

Meeting: NSS Board of 29/06/2018

Paper Number: B/18/83

Title of Paper: Considerations of the impact on NSS of the European Union (Withdrawal) Bill 2017-2019

Paper Type:

This paper was requested as an update for the Board to assure them that the potential impacts of EU withdrawal on NSS are being actively considered and managed to identify where mitigation is required.

Decisions Required:

The Board is asked to note the level of detailed thought that is being actively considered by management and staff. Additional thoughts and contributions from members are welcomed and the Board should note that a further update is planned for Autumn 2018 once the formal Government position on transition is known.

Analysis:

- The Government's passing of the EU Withdrawal Bill on 20th June 2018 has confirmed that the UK will leave the EU on the 29th March 2019.
- There remains no clarity on what a transition period will 'look like' or if there will be one; a no deal exit remains on the table.
- The impact on NSS remains unclear though it is currently understood that some of the programmes for which we have secured EU funding will continue through to December 2021 with the EI International Engagement team funded to 2022.
- Regulators continue to hold their opinion on the future position of members until there is more clarity of the negotiated settlement, i.e. watchful waiting continues.
- The lack of clarity on transition makes contingency planning for a post EU environment challenging. That said, NSS continues to work across all Strategic Business Units (SBUs) and alongside Scottish Government (SG) and wider stakeholders to ensure all possible impacts are identified and considered.

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Impact of the European Union (Withdrawal) Bill 2017-2019 on NSS

Situation

A formal review of the impact of EU withdrawal was considered over the winter of 2017-18. Attached is a SBAR submitted to the EMT in January 2018. The position was fully discussed and the undersigned has continued to monitor UK and Scottish Government websites, news media and wider feedback, e.g. service units' engagement with their affiliated European agencies. The detail in the SBAR remains extant but the following additional points are highlighted for the Board

Background

The European Union (Withdrawal) Bill 2017-2019. A Bill to repeal the European Communities Act 1972 and make other provision in connection with the withdrawal of the UK from the EU has been continuing its passage through Parliament. Consideration of a Commons amendment to the Bill took place in the House of Lords on 20 June. Both Houses have agreed on the text of the Bill which now waits the final stage; Royal Assent, making it a formal Act of Parliament. Said Royal Assent has yet to be scheduled. **This Bill has formalised the stated date of 29th March 2019 as the legal date the UK leaves the EU**

Assessment

The following points are given to augment / update the original SBAR submitted to the EMT in January 2018:

- **Strategic Discussions.** SG hosted a strategic leadership forum to explore the impact of EU withdrawal on the wider public sector in Scotland. The question set explored continues to be monitored:
 - Do we know what we need to do to prepare for EU exit?
 - Do we know the impact of different scenarios on our preparations?
 - Are we feeding these impacts into negotiations?
 - Will we be operationally ready for EU exit on 29th March 2018?
 - Do we know what resources we need now and in the future to get there?

Many of the points raised in the attached SBAR proved to be common themes, e.g.:

- Uncertainty of the relationship through and beyond transformation.
 - Recognition that most current legislation has EU standards and policy built in but the fear is divergence over time despite the need to remain aligned to our key market / partners.
 - Recognition that the planning and potential mitigation could be a significant drain on energy and resources.
 - Focus on idea of national consensus, incorporating local authorities input.
 - Impact on availability of skilled workforce.
- **Fiscal Position.** The UK is legally obliged to fulfil its financial commitments to the current Multi Financial Framework period (MFF). It is believed that this also means the UK is entitled to benefit from the terms of Membership of the EU until 31st December 2020, subject to continued compliance with the rules of membership. During the period 30th March 2019 to 31st December 2020, the UK will be a 3rd Party Country.

The Phase 1 Agreement, signed on 8th December 2017, proposes that, the UK Government would honour its commitments to the PEACE and INTERREG funding programmes under the current MFF. This included agreement to continued cross-border funding, post 2020, referred to as PEACE+. No detail is provided for a replacement fund post 2020.

On 7th June 2018, the UK produced a Technical Note: temporary customs arrangement – for the Council Working Party (A50) meeting on 8th June 2018. The technical note appears to backtrack from the backstop position for the Ireland/Northern Ireland border. This has a potential impact on the mPower project detailed below.

