The NHS Confederation - Written evidence (EEH0017)

This submission follows the NHS Confederation's oral evidence to the Sub-Committee on 27 January and addresses the inquiry from a health policy perspective.

Key points

- **The Trade and Cooperation Agreement (TCA) removes much of the uncertainty for health**. A no-deal scenario would have presented challenges for the NHS: for example, in implementing processes to recover healthcare costs from patients from 27 different EU member states.
- **The TCA guarantees a number of key health priorities**: access to **reciprocal healthcare** for UK and EU citizens; participation of UK scientists, researchers and clinicians in EU-funded **research** programmes; UK participation in EU systems to tackle **cross-border health threats**; and **tariff-free trade** in goods, including medicines and medical devices.

- **Work remains on mutual recognition**. We welcome the mutual recognition of **manufacturing inspections** for medicinal products, while regretting the **absence of mutual recognition of batch testing and authorisation** of these products. The complications that will result can be mitigated or avoided if the UK and EU can work together constructively towards mutual recognition through the **Medicinal Products working group** set up by the TCA.

- We support the government's call for an extension for a further year, until 1 January 2023, of the 'grace period' delaying the introduction of rules relating to the supply and marketing of medicinal products in **Northern Ireland**. This would provide more time for preparations and resolution of barriers to the supply of medicines to Northern Ireland.

- COVID-19 highlights the need for **swift agreement on cross-border public health issues**. We urge the UK and EU to make speedy progress towards agreeing a Memorandum of Understanding (MOU) maximising cooperation**.**

- **Agreement on data adequacy needed soon.** While we welcome the extension for a maximum of six months from 1 January of the free flow of personal data between the UK and the EU, failure to reach a positive decision on **data adequacy** would result in burdensome and costly alternatives for the processing and transfer of personal data.

- Should data adequacy not be granted, for the sake of patients we urge the UK and EU to reach agreement allowing the transfer of **patient data for medical research**.

- **New points-based immigration system will make the UK a less attractive destination for top European research talent**. We note that the agreement commits the parties to making every effort to facilitate the **movement of researchers**. However, the UK's new points-based immigration system will, unless modified, create cost and administrative barriers for researchers.

- **Frontline care workers will not qualify for visas** to enter the UK under the new immigration system. We are concerned that this will exacerbate existing staffing shortages in social care, with a knock-on impact on the NHS. **We welcome the UK government's commitment to review the impact of the ending of free movement on the social care workforce** and urge it to develop flexible and pragmatic solutions if the situation warrants.

About the NHS Confederation

The NHS Confederation is the membership body that brings together and speaks on behalf of organisations that plan, commission and provide NHS services in England, Northern Ireland and Wales. We represent hospitals, community and mental health providers, ambulance trusts, primary care networks, clinical commissioning groups and integrated care systems.

About the NHS European Office

The NHS European Office is the conduit for the NHS to engage with the EU agenda. Hosted by the NHS Confederation, we are the representative body for the range of NHS organisations in England on EU affairs and we regularly seek input from NHS representatives across England, Wales and Northern Ireland to help us assess potential implications for the NHS of EU policy and legislation, in order to develop our positions and influence our lobbying strategies at European level.

We play a key role in the Brexit Health Alliance, a coalition of NHS, patient groups, medical research/Royal Colleges and healthcare industries working together for the best possible outcomes for our sector from EU exit; and the Cavendish Coalition, speaking on behalf of the health and care sector on workforce issues.

What is your assessment of the relevant provisions in the UK-EU Trade and Cooperation Agreement, and their impact on health?

1. The provisions in the agreement impact positively upon some areas that are of particular concern to our members and the patients they serve, for example by agreeing access to healthcare for UK and EU citizens on either side of the UK/EU border, UK participation in EU-funded medical and scientific research programmes, and cross-border cooperation in tackling

threats to the public's health. They go some way towards easing trade in medicines and medical devices by agreeing mutual recognition of manufacturing inspections and tariff-free trade, but there are many gaps.

