

Board of Directors (in Public)

Item 3.2

Subject: Implications of Exiting the European Union – Briefing Document
Date of Meeting: 4th September 2018
Prepared by: Robin Wiggs, Assistant Director – Business Development
Presented by: Robin Wiggs, Assistant Director – Business Development
Reason for Report: To Note

BAF Ref	Impact on BAF
3.7	The report provides assurance that contingency planning processes are underway to mitigate the risks associated with the implications of exiting the European Union

1. Executive Summary

This paper updates the Board of Directors on the possible implications of the UK's exit from the European Union on 29th March 2019, in terms of:

- Workforce
- Supply of Medicines and Medical Devices
- Supply of other goods and services
- Research and clinical trials
- Other general economic impacts.

The paper outlines the process, timeline and legislative framework for an agreed exit.

The paper also outlines the contingency planning work that will be undertaken building on recently published national guidance.

2. Background

This paper provides an update to the Board of Directors on the range and complexities of issues that the UK's withdrawal from the European Union ("Brexit") presents to the Trust.

It sets out for reference, the Brexit process, timeline, legislative framework and links to key documents.

It also describes some of the key actions to be taken to prepare contingencies in the event of a no-deal scenario.

3. Brexit process and timeline

Following the referendum result in June 2016, and the formal submission of the Article 50 notice in March 2017 of the UK's intention to withdraw, negotiations between the UK and EU have been taking place within a specified 2-year timeframe. This period expires on 29th March 2019.

The negotiations have been in two main phases:

- securing a Withdrawal Agreement that settles issues such as the UK's financial liabilities, reciprocal residents' rights, shared land-border issues (Northern Ireland) and an implementation period until 31st December 2020.
- agreeing the nature of the future relationship between the UK and the EU, including trade, customs, market access and any continued participation in shared activities (regulatory bodies, etc).

It is understood that “nothing is agreed until everything is agreed”, and thus all of the elements of the withdrawal agreement, including the important implementation period between March 29 2019 and December 2020, are dependent upon a successful conclusion to the future relationship discussions.

The UK Parliament is enacting a legal framework to deliver a smooth Brexit:

- EU (Notification of Withdrawal) Act 2017.
- EU Withdrawal Act 2018 – repeals the European Communities Act 1972, transfers existing EU laws and regulations into domestic UK law on Brexit day and provides powers for secondary legislation to maintain coherent UK laws on and after Brexit.
- A Trade Bill and a Customs Bill – currently going through parliament.
- An EU (Withdrawal Agreement) Bill – which will enshrine in domestic UK law the provisions of the Withdrawal Agreement including EU citizens' rights and the implementation period.
- An immigration White Paper, followed by a Bill is expected in autumn 2018.

Further information on the UK legislative framework can be found

here: <https://www.deliveringforscotland.gov.uk/scotland-and-brexit/scotland-and-brexit-legislation/>

In order for an agreement to be ratified in time by the UK, EU and constituent parliaments, the two phases of negotiations (withdrawal agreement and an agreement on the future relationship) are scheduled to be complete in time for the EU Council meeting on 18th October 2018.

It is probable that the full agreement on the future relationship will not be complete by October 2018, but would contain binding timescales to reach treaty agreement during the implementation period.

Regularly updated content on the UK government's negotiations, preparations and statements can be found here:

<https://www.gov.uk/government/collections/article-50-and-negotiations-with-the-eu>

4. UK Negotiating Position

The UK government's negotiating position on the future relationship with the EU was set out in a statement in July 2018 referred to as the "Chequers Agreement" and published as a White Paper:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/725288/The_future_relationship_between_the_United_Kingdom_and_the_European_Union.pdf

In summary, it sets out proposals for an economic partnership at the end of the implementation period, that would see the UK leave the single market and customs union, in return for a UK-EU free trade area for goods, with a common rulebook, reciprocal market access and a facilitated customs arrangement. It also plans to end free movement of people, proposing replacing it with reciprocal mobility frameworks for visa free travel & tourism and reciprocal agreements to support movement of talent required for business, research, healthcare etc. It also proposes continued mutual recognition of professional qualifications (such as healthcare staff) and continued membership of agencies such as Euratom. Further it proposes continued participation in key regulatory organisation covering medicines, chemicals, and aviation.

