards to patient safety, and this is recognised by the respondents and the Government. The UK Government is negotiating on key priorities relating to patient safety that are aligned with stakeholders concerns. In particular, we are seeking to ensure that proposals such as the alert mechanism, language controls, the European Professional Card, and partial access are supportive of patient safety. In the main the Government is pleased with how the text has developed during the Council Working Groups, and the resulting further proposed amendments which generally offer pragmatic solutions. The Government's view is that the negotiations on the revision of the Directive are moving in the right direction but discussions are ongoing, and it would be premature to make any final judgement until all points are formally agreed. We also acknowledge that Government and stakeholders have worked extensively together on these issues and are grateful for all the important input from stakeholders throughout the process.

4.12.4 There is a need for greater transparency and coordination on the mutual recognition of professional qualifications, particularly in relation to the minimum training standards to ensure that Member States and stakeholders have sufficient input in developing any requirements. Greater coordination is required between Member States and within the Commission to ensure that patient safety concerns are balanced with free movement of person's objectives.

4.13 Implications of free movement of persons: healthcare provision

4.13.1 As discussed in chapter three, Regulation 883/2004 brings clear benefits for UK citizens, including, for example, for people travelling to other EEA countries, students studying there, and pensioners who have moved abroad. The Regulation also covers citizens of other EEA countries accessing healthcare in the UK for which the UK is likewise entitled to seek reimbursement. Whilst this provision supports free movement of persons, there are questions going forward about how the Regulation interacts with our domestic provisions about entitlement to NHS care, which is based on whether an individual is 'ordinarily resident' in the UK. There are also questions about how rigorously the domestic provisions are applied. While there are legitimate concerns that the complexity of the rules make them difficult to apply at the frontline, the culture of the NHS means staff can be reluctant to ask individuals to give details of their EHIC. Inadequate domestic mechanisms to record the data necessary to claim reimbursement under

Regulation 883/2004 also contribute to the UK's current low levels of reimbursement. The Government has committed to work with the NHS to increase appropriate cost-recovery from EEA countries. These questions are linked to the Prime Minister's speech on immigration in March 2013, and are currently part of a consultation looking at a range of options, including plans to improve how the NHS can identify and recover costs where appropriate.

4.13.2 Whilst these practical enforcement issues relate and will be corrected through changes to our domestic legislation, they highlight the conflict and difficulties of operating a residency based healthcare system compared to the direct contribution and insurance based model that operates in most Member States. The challenge going forward is to make the system work in the NHS, which will remain free at the point of use for UK residents.

4.13.3 This is also relevant in terms of organ transplantation. Citizens of other EEA countries ordinarily resident in the UK are entitled to, where necessary, transplantation under our domestic legislation. Similarly, UK nationals living in other European countries such as Spain obtain health care including transplantation in accordance with the legislation of the country in which they live.

4.13.4 There are concerns that the European Commission might be seeking to extend EU remit into fields of national competence by indirect routes. For example, the need to facilitate freedom of movement can be put forward as justification for extending the coordination arrangements set out in Regulation EC No. 883/2004 into other areas and restraint in this area from the Commission would be welcomed. The Commission held a consultation from December 2012 to March 2013 on the potential co-ordination of long-term care benefits. The Government would have concerns about the expansion of the remit of Regulation 883/2004 to achieve this.

4.13.5 However, ultimately it is the Council of Member States and the European Parliament that will decide whether or not to adopt any amendment to the Regulation which the Commission propose. In addition, under Article 48 TFEU the so-called "emergency brake" procedure allows a Member State that considers that a proposed legislative act would affect important aspects of its social security system or the financial balance of that system to request that the proposal is referred to the European Council which must decide by consensus whether to proceed.

4.14 E-health

4.14.1 There was support overall for continued voluntary co-operation in relation to e-health, rather than further action from the EU. The UK Government is supportive of the voluntary cooperation role led by the Commission in this area of work.

4.14.2 NHS organisations and other sectors could continue to benefit from funding mechanisms to support some of the actions in the future e-health action plan 2012-2014 as is the case with current funding opportunities.

