



National Audit Office

Report

by the Comptroller
and Auditor General

Department of Health & Social Care

Exiting the EU: supplying the health and social care sectors

Key facts

7,000 out of 12,300

number of prescription-only and over-the-counter medicines that come from or via the EU

40% – 60%

assumed capacity on the first day at ports serving the short Channel crossings compared with current flows, under the government's reasonable worst-case scenario

2,326

number of heavy goods vehicle spaces per week that the Department of Health & Social Care has asked the Department for Transport for, as part of the government-secured freight capacity

450,000 – 500,000

number of types of medical devices and clinical consumables – such as needles, syringes and stethoscopes – available to the NHS each year

£95 million

value of planned additional stockpile of high-volume clinical consumables, £85 million of which was in place by 20 September

91%

proportion of government-secured freight capacity earmarked for priority supplies to the health and social care sectors

25%

percentage of medicine product lines for which suppliers had reported to the Department of Health & Social Care (by 20 September) that they had secured freight capacity away from the short Channel crossings

72%

percentage of medicine product lines for which suppliers had reported to the Department by 20 September that they held at least 6 weeks' stock

Summary

The scale of the challenge

1 Following the EU membership referendum in June 2016, the government asked departments to begin preparing for all eventualities, including a ‘no-deal’ exit from the EU. The government is seeking to ensure that goods can flow through the UK border without significant delays. However, if the UK leaves the EU without a deal, the government’s assessment is that EU member states are likely to impose third country controls on UK goods entering the EU, with the potential to create delays for goods flowing through the short Channel crossings in both directions.¹

2 There is no way of knowing exactly what may happen at the UK/EU border when the UK leaves the EU. Departments have been working to an agreed set of assumptions about expected flows across the short Channel crossings. There are significant uncertainties over such scenarios but ministers expect departments to be prepared should a ‘reasonable worst-case’ scenario materialise. The current cross-government ‘reasonable worst-case’ planning assumption is that the flow of goods across the short Channel crossings could be reduced to 40%–60% of current levels on day one, with the flow of goods improving to 50%–70% of current flow after three months and returning to close to current levels within 12 months.

3 The Department of Health & Social Care (the Department) and NHS England and NHS Improvement (NHS E&I) have been working with a wide range of organisations to understand the scale and nature of the supply challenge within their responsibilities. Supplies to the NHS and social care sectors involve thousands of items, ranging from medicines and blood products to gloves and other non-clinical consumables. There are currently 12,300 medicines licensed for use in the UK and, of these, the Department estimates that 7,000 come from or via the EU. The Department’s own estimates suggest that between 450,000 and 500,000 different medical devices and clinical consumables are available to the NHS. These items are distributed throughout the UK to hospitals, GP and dental practices, care homes, community pharmacies and directly to recipients at home. This supply of goods relies on complex logistics operations involving manufacturers, hauliers, wholesalers and front-line public and private service providers in the health and social care sectors.

¹ There are three short Channel crossings: Dover to Calais and Dover to Dunkirk via ferry routes, and Folkstone to Coquelles via the Channel Tunnel.

4 Health and social care organisations purchase the supplies they need directly from the private sector, or in the case of some NHS organisations from NHS Supply Chain, a limited company wholly owned by the taxpayer. Usually, the Department only becomes involved if there are shortages, as happens from time to time for medicines and less commonly for medical devices.

5 In December 2018, the Department brought all its preparations for maintaining supplies in the event of a no-deal EU exit under a single Continuity of Supply Programme (the Programme). The Programme's objective is "to safeguard patient care and to ensure that the supply of medicines and medical products remains unhindered in a no-deal scenario". The Programme covers goods supplied to the primary, secondary and independent healthcare sectors, social care, community pharmacies and dental surgeries. The Department is working closely with the Border Delivery Group, which has responsibility for helping to ensure the UK border works effectively after EU Exit. It is also working with the Department for Transport (DfT), which is responsible for procuring freight capacity on behalf of the whole of government.