The EU has broadly welcomed this position, whilst identifying a number of aspects (eg parts of the proposed customs arrangements and Northern Ireland) as not possible from their perspective.

This briefing assumes that the basis of any agreement between the two parties is largely along the lines of the Chequers White Paper. This is far from certain, but the range and complexity of alternative scenarios is too extensive to undertake a meaningful Trust assessment.

Much of the withdrawal agreement has already been agreed between the two parties and published in March 2018. Therefore, assuming agreement is reached on the remaining issues, there is already a fair degree of clarity on what arrangements will be after the implementation period ends. The draft withdrawal agreement is here:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/691366/20180319_DRAFT_WITHDRAWAL_AGREEMENT.pdf

5. Probable Outcomes

If the above negotiation timeline is not met, then the ratification timescale could be shortened to allow further negotiations (with the EU Summit meeting in December 2018 viewed as the absolute backstop), or the Article 50 period could be extended past 29th March 2019, although this is generally considered unlikely.

Notwithstanding the complex and politically contentious nature of the negotiations and ratification process, there are two broad probable outcomes between now and 29th March 2019 that the Trust should plan for:

- A deal, including an implementation period to 31st December 2020.
- No deal and a withdrawal on 29th March 2019 almost certainly without any implementation period.

The UK government has so far published 25 documents in a series of technical guidance notices to support preparations for a no deal outcome for each sector of the economy, including healthcare. Publication of these commenced in late August and is expected to continue until the end of September. These can be found here:

<https://www.gov.uk/government/collections/how-to-prepare-if-the-uk-leaves-the-eu-with-no-deal>

The Secretary of State for Health & Social Care wrote to Trusts on 23rd August setting out plans to secure the supply of medicines and devices in the event of no deal:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/735742/Govt_preparations_for_potential_no_deal_-_letter_to_health_and_care_sector.pdf

6. Areas of Possible Impact on LHCH arising from Withdrawal from the EU

There are 5 main areas of impact upon LHCH of the deal and no deal outcomes:

- Workforce
- Supply of Medicines
- Supply of Other Goods & Services
- Research
- Other general economic impacts

7. Impact of an agreed withdrawal

The short-term impact upon the Trust of withdrawal in March 2019 following agreement between the two parties with an implementation period until December 2020, is likely to be minimal during the implementation period:

- The EU Withdrawal Act 2018 plus the current draft of the withdrawal agreement ensures existing EU law becomes UK law and that EU law will continue to apply in the UK during the implementation period – ie there will be no divergence on key standards or regulatory alignment and we continue to be members of all existing bodies with the exception of the EU's political structures. The implementation period therefore provides time for the details of the future relationship to be agreed and for the different sectors of the UK economy, including healthcare and life sciences to prepare for the new arrangements that will apply after December 2020.
- The government has announced plans to enable EU citizens and their families resident in the UK before 31st December 2020 to apply for “permanent settled status”. The online scheme will open prior 29th March 2019, and LHCH is one of 12 NHS Trusts in the North West piloting the scheme this autumn. The Trust continues to keep in close contact with our EU staff to support them throughout this process.
- Notwithstanding the recent moves to provide more certainty to EU citizens living and working in the UK, there could be a downward impact on the numbers of EU citizens wishing to come to the UK to work – certainly until the medium-term outlook became clearer. The impact of workforce issues is set out further below.

- Maintenance of regulatory and standards alignment should mean no change to the Trust's supply of medicines and goods during the implementation period. The UK will continue to recognise CE-marked material including medical devices and will continue to recognise medicines and clinical trials subjected to current EU approvals processes.
- The mutual recognition of professional qualifications during the period should also mean little or no impact to training schemes or the ability to recruit EU-trained staff.
- Membership of research bodies and other agencies will continue during the implementation period, and existing projects and schemes should be protected. The UK government is seeking clarification that funds awarded for multi-year projects will continue and has undertaken to underwrite these in a number of sectors. A specific assessment of LHCH projects will need to be undertaken. The same applies to the Ritmcore procurement project for complex devices - which has a value to LHCH of around €1.1m, and for which a contract is due to be completed prior to Brexit.