2. We remain concerned about the effect on supply of medicines and medical devices of border controls and regulatory barriers (especially for patients and providers in Northern Ireland), the lack of a longer term agreement on data adequacy which will impact many aspects of healthcare, especially research data, and the ambitious timeframe to conclude 'unfinished business' in the Medical Products working group. Our detailed analysis of the achievements and gaps in the TCA follows.

What do those provisions achieve?

Reciprocal healthcare

3. The provisions in the agreement largely preserve the rights to reciprocal healthcare enjoyed by UK and EU citizens before the end of the post-Brexit transition period.
4. Travellers will be able to use their EHIC or GHIC cards to access necessary treatment if they fall ill while abroad; resident pensioners will be able to use local health services on the same basis as nationals of their country of residence; and patients will be able to book pre-authorised treatment in another state, reimbursed on a state-to-state basis without the patient having to pay upfront.
5. There are a few gaps – for example, the agreement does not cover the EFTA countries. See paragraph 19 below.

Supply of medicines and medical devices

6. The TCA provides for tariff- and quota- free trade between the UK and the EU. It also provides for mutual recognition of 'good manufacturing practice' so that the UK and EU will not need to duplicate inspection of each other's factories.
7. However, the provisions in the TCA are limited and fall far short of the Confederation's 'asks' during negotiations. See paragraph 29 below.

Research

8. The TCA's provisions enable the UK to participate as a third country in Horizon Europe, the EU's science and innovation programme. The research involved is of enormous benefit to patients, offering hope of new and better treatments, especially for patients with rare diseases, where the small numbers in each country make international collaboration (for example on enrolling patients in clinical trials) indispensable.
9. This is an important opportunity for the UK to maintain and strengthen its position as a world leader in science and innovation, by maximising our participation in mutually beneficial collaborative projects. The deal will be reviewed in five years' time.

10. There are however other issues adversely impacting research, such as UK-EU data sharing and customs and regulatory barriers affecting importation of medicinal products and their ingredients, and the development and licensing of new products. We explain these and suggest solutions at paragraph 33 below.
11. We also have concerns about the UK's ability to continue to attract top research talent from the EU, following the ending of free movement for researchers and their families.

Public health cooperation

12. While the UK will no longer be a member of the European Centre for Disease Prevention and Control (ECDC), the agreement has provisions for the UK to request access to their Early Warning Response system database for exchanging intelligence, in order to tackle 'serious health threats'. Access has already been granted during the coronavirus pandemic, which augurs well for future cooperation.
13. The agreement also envisages an MOU between the UK and the ECDC in order to allow continuing, mutually beneficial co-operation on health security. We urge the parties concerned to expedite this.
14. For maximally effective cooperation, the UK and EU need to agree data adequacy to allow speedy and uncomplicated transfer of data on public health threats.

Mutual recognition of professional qualifications (MRPQ)

15. The TCA does not include agreement on MRPQ. An Annex to the agreement sets out a mechanism whereby stakeholders (regulators and others) may work together to devise a future framework for mutual recognition for the relevant profession(s) which would then need to be agreed by a Partnership Council, yet to be set up.
16. In the meantime, the UK healthcare regulators are continuing to recognise qualifications gained in the EU (with minor procedural changes) for incoming applicants to their registers. There is no reciprocity, so professionals with UK qualifications will be treated as third country applicants according to the rules of the Member State concerned.

Data flow between the UK and EU

17. The agreement provides a 'stopgap': for a maximum of six months from 1 January 2021, current data flows will continue uninterrupted. In the meantime, the UK is seeking a decision on data adequacy from the EU that will allow data to continue to flow in both directions in future.

What, if any, challenges arise because of those provisions? How could these challenges be resolved?