6 Since 2018, the Department estimates it has spent £50.1 million on the Continuity of Supply Programme and has committed to spend a further £37.2 million by 31 March 2020. In addition, it has set aside £281.5 million as a contingency fund in case of need. DfT is to receive £150 million from HM Treasury to secure freight capacity from October 2019 onwards, which will be mostly used to meet health and social care needs. It estimates that the 2019-20 administration cost in relation to its freight capacity work has totalled £1.7 million so far. We are planning to cover the overall costs to government of preparing for EU Exit in a separate study, and therefore have not audited the above costs in detail for this study.

7 This report examines the progress made by the Department – working with other government departments, NHS and social care providers, and with private sector suppliers – in implementing the Continuity of Supply Programme. It sets out the Department's plan and records the progress made. Given the rapid pace of the Department's work, we do not reach a final conclusion on the value for money of the Department's response. Nevertheless, we consider it important to record now where the Department has got to as it takes forward these preparations and to set out the remaining areas of risk.

Statement from the Comptroller and Auditor General

"The Civil Service has faced an unprecedented challenge preparing for the UK's exit from the European Union. It has done so within a context where the form of the UK's departure has been uncertain, subject to shifting timetables and vigorous political debate.

In this report I record the progress made by the Department of Health & Social Care, working with others, to secure continuity of supply for both the health and social care sectors should the UK depart without a deal with the EU on 31 October. In doing so, I am obliged to point out the work that still needs to be done and the risks that remain. However, I wish to record that these have not been normal times for the Department and that it has already achieved a great deal in the midst of great uncertainty."

The Department's response

8 The Department has carried out extensive work to understand the existing supply networks and assess the impact of leaving the EU without a deal on 31 October. Its work shows that suppliers to the health and social care sectors make significant use of the short Channel crossings, for example (paragraph 1.5 and 1.6):

- Of the 12,300 prescription-only and over-the-counter medicines used in the UK, 7,000 come from or via the EU and the vast majority use the short Channel crossings.
- More than half the clinical consumables the UK uses come from or via the EU and the vast majority use the short Channel crossings.
- Half of all supplies for clinical trials come from or via the EU, and half of those (25% of the total) come through the short Channel crossings.

9 The Department developed a plan that aims to secure continuity of supply to the health and social care sectors. The Department developed the plan ahead of 29 March 2019, the original scheduled date for the UK's exit from the EU, and has modified the plan ahead of 31 October. It has a number of elements (paragraphs 1.7 to 1.10):

- Building up stockpiles and procuring additional warehouse space.
- Re-routing supplies, procuring freight capacity and improving supplier readiness.
- Improving the information it receives on supply needs and its ability to act on that information.

Building up stockpiles and procuring additional warehouse space

10 The Department asked pharmaceutical suppliers to build up a sufficient stockpile of medicines for 31 October but at present has incomplete information about the level of stockpiles in place. The NHS usually holds sufficient stocks of medicines to meet its immediate needs. Ahead of EU Exit, the Department has relied on suppliers building up their own stocks at their own expense. It can advise suppliers to build up stocks but cannot instruct them to do so. For 31 October, the Department asked pharmaceutical suppliers of medicines from, or via, the EU to ensure they can continue to supply medicines through a combination of stockpiling and securing alternative routes into the UK. It has suggested a default stockpile of six weeks' supplies. The Department is surveying its suppliers to determine their progress in building stockpiles and re-routing supplies. As at 20 September, suppliers reported that 72% of medicine product lines had at least six weeks' worth of supplies stockpiled and for 25% of medicine product lines suppliers had secured freight capacity away from the short Channel crossings (paragraphs 2.2 to 2.4 and Figure 3).