The degree to which the UK diverges from existing regulatory and standards alignment after December 2020 and the impact this might have on the Trust is impossible to assess at this stage. The no-deal guidance issued by the government sets out a number of new regulatory responsibilities for organisations such as the MHRA to assume once the UK is not a member of EU agencies. It is assumed that considerable further discussion and guidance will be taken place during the 21-month implementation period to enable the Trust to prepare fully for any changes.

8. Impact of a no deal withdrawal

The impact of a no-deal withdrawal in March 2019 is potentially much more significant in the short term, due to the direct practical implications for the NHS, as well as the wider uncertainty that would undoubtedly prevail and could cause secondary effects for the NHS.

Much of the impact would be dependent upon what action the UK government took to smooth the change:

- The EU Withdrawal Act 2018 will still transfer as much EU legislation into UK law as practicable, which can be amended at a later date.
- The UK government announced on 21st August 2018 that in the event of no deal being reached, the UK would move swiftly to secure the legal status of EU citizens resident in the UK.
- It is within the UK government's control as to whether the UK continues to follow and recognise EU regulations and standards for a period of time following a no-deal withdrawal, and also which import/border checks to impose. This could be used to minimise the initial impact of a no deal and could be a de facto implementation period.
- How much of the guidance on no-deal preparation that is being published currently is acted upon by government and the NHS and its supply chain.

7.1 Workforce

The detailed breakdown of the Trust's workforce in terms of UK/EU/Non-EU nationality as well as professional group is shown in the three tables in appendix 1.

Staff in Post - August 2018

Staff Group	British		European Union		Non-EU		Total Heads	Total FTE
	Heads	FTE	Heads	FTE	Heads	FTE		
Add Prof Scientific and Technic	93	83.15	5	4.60	2	1.76	101	90.11
Additional Clinical Services	227	204.75	4	4.00	4	4.00	241	217.88
Administrative and Clerical	342	293.93	1	1.00	3	2.80	349	300.66
Allied Health Professionals	81	74.61	8	7.60	6	5.80	95	88.01
Estates and Ancillary	98	81.19	2	1.53	2	1.67	104	85.60
Healthcare Scientists	43	41.14	4	4.00			47	45.14
Medical and Dental	72	69.75	13	12.90	19	18.94	107	104.59
Nursing and Midwifery Registered	488	449.07	27	24.86	50	47.78	571	527.72
Grand Total	1444	1297.59	64	60.49	86	82.75	1615	1459.71

Information based on Nationality held in ESR and excludes Bank and other as and when staff

In summary, as at August 2018:

- 4.1% of our staff (64 heads) are EU citizens
- 5.7% of our staff (86 heads) are from outside the EU
- 88.9% of our staff (1444 heads) are British citizens.
- We have no nationality data for 1.3% of staff (21 heads) in the ESR (electronic staff record)
- There are EU staff spread across all professional groups, but a concentration in medical staff (12% of this group) and nursing (5%).
- The numbers vary, but there are around 20-30 new starters at LHCH from the EU and a similar number from outside the EU in a typical year, around half of whom are medical and nursing staff.

Data from ESR indicates that the proportion of EU staff and non-EU staff in LHCH posts has shown a considerable net increase since the EU referendum in 2016. Although there was an initial drop between 2016 & 2017, this appears to have recovered in the year to date. This drop was due to a decrease in new starters in 2017 (which was compensated for in some staff groups by an increase in non-EU starters), whilst the numbers of leavers from the EU and outside the EU has remained stable throughout.

This data suggests that LHCH is not exposed to a significant workforce risk from Brexit and overseas recruitment has continued successfully since the referendum. The Trust has made a number of positive communications to our EU staff recognising their invaluable contribution to our success and providing as much reassurance about post-Brexit arrangements as available.

It is assumed that continuing the "settled status" scheme is what the government meant when it announced it would move swiftly to secure the status of EU citizens if no deal is reached.