- **People.** SG has asked Public Health and Intelligence Strategic Business Unit (PHI SBU) to support analysis on the nationality of the NHSScotland workforce. The aim is to understand the scale of challenge should EU workers become less available. Each organisation has also been asked to review its workforce subjectively to assess the potential impacts of a revised immigration model.
- **SNBTS.** The position of Blood, Tissues and Cells is explained on pages 3 and 4 of the attached SBAR. It should be noted that the constitution of the European Blood Agency (EBA) states that no nation can be a member unless they are within the EU or the European Single Market. An EBA conference is being held in Belfast on 22nd June 2018 and Mary Morgan, Director SNBTS will be seeking further clarification on the position of SNBTS. As it stands, without an agreement being written into Transition, SNBTS will not be able to host the planned EBA conference in Spring 2019 and Mary Morgan will no longer be able to sit as an executive member of the EBA; reducing our influence over standards and policy. The undersigned will seek feedback from Mary before the Board to ensure the latest position is available.
- **Governance.** Health Protection Scotland (HPS) share many potential impacts with other UK organisations, e.g. the Food Standards Agency (FSA). The FSA has outlined the need to remain aligned to EU standards as the nutritional value of food, associated animal welfare and health protection standards are all currently aligned to EU legislation.
- **Research and Development.** The NHSScotland EU International Engagement Team transferred from NHS24 into NSS (CEaD Directorate) in late 2017. The Team's focus is to identify possible funding solutions / opportunities so that NHSScotland can contribute to and benefit from the associated research and developments. This secures expertise in Scotland for the benefit of the Nation and its citizens. The Team transferred with associated SG funding, c£385k pa. This funding appears to be secure through to 2022.

To date funding has been secured for programmes across Telehealth, Telecare and Digital innovation and development projects across NHSScotland. Many of these initiatives are cross border alliances; encouraging the sharing of best practice. The majority of funding is sought and administered through the European Consumers, Health, Agriculture and Food Agency (CHAFAEA). Some funding also comes from the PEACE+ and INTERREG funding mentioned above.

CHAFAEA is entrusted to by the European Commission to implement the Health Programme objectives:

- Promoting health, preventing diseases and foster supportive environments for **healthy lifestyles** taking into account the 'health in all policies' principle.
- Protecting Union citizens from serious **cross-border health threats**.

- Contributing to innovative, efficient and sustainable **health systems**.
- Facilitating access to **better and safer healthcare** for Union citizens.

The current Plan covers 2014-2020 with provision for horizon funding out to 2022. It remains unclear if the EU-UK Transition Agreement will incorporate funding commitments beyond 2022.

- **mPower**. This project was transferred to NSS in June 2018 from NHS24; indeed while the team has transferred funding and governance alignment is ongoing. mPower is a 5-year (2017-2021), cross border project seeking to create services for older people (age 65+) living with long-term conditions. These services will be created across Scotland, Northern Ireland and the Republic of Ireland. The project output is to deliver 2,500 wellbeing plans and 4,500 eHealth interventions and it has agreed funding of >€8m via the EU INTERREG V Cross Border Programme 2014–20.

EU withdrawal might have far-reaching implications for the mPower project as its planned deliverables go beyond known EU funding commitment timeframes. There is also a potential strategic issue of cross border commissioning of services in a post EU regulatory environment. Finally, as highlighted elsewhere, the availability of staff and freedom to move across borders to provide services might also be impacted. A full risk assessment is being worked up by the Programme management Support Team receiving the project. This will be shared with the Executive, Board and its Committees in due course.

Recommendation

The Board is asked to:

- Acknowledge the level of detailed thought that is being actively considered by management and staff in relation to the impact of EU withdrawal on NSS services.
- Contribute additional thoughts and challenge on considerations to date (and)
- Note that a further update is planned for Autumn 2018 once the formal position on Transition is known.

