Cabinet Minister Subject Area: **Health, Well-being and Sport**

Portfolio Co-ordinator Contact: **(Information redacted section 40)**

Subject Area Contact: **(Information redacted section 40) DHP Support Unit**

Policy or operational area/dossier: Healthcare Policy: Primary Care, Public Health, Research and Development, Major Health Conditions, Quality and Safety	
1. Headline outcomes sought	**Health protection** Continued access to the outputs of EU health protection agencies whose outputs enable sharing of information about communicable diseases across member states and coordinates an early warning and response system. **Research and development** Continued access to EU research funding and other related EU initiatives that have contributed to the development of Wales' research infrastructure and many research programmes and projects – e.g. European Structural & Investment funds, Horizon2020, Erasmus. Ability to retain and build collaborative research relationships with other EU countries. Recruitment and retention of high quality researchers from other EU countries who work in the UK. Recruitment and retention of high quality researchers from the UK who may become more attracted to working elsewhere to maximise collaboration and funding opportunities. The continuation of a single process for authorising medicines across EU to ensure rapid access to innovative medicines in the UK **Safety of medicines and medical devices** Continued EU wide pharmaco-vigilence arrangements to ensure the safety of medicines used in the UK and similarly for medical devices which are currently approved by a network of EU notified bodies (overseen by MHRA in the UK). **Free movement of health professionals** Continued free movement of Health Professionals. As the UK has been a net importer of health and social care professionals, Primary care services are highly dependent upon the wider health and social care workforce, including support for care homes which may need particular attention. It will be necessary to establish mechanisms to share information about doctors to maintain the integrity of the register and under current EU rules there is also no restriction on the free movement of pharmacists or pharmacy technicians to the UK from other parts of the EU. Therefore any implications of withdrawal from the Directive on Recognition of Professional Qualifications will need to be

	understood. **Cross-border patient safety** The need to retain cross border co-operation in quality and patient safety matters **Environmental Health** Commitment to comparable and connected environmental standards between EU and to address environmental risks. **Food safety and nutrition** Ongoing access by the Food Standards Agency to EU Institutions and particularly the European Food Safety Authority to allow for sharing of evidence on risks and to secure a robust regulatory framework across boundaries.
2. Red line issues and top priorities	**Access to the European Centre for Disease Control (ECDC)** Engagement with and access to the outputs of the European Centre for Disease Control. Alternative would be to depend on the World Health Organisation's apparatus for these functions, but it resources and focus would be diluted. **Access to EU funding for research and development** Access to EU research funding. At present the UK overachieves in comparison to most other EU countries in terms of the amount of EU research income generated. Without this, or an alternative source of funding of a similar magnitude, research will contract. **Regulation of medicines and medical devices** Clarity of the future regulation of medicines and medical devices in the UK. Immediate risk is that uncertainty drives away industry customers, undermines sustainability and the wider public health role associated with this aspect of regulation.
3. Current international and EU legislative base (summary)	**International health regulations** International Health Regulations and Legislation and policy development on other determinants of health such as environmental protection, food and employment law are also made at EU level. Safe to assume access highlighted above would be dependant on adoption of equivalent legislation on communicable diseases. **Research and development regulations** EU regulations on research. **Medical devices regulations** The EU's Medical Device Regulations underpin the UK's approach to medical device regulation. They provide for the harmonisation of controls within a single regulatory system eliminating the need for different national rules and the compliance costs involved, while purchasers and users of medical devices can be assured that devices manufactured

	within the EU meet common standards of performance and safety. The EU wide regulatory framework also links to other markets in the USA and Asia to mirror the international networks of manufacturers of medical equipment, devices and medicines. The EU is in the process of revising the medical device regulations which are expected to be adopted in the Autumn. The revised regulations will further develop the international approach to regulation allowing for cross-border assessments and approval of devices by a network of EU notified bodies, according to agreed criteria and standards, the sharing of information on device safety and performance, including the market surveillance of high risk devices. The revised regulations are regarded as largely acceptable by the UK, in spite of it having previously expressed concern about some aspects. Prior to the Referendum the UK had plans to implement the regulations with its EU partners and did not have proposals to implement any alternative or additional requirements for medical devices. It is difficult to pre-judge whether this will change in the light of the regulatory framework which will apply once the UK has left the EU. It is possible that the UK could continue to operate under the EU legislation. The system of EU regulation is sufficiently flexible to allow for UK involvement as the system includes all EU, EEA members, but also a small number of third countries, including Turkey. In addition, the UK through the MHRA has significant experience in medical devices and regulation including exposure to high risk medical devices, the majority of which are approved by the UK. Should the UK seek to go it alone it could amend the EU regulations to reflect its specific requirements. However, this could adversely affect their effectiveness and the UK could be separated from the shared learning, hindering surveillance and monitoring. The UK could also incur additional costs as the original intention was that the expert groups would be funded by the EU and manufacturers. The incidence of uncertainty over the future of medical device regulation in the UK could result in some manufacturing companies seeking authorisation from non-UK notified bodies.
4. Key issues for domestic legislation post-Brexit.	See above.
5. Key devolution considerations	**International Health Regulations (IHR)** Public Health England is the designated 'National Focal Point' for the UK for the implementation of the International Health Regulations (IHR) (2005). The National Focal Point must be accessible at all times for communication with WHO, both to consolidate and send information to WHO concerning the implementation of the IHR in the UK and to

	receive and disseminate information from WHO to those involved in surveillance and response in the UK. These arrangements are likely to remain unaffected.
6. Sector/area vulnerability and/or potential	**Global Health Agencies** Lack of ongoing engagement with ECDC and other agencies may increase risk of unpreparedness to meet global health risks **Universities/Higher Education Institutions (HEIs)** There are major risks in terms of institutional impacts, especially on universities in Wales. **General Practitioners (GPs)** Brexit casts doubt on efforts to give GPs same status as specialists – this could adversely impact GP recruitment if an EU Directive is not introduced in next two years. Professional medical organisations fear working conditions of British physicians in terms of working hours could be impacted. A recent change in EU regulations requires *all* contracts issued by the NHS to be <5 years only. Existing GDS regulations which provide for a permanent, if frequently reviewable, contract, could take precedent. **Product Safety** British Standards committees may need to be re-established to replace the EU CE mark, which is on all the equipment used in practices from spectacles to diagnostic equipment. It shows that the manufacturer has checked that products meet EU safety, health or environmental requirements.
7. Other critical considerations	**Demand on primary care services/population health levels** Socio economic inequalities will also have an impact on health outcomes and any financial implications of BREXIT are likely to increase demand on primary care services and affect population health generally.
8. Key public messages	**Research and development** Our aspiration is for Wales to be internationally recognised for its excellent health and social care research that has a positive impact on the health, wellbeing and prosperity of the people in Wales. We have strong record of working collaboratively with European Union partners to undertake high quality research in health and social care research. **Public health (including health protection; environmental health; legislation; food and nutrition)** Cross-border cooperation is critical to addressing health threats. We remain committed to effective collaboration on policy, legislation, and information sharing to ensure a robust and proportionate response to minimising these risks.

Lead Director: **Dr Chris Jones**

Author: **Deputy Directors, Directorate for Health Policy**

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