The government has also exempted healthcare workers from the tier 2 visa cap for highly-skilled workers from July 2018, assisting overseas recruitment.

Given the low and stable numbers of EU staff at LHCH, at this stage there are no anticipated additional workforce costs to the Trust arising from a no-deal outcome. However, this will need to be monitored closely should the prospect of no deal increase over the course of the

next 2-3 months.

7.2 Supply of Medicines, Medical Devices, Blood and

In the Secretary of State's letter to the NHS and also to the pharmaceutical sector he requests:

- hospitals and pharmacies not to stockpile medicines (any overordering will be investigated).
- prescribers not extend the length or quantity of prescribed medicines.
- patients should not stockpile medicines
- the pharmaceutical industry should make and share plans by 10th September to maintain an additional 6 week supply of medicines on top of normal stock in the UK to smooth any supply issues.

At this point the Chief Pharmacist does not anticipate medicines supply issues for LHCH nor special action required, but this will need to be reviewed in the light of the sharing of the industry's contingency plans in September and any further technical guidance notices.

A no deal Brexit will mean the UK ceases to be a member of the European Medicines Agency, and the MHRA would take on the functions currently undertaken by the EU for medicines on the UK market. This would require changes to UK law. The MHRA is planning a public consultation in early autumn on some of the key proposed legislative changes.

The Trust is a very significant user of medical devices and medical equipment and any unplanned changes in this area could present significant risks to our services and patients. In the no deal guidance, the government has confirmed that the UK will continue to recognise medical devices approved for the EU market and CE-marked (marked to indicate they conform with health, safety, and environmental protection standards). Should this change in the future, adequate time will be provided for businesses to implement any changed requirements.

The transfer of our more complex devices to national NHS procurement will help insulate the Trust from any changes to regulatory or procurement processes for medical devices.

The UK will also continue to comply with all key elements of the medical devices regulation (MDR) and the in vitro diagnostic regulations (IVDR), which will apply in the EU from May 2020 and 2022 respectively. Formal UK presence at EU committees in respect of devices will cease.

In terms of any other medicines or medical devices regulatory networks issues (pharmacovigilance or device safety events), the Trust will need to consider the technical guidance notes still to be issued and the proposed UK-wide arrangements to replace the functions of EU agencies. Sufficient detail on this is not yet available.

NHS Blood and Transplant is working with the UK Human Tissue Authority, to ensure that appropriate written agreements are in place for organ donation and exchange. The Trust will need to await this to assess any impact on LHCH and the harvesting of donated organs. There are not expected to be any.

The UK is largely self-sufficient in the supply of blood and blood components. It imports around 6.5% of plasma units issued in the UK from the EU per year. If there is no deal, the current blood safety and quality standards for blood and blood components would not change. The EU blood directives would no longer apply to the UK, but would be incorporated into UK law. NHS Blood and Transplant is also working on these arrangements and it is not anticipated that there will be any impact on LHCH or its services.

7.3 Supply of Other Goods & Services

LHCH uses a wide range of more routine goods and services with links to the EU market and regulatory frameworks. We await further guidance on preparedness from the government. However two principal risks apply, once CE-marking and EU procurement law has been transferred to UK law:

- Cost increases & supply chain issues linked to WTO-based customs and tariff arrangements. These are largely dependent upon the actions the UK government chooses to take. The imposition of new tariffs could lead to price increases for the Trust. The imposition of new customs checks could extend supply chains and delay delivery. The Trust will need to undertake a detailed assessment of which supply chains are at risk, once the technical notices are published.
- The Trust will no longer have legal access to networks, databases and information resources which are reserved for EU member states. This is a potential risk to clinical trials data (see below). Again, a full assessment of risks will need to be undertaken.