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21 June 2018

Attached:

EMT SBAR January 2018 – Implications of Brexit on National Services Scotland (NSS)

Implications of Brexit on National Services Scotland (NSS)

Board – June 2018

Situation

Leaving the European Union (EU) undoubtedly represents the greatest change for the UK's economy in a generation; be that in how we trade, gain sources of investment or secure a future workforce. Conversely, there might be opportunity as the UK will no longer be formally tied to EU rules. The expected implementation period of c21 months will mean that NSS will initially be operating in an environment that is very similar to pre-Brexit position. Any real change should be expected beyond December 2021 as the UK's economic, social, environmental and financial policy diverges thereafter.

This SBAR seeks to pull together existing work from across NSS SBUs and thinking from wider organisations to consolidate the current position of NSS in regard to potential implications of Brexit on its services.

The NSS Executive Management Team (EMT) have considered potential Brexit impacts and raised a strategic risk on the subject (Appendix 1). Activity has also included (informal) liaison with UK regulators and relevant European associations to understand emerging thinking and issues. Feedback to date suggests organisations await the progression of the Brexit negotiations before forming any firm opinions. In sum, we are in a period of watchful waiting.

Background

In July 2016, NSS Procurement, Commissioning and Facilities (PCF) carried out an initial, high level, analysis of the possible impact of the referendum outcome on procurement and contract activity. This was shared with Chief Executives and covered points including the potential impact of exchange rate fluctuations. Subsequent assessment also points to the fact that European procurement legislation has been fully transposed into a Scottish Statutory instrument, thereby mitigating the impact of any legislative changes.

The NSS Central Legal Office (CLO) has also provided some information for clients on the possible employment law implications of Brexit through its Employment Newsletter. Some high-level training has also been conducted during quarterly training sessions.

Finally, SNBTS have conducted significant analysis which informed a formal response to SG Health Committee questions on the topic. Some of this analysis is utilised below. All SBUs continue to monitor the situation regarding Brexit negotiations and associated impacts to markets and regulation.

Assessment

Fiscal Position

There remains considerable uncertainty about the costs and benefits of Brexit. RBS publications indicate a *"consensus view on economic growth for 2018 of 1.5% with 2019 looking similar ...also inflation running at 3.1% would appear to be direct reflection of the Brexit vote on sterling ... the expectation is for a gradual moderation over 2018 but growth is still forecast to be above 2% come Q4. If wage growth doesn't improve the squeeze will endure"* with an implication for economic growth. This could further challenge public sector funding particularly in Scotland with devolved powers placing an increasing reliance of self funding for Health.

There remain uncertainties around the issue of replacing current EU funding for research, development and innovation. Elements of NSS benefits from this and longer-term planning to mitigate potential shortfalls is required. Furthermore, there might be an opportunity (risk) for NSS to deliver shared services beyond health and into Local Authorities / Social Care. The latter currently receive significant funding from EU sources that are not built into central government grants. This money currently allows local authorities to undertake infrastructure development whilst protecting core grants and internally generated tax revenue for local services. Without obvious replacement for these EU funds councils will be required to seek mitigation which might result in a request for shared services provision from NSS.

People

Neither NHS Scotland, nor NSS, formally records the nationality of staff. There is also no measure of EU nationals' movement into or out of Scottish health and social care organisations.

The Scottish Government (SG) issued a letter in December 2017 summarising the outcomes of the *Joint Report from the Negotiators of the European Union and the United Kingdom Government*. While these 'common understandings' remain subject to the successful conclusion of the withdrawal negotiations they do offer some assurance on EU citizens' rights. In particular, the *Joint Report* specifies that, "*where EU citizens, in accordance with EU law, are lawfully resident in the UK at the date of the UK's withdrawal from the EU, those citizens as well as their family members (as defined by Article 2 of Directive 2004/38/EC), will fall within the scope of the Withdrawal Agreement ... where they have already exercised their free movement rights.*"

The UK Government has already signalled its intention to introduce a settled status scheme for EU citizens' living in the UK post-Brexit. Those who already hold a permanent residence document issued under Union law, including a valid UK immigration document (such as Indefinite Leave to Remain status) will be entitled to have this converted to a document conferring settled status.

While the position for those EU nationals already working in the UK becomes clearer there remains a lack of clarity regarding the ability to recruit workforce shortfalls from the EU post Brexit. Highly specialised talent remains internationally mobile and any barriers to immigration will impede the recruitment of the best scientists, clinicians and technical experts, undermining our competitiveness. The Nursing and Midwifery Council (NMC) have highlighted this risk identifying that the vast majority of new registrations to the nursing register over the last 8 years have been from EU nationals as opposed to those from outside the EU.