4.14.3 New technologies and new challenges faced by Member States in providing healthcare make the field of e-health an evolving one. The Commission aims to support Member States in addressing these new challenges through their revised e-health Action Plan for 2012-2020.

4.15 Health research

4.15.1 In the area of research, there is consensus that European legislation is welcome in principle, as a harmonised approach to research across the EU has many potential benefits for both commercial and non-commercial trials, and could even mean a reduction in red tape if implemented well. In practice, whilst designed to protect patients and aid a consistent approach to clinical trials across the EU, European legislation has proven to be counter-productive and has had an adverse impact on the number of trials operated in the EU.

4.15.2 This led to a lack of harmonisation of the regulation of clinical trials across the EU because Member States introduced national rules when transposing. However, the Commission's proposed revision to the Clinical Trials Directive (which includes changing it to a regulation directly applicable across all Member States) has been broadly welcomed by most stakeholders and is an example of the fact that mistakes can be corrected effectively at the European level. Stakeholder views on this legislation are outlined in more detail in the medicines section of the report.

> "We therefore welcomed the proposal for a Clinical Trials Regulation released by the European Commission. The Regulation appears to improve the legislation associated with running clinical trials. This will give researchers a better framework for developing and testing treatments, to benefit patients across Europe, while maintaining the high standards of patient safety that currently exist in European clinical research. The harmonisation of clinical trials legislation and the streamlining of the application process for starting trials should particularly benefit the set up and running of multi-national trials in Europe. The proposed Clinical Trials Regulation builds on the existing directive, while also addressing criticisms of the Directive and promises a much more efficient system. A regulation in this instance, which will ensure proper harmonisation across the EU, seemed the most appropriate legislative tool (rather than a new directive)."
>
> Liberal Democrat Health and Social Care Parliamentary Party Committee

4.15.3 Concerns over current proposals on data protection were discussed in chapter three (paragraph 3.17.8). This is not an issue regarding competence as most stakeholders agree that good consistent legislation on data protection across the EU would be positive in the field of research and elsewhere. Therefore, the best way forward is a positive negotiated settlement on this issue. The outstanding question is what can be done if a negotiated settlement acceptable to the UK is impossible to reach. It is important that health concerns can properly and most effectively input into a process that is not led by health departments at either the national or European level. The best way forward on data protection will need to be determined by working with colleagues from the Ministry of Justice.

4.15.4 In the past, there has been criticism of the way that directives have been implemented in the UK in the area of research. However, it is important to note that much progress has been made in recent years to improve the way that directives are implemented including the Government's commitment to end gold-plating of legislation in the UK. However, the Government must continue to ensure this is the case in research and in other areas going forward.

> "As the 7th Framework Programme for research and technological development, (launched in 2007) comes to an end in 2014, the UK has to ensure that it is able to maximise on the monies available from the Horizon 2020 Programme (replacement for Framework Programme 7) which will be beneficial to the research and surveillance programmes undertaken by Public Health England (PHE)."
>
> Health Protection Agency (now PHE)

4.15.5 None of this should detract from the benefits of research at the European level. If multi-national trial approval can be made less bureaucratic, that is also a great win for the UK and researchers working in the NHS.

4.15.6 The positive impact of EU health research funding on the UK cannot be understated given the benefits to patients. However, the UK should play its part in promoting a more transparent process at the European level and in ensuring that more research is applied in practice.

4.15.7 There were varied responses from stakeholders with views ranging from the fact that the money could be spent much more effectively to this area being one of the EU's most positive impacts on the UK. Therefore, the UK may wish to look at ways to build on the massive potential of this research funding but also ensure its positive impact becomes greater and more cost-effective.

4.15.8 Overall, the view does not seem to be that competence should change but that improvements are needed to the way the EU operates in the field of research.

Chapter 5: Conclusion

5.1.1 In conclusion, based on the evidence submitted, the **current balance of competence between the EU and the UK was considered by stakeholders to be broadly appropriate** and that these competences are properly applied but that competence should not be extended further. The definition of health policy, management of health services and medical care and the allocation of resources are all Member State competences, and thus matters for the UK. However, EU activity in areas relating to the single market and public health is recognised to add value in the health sector.