7.4 Research & Clinical Trials

In the event of a no deal Brexit:

- UK institutions would cease to have access to EU funding for research projects, including Horizon2020. However the UK government has committed to underwrite the UK centre costs of projects that have been agreed prior to Brexit and continue afterwards. Brexit is not expected to impact upon industry-funded / international multi-centre research projects.
- Clinical trials – the existing 2004 regulations will remain in force, although they will be modified using powers under the EU Withdrawal Act to make sure they still work in the UK after exit. The new EU clinical trials regulation (CTR) 536/2014 will not be in force in the EU at the time of exit and so will not be incorporated into UK law. However, the UK will align where possible with the CTR without delay when it does come into force in the EU, subject to parliamentary approvals. The two key elements of the new CTR regulation that the UK would not be able to implement on its own after December 2020 are the use of a shared central IT portal and participation in the single assessment model, both of which would require a negotiated UK/EU agreement regarding UK involvement following the end of the implementation period.

The Trust will need to undertake a detailed assessment of the risks to its current and likely research and clinical trials activities. It is expected that further technical notices will be

published in the next month that will support this.

7.5 Other general economic impacts

A no deal Brexit is likely to result in considerable uncertainty which in itself could present unanticipated risks to the Trust:

- The state of the public finances is linked to the overall state of the UK economy – and any negative economic consequences could in time feed through into NHS funding; notwithstanding the government’s commitment to increase funding by a further £20bn by 2023.
- The Trust could be exposed to general inflationary pressures.
- The Trust has some limited exposure to currency fluctuations:
 - Some charitable funds are linked to overseas investments – in the region of £400k
 - Some payments for goods/services are made in foreign currencies, but these are generally low value.
- Our supply chain, particularly for medical devices, has a significant international component and is subject to cost risks from currency and customs changes.
- The regulations relating to reciprocal healthcare agreements would change. This would likely result in an increased requirement for the Trust to identify and charge a greater number of patients classified as overseas visitors. Since the NHS England mandated overseas tariff is 150% of NHS tariff (to cover non-payment risks and additional admin overheads), this may have an overall small positive impact on LHCH income.

The extent of these risks is not quantifiable at present, and in any event they are inherently unpredictable much in advance. There is little that the Trust can do to prepare for or mitigate the wider economic impacts; and many of our high cost purchased items are already part of longer-term price commitments or transferring to national procurement.

9. Contingency Arrangements

The Trust is taking the following actions to prepare for both Brexit outcomes:

- Convening a multi-professional Brexit contingency group to:
 - Review the government’s technical guidance notices as they are published;
 - Undertake a detailed risk assessment of the above areas of possible impact;
 - Review and update existing business continuity plans to support Brexit preparedness;
- Liaising with local and national partners on risk assessment and contingency planning.

Further updates will be provided to the Board of Directors in due course.

10. Recommendations

The Board of Directors is recommended to:

1. **Note** this update on the possible impact on the Trust arising from the UK's withdrawal from the European Union, and the contingency planning that will take place over the next 7 months.
2. **Note** that the Trust's updated business continuity plan will be presented to the Board of Directors in public in due course, in line with the NHS England Emergency Preparedness, Resilience and Response Framework annual assurance process.

Appendix 1 - LHCH Workforce Statistics

Staff in Post - August 2018

Staff Group	Heads	FTE
Add Prof Scientific and Technic	101	90.11
Additional Clinical Services	241	217.88
Administrative and Clerical	349	300.66
Allied Health Professionals	95	88.01
Estates and Ancillary	104	85.60
Healthcare Scientists	47	45.14
Medical and Dental	107	104.59
Nursing and Midwifery Registered	571	527.72
Grand Total	1615	1459.71

Breakdown.....

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Nursing and Midwifery Registered	488	449.07	27	24.86	50	47.78	571	527.72
Grand Total	1444	1297.59	64	60.49	86	82.75	1615	1459.71

Information based on Nationality held in ESR and excludes Bank and other as and when staff