Reciprocal healthcare

18. Despite the TCA provisions, there is some confusion among patients and healthcare providers about entitlements. The NHS Confederation has raised the issue of clear communication to the public with the UK government, and we are using our contacts and channels of influence among EU healthcare organisations to disseminate accurate information. Monitoring of implementation through the mechanisms set up in the Withdrawal Agreement and TCA will be important to ensure that citizens' rights are respected.
19. The TCA does not cover the EFTA countries. The UK has come to a separate arrangement with Norway, but UK citizens who need healthcare in Iceland, Switzerland or Liechtenstein, or citizens of those three countries who need treatment in the UK, will be chargeable. For some high risk patients with pre-existing conditions, affordable insurance may be unavailable.
20. We hope that reciprocal agreements will soon be made to resolve the problems for these patients, and for the UK healthcare staff who will have to start charging them.

Supply of medicines and medical devices

Border checks and paperwork/NHS supply chain

21. While the agreement provides for trade in goods between the UK and EU to be tariff-free, it is not 'frictionless'. The agreement does not obviate the need for border checks and controls, leading to extra paperwork and potential delays.
22. Goods impacted include not only medicines but medical devices ranging from syringes, ventilators and PPE to dialysis equipment and MRI scanners. Seventy per cent of medical equipment is imported to the UK via the EU, and one in five devices used for specialised procedures arrive 'just in time'.
23. The UK government, industry and the NHS have worked hard together to ensure continuity of supply for essential services (e.g. by stockpiling, trader readiness schemes, alternative supply routes, etc.). All NHS organisations have local resilience plans that take into account COVID-19 and winter pressures, as well as the challenges of adapting at short notice to new arrangements after the end of the post-Brexit transition period. Serious issues can be escalated to national level and dealt with by the National Supply Disruption Response unit.
24. Inevitably we have heard of some problems, for example research institutes who have told us it has been touch and go for some of their temperature-sensitive deliveries (e.g. ingredients for cell cultures that have to be delivered on dry ice). We know that some organisations are incurring extra costs by paying couriers to guarantee speedy delivery.
25. We are conscious that the supply of vaccines to the UK from the EU is potentially vulnerable to disruption at the borders (or political pressures, as we have seen recently), but are confident that the UK has adequate supplies for our needs.

Northern Ireland/rules of origin

26. Tariff-free trade only applies if goods intended for the EU market meet the EU's 'rules of origin' requirements (the bulk of the ingredients/components must be sourced from the UK or EU). This presents particular problems for traders supplying goods from Great Britain into Northern Ireland, where there is the possibility that the goods may cross the border into the Republic of Ireland and hence the EU market.
27. Ninety-eight per cent of NI's medicines are imported from the UK. The EU and UK have agreed a 'standstill' until 31 December 2021, during which period current arrangements will continue to apply in Northern Ireland. After 31 December 2021, medicines imported from GB to NI will need to be imported via a Manufacture and Importation Authorisation (MIA) holder and batch tested and certified by a 'qualified person' (QP) in order to meet EU requirements for sale in NI, adding costs and complexity for businesses and end users.
28. For the sake of patients in Northern Ireland and the businesses who supply them, the Medicinal Products Working Group (envisaged in an Annex to the TCA) should be set up and start developing practical solutions for implementation as soon as possible.

Batch testing and future authorisation

29. The TCA contains no mutual recognition agreement (MRA) on batch testing, which would have obviated the need to duplicate testing of products already tested on the other side of the UK/EU border. Nor is there agreement that the UK and EU will mutually recognise products that have been authorised for marketing by the relevant competent authorities (in the UK, the MHRA; in the EU, the EMA).
30. The UK has unilaterally decided to recognise batch testing conducted in the EU and to accept European 'CE' product markings for two and a half years (and without limit in NI), but without reciprocity.
31. It will be important for the Medicinal Products working group to make as much progress as possible towards mutual recognition, to minimise costs and disruption.