"Nursing in the UK has benefited enormously from the UK's membership of the EU, from free movement of professionals and from agreed minimum employment and working conditions in Europe. It has also heralded much closer cooperation between counterpart organisations and greater understanding and sharing of best practice to deliver better health services and improve health. The RCN does not currently see the need for an expansion of EU competences, nor would it want to see repatriation of the EU's existing powers in relation to health or social affairs. However, the balance between differing EU competences, whose objectives at times may conflict with each other, do need to be addressed."

Royal College of Nursing

5.1.2 There were very few areas where it was suggested that competence should lie elsewhere, although a large number of **concerns were raised about specific pieces of legislation**, including the Working Time Directive, and a number of themes have emerged with regard to the role of the EU and its impact on health in the UK.

"This discussion should respect the national competence for the resourcing, planning and running of a Member State's own health system, and focus on supporting the development, spread and adoption of innovations, systems and ideas in health and social care delivery which can be applied across Europe."

NHS European Office

> "The BMA is committed to improving the health of the UK citizens and welcomes EU activities which complement UK government work in this field. Future policy developments in this sector should continue to respect the principle of subsidiarity and the right, enshrined in the EU Treaties, of Member States to organise and finance their healthcare systems according to national practices."
>
> British Medical Association

Themes looking forward

5.1.3 A number of themes have been outlined in this report, and it has been possible to identify five key areas where, in future, action could be taken to maximise the benefits of EU activity and minimise the potential risks:

- **The importance of working closely across Government and with stakeholders**. The ongoing discussions around MRPQ provide a good example of how Government departments can work together with stakeholders to ensure that healthcare concerns are taken into account in discussions at the European level. It is important that this is the case in future and that Government and stakeholders continue to work closely together, and we will explore how this can best be achieved going forward.
- **The importance of ensuring that the UK implements legislation appropriately**. This was a theme throughout the report, whether on tissues and cells, medicines, or on employment matters. The reasons for issues around implementation vary in each of these examples but it shows that the UK needs to implement legislation appropriately. It is important to engage stakeholders in the development of transposition proposals and reviewing our plans against those of other Member States whilst recognising that there are differences in legislative and administrative systems across the EU that are reflected in the way Member States implement Directives. This is also very relevant given current work on transposition of both the Falsified Medicines and Cross-Border Directive.
- **The need to work swiftly in order to ensure positive changes are made as soon as possible.** Recent experiences with notified bodies and medical devices identified flaws in an otherwise effective system, which needed to be rectified. This is why the UK Government has acted to ensure that progress is made quickly, and the MHRA are playing a key role in looking at what can be done now at both the national and European level. Learning from this issue can also help inform work on other issues that occur in the coming months and years.
- **The importance of supporting all steps being taken by the Commission to increase transparency**. Whilst progress has been made, more can be done including simplifying processes for those applying for research funding and giving clearer feedback when funding is not awarded. The UK Government acknowledges the recent steps taken by the Commission in both creating an Impact Assessment process and having a more accessible relationship with stakeholders, and welcomes any further steps to promote transparency.
- **The importance of sharing information,** which benefits patients in the UK and across the EU. However, networks and joint actions must not become a vehicle for any change in competence, and there is a need for some clearer prioritisation across health on where focus should be given, as resources are limited. The UK Government is keen to work together with the Commission and other Member States on this point.

Next steps

5.1.4 As outlined in this report, there are a number of links with further Balance of Competences Review reports, including:

- animal health, welfare and food safety (semester 1)
- free movement of persons (semester 2)
- research and development (semester 2)
- social and employment (semester 3)

5.1.5 Evidence has been shared with the relevant Government departments so there is no need to re-send any evidence in response to these reports, although stakeholders may wish to send further evidence on other points raised in these reports. More information on further reports can be found at the www.gov.uk website.

5.1.6 The Department of Health is extremely grateful to parliamentarians, Government bodies, stakeholders and individuals, who have taken the time to attend meetings, seminars and events and contribute written evidence to the Balance of Competences Review health report.