Procurement

PCF's paper: *Post-Referendum Impact on Procurement and Contract Activity* (July 2016) gave a short-term (<6 month), commercial view on the impacts of the referendum in relation to 3rd party supplies and services provided to NHS Scotland. Their view that underpinning framework legislation relating to thresholds, advertising requirements and award procedures was unlikely to change is reflected in the Scottish Government's (SG) implementation of the Procurement Reform (Scotland) Act 2014. This sets thresholds below the EU levels and is expected to continue to apply in Scotland post Brexit.

The immediate commercial risk of the Brexit result came from the reduced value of Sterling. As NHS Scotland procures primarily in this currency, costs associated with imported goods and services could increase. Some of this risk is mitigated through the use of two-year, fixed term contracts. As contracts are renewed the associated level of exchange rate risk could be £5.95m against a contract portfolio of c£1.38bn. In the first year post referendum, actual national contract price increases were approximately £420k on a spend value of £16.4m; comparing well with assumptions.

Elsewhere, risk around utilities is more closely related to geo-political issues. These can be mitigated through procurement of services out to 2021 at current prices. The volume of NHS Scotland pharmaceutical spend could be suffer significant impact due to the challenging oil prices linked to

production costs. That said, in the period since the referendum there is little sign of significant movement. This suggests pharmacy products had sufficient margin not to be impacted by exchange rate movement up to this point.

Data, Analytics and Cyber Security

There will be limited impact to the General Data Protection Regulation (GDPR) as this will come into force across the EU on 25th May 2018. In September 2018, the UK Government introduced a Data Protection Bill to Parliament to expedite its implementation, as well as other new EU-initiated rules on intelligence and law enforcement. It is anticipated that the Bill will complete its legislative journey by the end of March 2018. NSS has preparations for this legislation underway with governance through the Information Governance Group and Committee.

NSS will be impacted by the implementation within the UK of the EU Security of Network and Information Systems Directive (NIS Directive) from May 2018. This requires certain types of cyber incidents to be reported to a new Competent Authority or Authorities. Within the devolved Scottish public sector this will only impact on Health, Water and parts of Transport. This policy itself concerns incident management for co-ordination purposes and not incident reporting to meet regulatory obligations

Given the UK government's intent to adopt (and expedite) new EU regulations it is believed that the same situation will apply to other, existing EU directives throughout transition and beyond.

Blood, Tissues and Cells

SNBTS acknowledge that the European Blood Agency (EBA) are not moving forward with any decision regarding UK membership, post Brexit at this stage. Also, the Medicines and Healthcare products Regulatory Agency (MHRA) and UK Accreditation Body (UKAS) will not speculate regarding impact. With this in mind a brief summary of SNBTS thoughts on potential impacts follow:

- Potential loss of membership to EBA will limit access to shared experience, standards, benchmarking, common procurement and potential loss of early visibility on emerging infectious diseases through the European Centre for Communicable Diseases (ECDC).
- Blood, Tissues and Cells are regulated at EU and UK level. There may be an opportunity to amend the latter, but SNBTS would want to keep UK blood and tissue standards as close to those of Europe and other developed economies as possible. Without this commitment there is a risk that divergence will reduce the quality and safety of our blood and tissue products. Similarly with medicines including Advanced Therapy Medicinal Products (ATMPs), it is likely that pharmaceutical regulation will remain aligned with that in the rest of Europe if for no other reason than UK needs to be able to accept pharmaceuticals manufactured in the rest of Europe and UK life sciences companies need to be able to sell products in Europe. Regulatory approval timelines might however, be shortened to give UK a competitive advantage in adoption of new medicinal products.
- Blood, Tissues and Cells Directives are already transposed into UK law. Even with a transformation period, there is little time to have EU Directives, including Pharmaceutical Regulations (Eudralex) and ATMP Regulations transposed. ATMPs are subject to European level review and Marketing Authorisation through the European Medicines Agency. This work will all need to go into the MHRA and Commission on Human Medicines (CHM); necessitating additional resources to replicate expert European assessments and advisory committees such as the Committee on Advanced Therapies. This can add time and possible procedural change to the accessibility of ATMPs.
- The UK will lose its direct influence on EU regulatory policy and standards relating to life sciences post Brexit. It can continue to influence international standards through the

Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

- Medical research and development will be significantly impacted if lost EU funding, e.g. Horizon 2020, is not mitigated through new UK frameworks. Long-term investment in medical R&D might also suffer if international companies shift their focus to EU based facilities, including manufacturing. This would allow them access to the EU market, some ten times greater than the UK, without risk of tariffs and other barriers to trade. For similar reasons international pharmaceutical companies may choose to clinically trial and obtain marketing authorisation in Europe first rather than UK leading to delayed access to new medicines.

Finance

It is assumed that NSS will continue to comply with the European System of Accounts 2010; the set of rules issued by Eurostat that determine how the public sector reports its overall levels of debt in relation to the national accounts which are prepared by the Office of National Statistics (the ONS). These rules have impacted on the public sector's ability to structure finance solutions and delivery models, including the SG's Non Profit Distributing Revenue Finance model. Brexit might offer the opportunity to no longer follow Eurostat prescribed rules. NSS would need to adapt to change should the ONS prescribe an alternative accounting model.

Governance

A substantial proportion of the UK's statutory and regulatory framework originates from EU legislation. In particular the Charter of Fundamental Rights, Human Rights Act and various equality and diversity legislation has been developed jointly to protect our people / citizens. This includes: data protection, human trafficking, rights of victims of crimes, disability rights, workplace discrimination and equal pay.

Employment law provides important protections for staff, particularly around health and safety at work, working time and on information and consultation on collective redundancies and safeguarding employment rights in the event of transfers of undertakings (TUPE).

EU standards for training and the recognition of qualifications, in particular through the Professional Qualifications Directive 2013/55/EU are also key provisions. This enables mobility and helps raise educational standards and put safeguards in place across Europe; facilitating the UK to recruit from Europe to mitigate shortfalls. The Directive also includes language checks on EU nurses and a duty to inform other health regulators about suspended or banned professionals; important and positive developments for the UK.

While the above legislation has been fully transposed into UK law and the expected transformation or implementation period of 21 months post Brexit should mitigate any immediate impact, there remains concern of divergence from the EU position over time. This concern currently centres on the development of the proposed Great Repeal Bill. Some fear this might seek to undermine the standards of existing legislation.

The risk of longer-term drift from EU standards could lead to a loss of safeguards, loss of access to alert mechanisms and other exchange between regulators and potentially much slower recognition mechanisms for both inward and outward mobility.

The House of Commons Select Committee for Brexit have also raised concern at the wider regulatory dimension in which alignment with the EU and its single market will be crucial for patient safety and access to cutting-edge treatments; this includes the regulation of pharmaceuticals, medical devices, research data and clinical trials.

SG and more recently the UK government are already indicating that sustainability will remain a significant policy agenda in the years to come, regardless of Brexit.

Recommendations

The EMT is asked to:

- Comment on the possible implications of Brexit, to NSS services.
- Confirm or suggest amendments to the corporate risk on the implications of Brexit on NSS (Attached).

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12 January 2018

Appendix 1 BREXIT – RISK 4561

There is a risk that the UK's exit from the European Union impacts on the way that NSS operates due to resultant change in membership/access to EU organisations and institutions in which NSS SBUs participate.

Reputation (Primary Risk Category). NSS reputation may be adversely affected if we are unable to sustain business effectively. In addition, our International influence may be diluted.

Business. Information sharing may be reduced. Access to, for example, collaborative procurements or research grants may be restricted. The impact on the regulatory / Accreditation environment (MHRA/UKAS) may remain unclear.

Clinical. Access to intelligence, particularly emerging infections through European Blood Alliance (EBA) / European Centres for Disease Control (ECDC) may reduce.

Staff. There may be impact on senior experts, who are reliant on International collaborations to maintain expertise. The risk to continued or further employment of staff from EU countries is unclear but may result in increased or prolonged vacancies and loss of expertise.

Overall Impact: 5 Likelihood: 2 Combined Risk Score: 10 (Amber)

Mitigation Strategy: Acceptance