Starters by Year/Staff Group Since 01/01/2016

Year / Staff Group	British		European Union		Non-EU		Total Heads	Total FTE
	Heads	FTE	Heads	FTE	Heads	FTE		
2016	211	190.43	32	30.63	19	18.93	267	244.42
Add Prof Scientific and Technic	12	10.60	4	4.00	1	1.00	17	15.60
Additional Clinical Services	37	35.25			2	2.00	40	38.25
Administrative and Clerical	58	49.97			1	0.93	60	51.33
Allied Health Professionals	7	6.20	4	3.50	1	1.00	13	11.70
Estates and Ancillary	10	7.13	1	0.53			11	7.67
Medical and Dental	16	14.90	9	8.60	11	11.00	37	35.50
Nursing and Midwifery Registered	71	66.37	14	14.00	3	3.00	89	84.37
2017	204	187.37	19	18.53	34	33.94	261	243.77
Add Prof Scientific and Technic	15	13.30					15	13.30
Additional Clinical Services	68	62.59	5	5.00	12	12.00	85	79.59
Administrative and Clerical	43	37.99			2	2.00	47	41.92
Allied Health Professionals	11	10.00	3	3.00	1	1.00	15	14.00
Estates and Ancillary	6	4.83	1	0.53			7	5.36
Healthcare Scientists	2	2.00	1	1.00			3	3.00
Medical and Dental	17	16.40	6	6.00	17	16.94	41	40.34
Nursing and Midwifery Registered	42	40.27	3	3.00	2	2.00	48	46.27
2018 YTD	120	110.79	21	20.29	9	8.37	153	142.45
Add Prof Scientific and Technic	7	6.50	3	3.00			10	9.50
Additional Clinical Services	25	24.08	2	2.00			27	26.08
Administrative and Clerical	26	21.71					27	22.71
Allied Health Professionals	8	8.00			2	1.80	10	9.80
Estates and Ancillary	6	3.92	1	1.00			7	4.92
Healthcare Scientists	3	2.56					3	2.56
Medical and Dental	15	15.00	7	7.00	5	5.00	28	28.00
Nursing and Midwifery Registered	30	29.03	8	7.29	2	1.57	41	38.89
Grand Total	535	488.59	72	69.46	62	61.24	681	630.64

Leavers by Year/Staff Group Since 01/01/2016

Year / Staff Group	British		European Union		Non-EU		Total Heads	Total FTE
	Heads	FTE	Heads	FTE	Heads	FTE		
2016	128	113.10	15	14.60	10	10.00	173	155.70
Add Prof Scientific and Technic	5	4.76	3	3.00			8	7.76
Additional Clinical Services	15	13.53	1	1.00			21	18.74
Administrative and Clerical	39	33.83			1	1.00	46	40.03
Allied Health Professionals	8	6.89	3	3.00			11	9.89
Estates and Ancillary	8	6.64					8	6.64
Healthcare Scientists	2	1.59					3	2.59
Medical and Dental	10	9.00	7	6.60	7	7.00	26	24.60
Nursing and Midwifery Registered	41	36.84	1	1.00	2	2.00	50	45.44
2017	158	141.45	13	13.00	16	15.93	197	179.85
Add Prof Scientific and Technic	8	7.63					9	8.63
Additional Clinical Services	25	21.94			2	2.00	29	25.94
Administrative and Clerical	39	34.15			1	0.93	43	37.95
Allied Health Professionals	16	13.84	2	2.00	2	2.00	21	18.84
Estates and Ancillary	8	7.32					8	7.32
Healthcare Scientists	4	3.60	1	1.00			6	5.20
Medical and Dental	13	12.70	6	6.00	11	11.00	31	30.70
Nursing and Midwifery Registered	45	40.27	4	4.00			50	45.27
2018 YTD	123	109.70	14	12.77	14	13.35	158	142.42
Add Prof Scientific and Technic	3	2.80	2	1.60			5	4.40
Additional Clinical Services	12	9.43	1	1.00			15	12.43
Administrative and Clerical	29	24.19			1	1.00	32	26.79
Allied Health Professionals	9	8.63	2	1.50			12	11.13
Estates and Ancillary	8	7.08					8	7.08
Healthcare Scientists	4	3.76					4	3.76
Medical and Dental	12	11.80	4	4.00	10	9.50	26	25.30
Nursing and Midwifery Registered	46	42.01	5	4.67	3	2.85	56	51.53
Grand Total	409	364.25	42	40.37	40	39.29	528	477.98