Annex A: Submissions Received for the Call for Evidence

Academy of Medical Royal Colleges
Action on Smoking and Health
Alcohol Health Alliance UK
Alliance for Natural Health International
Alliance of UK Health Regulators on Europe
Andrea Leadsom MP
Anthony Nolan
ASH Wales
Association of British Healthcare Industries
Association of British Pharmaceutical Industry
Association of Directors of Public Health
Association of Medical Research Charities
Brighton and Sussex University Hospital NHS Trust
British American Tobacco
British Dental Association
British Generic Manufacturers Association
British Medical Association
British Nutrition Foundation
British Society for Histocompatibility and Immunogenetics
Brussels and Europe Liberal Democrats
Cancer Research UK
Care Quality Commission
Charlotte Leslie MP
Consumers for Health Choice
Electronic Cigarette Industry Trade Association
Embassy of Japan
Europe Economics
European Commission
European Scrutiny Committee
European Society of Radiology
Faculty of Public Health
Federation of Surgical Specialist Associations

Food and Drink Federation
Food Drink Europe
Food Standards Agency
Fresh Produce Consortium
General Medical Council
General Optical Council
General Pharmaceutical Council
Genetic Alliance UK
GlaxoSmithKline
Guy's & St Thomas NHS Foundation Trust
Health & Social Care Information Centre
Health Education England
Health Food Manufacturers' Association
Health Protection Agency
Human Fertilisation & Embryology Authority
Human Tissue Authority
Imperial College
Imperial Tobacco Ltd
Institute of Alcohol Studies
Japan Tobacco International
Liberal Democrat Parliamentary Party Policy Committee
Marina Yannakoudakis MEP
Medical Research Council
National Grid
National Heart Forum
National Institute for Health and Care Excellence
NHS Blood and Transplant
NHS European Office
NHS Partners Network
North of England EU Health Partnership
North West London Hospitals NHS Trust
Nursing and Midwifery Council
Optical Confederation
Oxford University Hospitals NHS Trust
Planet of the Vapes
Portsmouth Hospitals NHS Trust
PricewaterhouseCoopers LLP
Proprietary Association of Great Britain
Provision Trade Federation
Rebecca Taylor MEP
Royal College of General Practitioners of Scotland
Royal College of Midwives
Royal College of Nursing UK
Royal College of Ophthalmologists

Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Physicians
Royal College of Physicians and Surgeons of Glasgow
Royal College of Physicians of Edinburgh
Royal College of Radiologists
Royal College of Surgeons
Royal College of Surgeons of Edinburgh
Royal College of Veterinary Surgeons
Royal Pharmaceutical Society
Royal Society for Public Health
Royal Surrey County Hospital Foundation Trust
Royal Wolverhampton Hospitals NHS Trust
Safety of Bloods, Tissues and Organs
Scotch Whisky Association
Scottish Government
Scottish Health Action on Alcohol Problems
Seafish
Seakens Solicitors
Senior European Experts Group
Southend University Hospital NHS Foundation Trust
Sugar Nutrition
The Freedom Association
The Medical Schools Council
The National Pharmacy Association and the Pharmacy Forum NI
The Wellcome Trust
The Wine and Spirit Trade Association
UK Council for Health Informatics Professions
Very Low Calorie (VLCD) Industry Group.
Welsh Government – Department for Health, Social Services and Children
West Hertfordshire Hospitals NHS Trust
York Health Economics Consortium Ltd

*We also received 11 responses from individuals

Annex B: List of events

List of events

5 February 2013	Stakeholder event • Attendees included representatives from the Royal Colleges and NHS Foundation Trusts.
12 February 2013	ALB event • A small scale roundtable discussion attended by arms length bodies.
13 February 2013	Peers seminar • Held in the House of Lords, the seminar was attended by interested Peers and chaired by Earl Howe.
12 March 2013	MPs roundtable • Members of the Health Select Committee attended a roundtable discussion chaired by Anna Soubry MP
24 April 2013	Seminar hosted by the Secretary of State • The Secretary of State for Health chaired a seminar for stakeholders to discuss significant issues raised in the call for evidence, including the Working Time Directive and health research.