<u>Public health cooperation</u>

32. In order to ensure optimally effective joint working, the UK government should work to secure a <u>good, wide-ranging MOU</u> that preserves the elements of former joint working that both the UK and EU found valuable.

<u>Research</u>

33. While UK patients can continue to be involved in clinical trials, researchers are concerned by the additional cost and complexity introduced now that the UK is a third country and there is no mutual recognition of sponsorship of clinical trials.
34. Lack of a data adequacy agreement would especially impact clinical research, as this involves storing and transferring large volumes of patient

data (e.g. clinical trials test results). Some of this UK patient data is held in 'cloud' databases in EU member states. Alternative mechanisms (standard contractual clauses, administrative arrangements, legally binding instruments, etc.) are burdensome, costly, and take time to set up. This could lead to delays sharing data and hold up research, to the detriment of patients for whom the trial may hold out the hope of a cure.

Mutual recognition of professional qualifications (MRPQ)

35. UK healthcare regulators are continuing to recognise qualifications obtained in the EEA for two years after 1 January 2021, so there will be no impact on incoming healthcare professionals in the short term.
36. In the meantime, the UK will be developing a new overarching global regime for MRPQ. The ambition is to replace the present unwieldy procedures for recognition of international qualifications with a faster, more streamlined system.
37. The impact of the lack of MRPQ in the TCA agreement is on outgoing professionals with UK qualifications, unless registered with the appropriate regulator in their destination country prior to 1 January. This will affect EEA students studying in the UK for a professional qualification, who will be treated as applicants with third country qualifications when applying for professional registration in EEA countries. Other countries will also apply their own rules when deciding whether periods of practice in the UK will count in future for CPD (evidence of continuing competence).
38. Some EU member states such as Ireland have however already exempted UK applicants from some of their normal requirements for non-EEA applicants.
39. There may be additional costs for some practitioners who practise on both sides of the Irish border and can no longer register free of charge on a 'temporary and occasional' basis, or who are registering for the first time with one or both regulators. The Northern Ireland Confederation for Health and Social Care (NICON) is pursuing this issue with the relevant government departments.

Data flow between the UK and EU

40. Without a data adequacy agreement **all** transfers of personal data from the EU to the UK will be affected. There could be problems exchanging information about applicants between regulators in the UK and EU after 30 June this year.
41. It will also be important to secure data adequacy to allow the smooth transfer of research data and intelligence on public health threats without having to resort to costly and burdensome alternative transfer mechanisms.
42. Standard Contractual Clauses, the primary alternative transfer mechanism in a non-adequacy scenario may not be sufficient in light of the Schrems II ruling that raised the bar for transfers of data from the EU.

Workforce challenges in the health and care sector

43. Currently, around 5.6 per cent of NHS staff in England are from the EEA, 7.5 per cent from the rest of the world (RoW) excluding the UK. In social care in England, 7 per cent are from the EEA, 9 per cent from the RoW. In both the NHS and social care there is wide regional variation.
44. The recent report commissioned by the Welsh NHS Confederation, UK Migration Policy and the Welsh NHS and Social Care Workforce, found that in 2020 approximately 8 per cent of staff working in the Welsh NHS identified as non-UK nationals. The research found that if the new immigration rules had been introduced previously approximately 1 per cent of the current NHS workforce would be ineligible to work in the NHS. These roles include ambulance drivers, dental surgery assistants, social care support workers, health care support workers/healthcare assistants, patient care assistants and emergency care assistants. The implications for social care are more severe, with fewer roles qualifying for the HCV or Skilled Worker visa, and the greater turnover of staff in the sector presents particular challenges, with likely knock-on impacts for the NHS.
45. The health and social care sector in the UK suffers from a workforce shortage and unless there is significant additional recruitment and retention, this is predicted to worsen as the demand from an increasingly elderly population increases. The UK government announced a target of recruiting an additional 50,000 more nurses in England over the next five years and a substantial proportion of that target relies on inward migration.