Appendix 1: Glossary

ABHI	Association of British Healthcare Industries
ABPI	Association of British Pharmaceutical Industry
AoMRC	Academy of Medical Royal Colleges
ASH	Action on Smoking and Health
BGMA	British Generic Manufacturers Association
BMA	British Medical Association
CA	Competent Authority
CHC	Consumers for Health Choice
Court of Justice of the European Union (CJEU)	The CJEU has jurisdiction to rule on the interpretation and application of the Treaties. In particular, the Court has jurisdiction to rule on challenges to the validity of EU acts, in infraction proceedings brought by the Commission against Member States and on references from national courts concerning the interpretation of EU acts. The Court is made up of three sub-courts: the General Court, the Civil Service Tribunal (which hears cases about EU staff members) and the Court of Justice (which is sometimes called the ECJ). The term "ECJ" was previously used more broadly, including as a collective term for the EU's judicial arm. [Article 19 TEU and Articles 251 to 281 TFEU]
CQC	Care Quality Commission
CTAs	Clinical Trial Approvals
CTD	Clinical Trials Directive
DG	Directorates General
Directive	A legislative act of the EU which requires Member States to achieve a particular result without dictating the means of achieving that result. Directives must be transposed into national law using domestic legislation, in contrast to Regulations, which are enforceable as law in their own right. [Article 288 TFEU]
ECDC	European Centre for Disease Control

EEA	European Economic Area
EMA	European Medicines Agency
EMFs	Electromagnetic fields
ERNs	European Reference Networks
EU	European Union
European Commission	The Commission is the main executive body of the EU. It has general executive and management functions. In most cases it has the sole right to propose EU legislation. In many areas it negotiates international agreements on behalf of the EU and represents the EU in international organisations. And the Commission also oversees and enforces the application of Union law, in particular by initiating infraction proceedings where it considers that a Member State has not complied with its EU obligations. [Article 17 TFEU and Articles 244 to 250 TFEU]
EWRS	Early Warning Response Systems
FAO	Food and Agricultural Organisation of the United Nations
FCTC	WHO Framework Convention on Tobacco Control
FMC	General Medical Council
FP7	7th Framework Programme
FSA	Food Standards Agency
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
Harmonisation	The introduction of common standards and laws throughout the Member States of the EU.
HCAIs	Health Care Associated Infections
HEE	Health Education England
HFEA	Human Fertilisation & Embryology Authority
HFMA	Health Food Manufacturers' Association
HPA	Health Protection Agency (now part of Public Health England)
HSCT	Hematopoietic Stem Cell Transplantation
HTA	Human Tissue Authority
IHR	International Health Regulations
Single market	The single market of the European Union is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured. [See, in particular, Articles 26 to 66 and 114 to 118 TFEU]
Joint Actions	Joint Actions are voluntary networks of Member States working together on specific issues.
Legal Base	An Article in the Treaties which gives the EU competence to adopt a legal act.

MEP	Member of the European Parliament
MHRA	Medicines and Healthcare products Regulatory Agency
MRPQ	Mutual Recognition of Professional Qualifications (the Recognition of Professional Qualifications irective)
MUP	Minimum unit pricing
NGO	Non-governmental organisation
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NICE	National Institute for Health and Care Excellence
OIE	World Organisation for Animal Health
PAGB	Proprietary Association of Great Britain
PHE	Public Health England
PTF	Provision Trade Federation
RCN	Royal College of Nursing UK
RCP	Royal College of Physicians
RCP (Edin)	Royal College of Physicians of Edinburgh
RCS	Royal College of Surgeons
Regulation	A legislative act of the EU which is directly applicable in Member States without the need for national implementing legislation (as opposed to a Directive, which must be transposed into national law by Member States using domestic legislation)[Article 288 TFEU]
SABTO	Safety of Bloods, Tissues and Organs
SWA	Scotch Whisky Association
TFEU	Treaty on the Functioning of the European Union
Troika	The European Commission, the European Central Bank and the International Monetary Fund
WHO	World Health Organization
WTD	Working Time Directive