Existing employees

46. EEA citizens already in the UK before 1 January this year are protected by the Withdrawal Agreement between the UK and EU. They and their family members will enjoy the same rights as before, provided they apply for settled or pre-settled status in the UK by 30 June 2021. NHS employers, trade unions and professional bodies are redoubling their efforts to support UK and devolved governments outreach and encourage all eligible staff to apply.
47. We are aware that, in addition to existing staff who may fall through the net and fail to meet the deadline, EEA citizens may arrive in the UK during the first six months of this year and find employment in the health and social care sector. They will satisfy current legally prescribed recruitment checks, but employers could subsequently discover that these employees do not have the right to live and work in the UK after 1 July. The Cavendish Coalition, which the NHS Confederation hosts, will be raising these two issues with the Home Office and hopes that, in the same way that government has shown flexibility by abolishing or reimbursing the immigration health surcharge for health and care workers, they may exercise discretion in the case of these sorely needed key workers.

The new UK immigration system

48. Free movement between the UK and the EU ended on 31 December 2020. The new UK immigration system requires immigrants to be sponsored by an employer and obtain a visa. Nearly all professional health and senior social care workers (doctors, nurses, allied health professionals, etc.) will meet the points-based entry criteria and will benefit from the Health and Care visa fast-track entry route, reduced fees and exemption from the immigration health surcharge. However, there will be administrative barriers that did not previously exist for EEA citizens, and possibly a changed perception of how 'welcome' they feel in the UK.

Social care

49. 850,000 people are employed in frontline care worker roles in England alone, and despite the recent recruitment campaign and a slight upturn in recruitment of people displaced from other jobs as a result of the pandemic, there is still a yawning gap between demand and supply. Skills for Care estimate the vacancy rate in England at 7.3 per cent, or 112,000 jobs. Annual turnover is 30.4 per cent.
50. Frontline care workers do NOT qualify for visas to enter the UK under the new points-based immigration system. The NHS Confederation, together with our partners in the Cavendish Coalition, have expressed severe concern over the impact of the new system on the social care workforce, both in care homes and in domiciliary care. We are also very concerned by the knock-on pressures on the NHS of inadequate staffing in the social care sector.
51. We have consistently argued for a long-term, sustainable plan for funding and staffing social care as part of a sorely needed integrated health and social care policy.
52. The Cavendish Coalition highlighted the staffing crisis in social care in very stark terms in their evidence to the Migration Advisory Committee (MAC), arguing that while every effort is being made to increase domestic recruitment into the care sector, not everyone has the right attitudes and attributes for this kind of work. Reliance on overseas immigration cannot be the only solution to this complex issue, but in the short term there must be the safety net of being able to continue to recruit international workers for social care.
53. The MAC acknowledged in their report that there will be an adverse impact on social care. The government has committed to review the impact of the end of free movement within the first six months of 2021 and if this shows adverse consequences for this very fragile sector, we urge them to consider flexibilities to address the needs of our labour market.

What should the UK seek to accomplish with the EU in relation to health within the parameters of the agreement in the short- and mid-term?

- Mutual recognition for batch testing and authorisation of medicinal products.

- Clarity on post-31 December 2021 arrangements for the authorisation and marketing of medical products in NI, and for the issuing and dispensing of prescriptions and over-the-counter medicines.
- MOU with ECDC on health security.

And outside the parameters of the agreement:

- Secure data adequacy - or if overall data adequacy is not granted, a specific agreement around the exchange of data for research purposes.
- Domestic review of the impact of ending of freedom of movement on the UK social care sector (and by extension, its impact on the NHS), and action to address workforce shortages if necessary.
- Flexibility and discretion in the case of EU health and care workers in UK who have not met the deadline for settled/pre-settled status by 30 June 2021.
- Review the immigration costs and barriers for incoming researchers and scientists if these appear to be a deterrent to attracting global talent.