11 As a contingency measure, the Department has secured additional warehouse space to enable manufacturers to stockpile their medicines and material for clinical trials. In December 2018 and January 2019, the Department signed 12-month contracts with three specialist providers of storage space to provide additional storage capacity for 58,850 pallets, of which 5,000 could be used for refrigeration and 850 for temperature-controlled drugs. The contracts were originally put in place for a possible no-deal exit on 29 March. The Department's latest assessment for 31 October is for a lower requirement – a maximum of 48,000 pallet spaces. As a result, the Department terminated one of the contracts, although it is keeping the overall situation under review in case of additional need. The total cost of the contracts is expected to be £10.9 million, of which the Department had paid out £8.2 million by the end of August 2019. The Department pays the cost of preparing the warehouses for use. The space is then let out to suppliers at normal commercial rates (paragraphs 2.9 and 2.10).

12 The Department has created its own stockpile of some high-volume medical devices and clinical consumables to meet NHS needs. NHS Supply Chain usually buys items such as rubber gloves and syringes on behalf of hospitals and holds a stock. The Department worked with NHS Supply Chain to create an additional six-week central stockpile of the most frequently used supplies, with a current value of around £85 million. It estimated that 90% of the planned stockpiles were in place by 26 March. As of 20 September, 88% of the planned stockpiles were in place for 31 October and £10 million of further stocks were on order (paragraph 2.5).

13 The Department asked social care providers, for example nursing homes and domiciliary care providers, to put in place robust contingency plans for the possible implications of a no-deal EU Exit. The NHS supplies medicines for people in social care so they are already included in the Department's planning for medicine supplies. But social care providers also rely on non-medicine supplies that are not usually bought via the NHS. The Department does not have its own stockpiles of non-medicine items for social care. Its advice to social care providers was not to stockpile medical devices or clinical consumables, for example rubber gloves, but instead ensure they are ready to deal with any disruption (paragraph 2.6).

14 The Department does not currently know what proportion of social care providers have followed its advice, what preparations providers have made with their suppliers and whether suppliers will meet their priority needs. The Department faces a more complex task working with social care providers and their suppliers. Social care provision in England is much more fragmented than the NHS, with 24,000 regulated providers supplying services. Many providers are small and operate at a very local level, with 80% of care home providers only operating one home. During 2019 the Department issued guidance for the health and social care sectors on the need to prepare for EU Exit. In addition, NHS E&I ran a series of roadshows for NHS bodies and some social care commissioners and providers on the need to prepare for EU Exit (paragraph 2.7).

Re-routing and procuring freight capacity

15 Suppliers of medicines will be able to use a share of freight capacity procured by DfT to carry priority goods.

DfT is procuring, on behalf of government, freight capacity away from the short Channel crossings to carry priority goods. The government has defined priority goods, known as Category One goods, to be those it regards as “critical to preservation of human or animal welfare and/ or national security for the United Kingdom”. Medicines and other crucial clinical products fall within this definition. Eligible suppliers will be able to buy priority tickets from participating freight operators at a commercial rate. The definition does not encompass all supplies to the health and social care sectors. For example, it excludes non-clinical goods such as most food and bed linen. The Department of Health & Social Care identified a freight capacity need equivalent to 2,326 heavy goods vehicle (HGV) spaces per week and would like this from 31 October (paragraphs 2.11 to 2.15).

16 A DfT-led procurement of freight capacity is under way but the time available to put the capacity in place for 31 October is extremely limited.

DfT published the contract notice that launched the formal procurement process on 30 July. This was 19 days later than the date it estimated in June, for the procurement to have started in order to have all the capacity in place for 31 October. As a consequence, the time available for mobilisation has been reduced. Its ability to get freight capacity in place as needed now depends on the rest of the procurement process running smoothly and how quickly the successful operators can respond. The procurement is in two stages. DfT ran a competition for operators to join a framework agreement. This was intended to create a pool of operators to provide freight services. The framework was established on 20 September 2019. Government has now launched mini-competitions among its pool of chosen operators to provide freight services in the event of a no-deal exit from the EU (paragraph 2.16).

17 DfT’s aim is to have as much as possible of the freight capacity for priority goods in place by 31 October, and all of it by 30 November at the latest.

DfT’s market testing suggested it might not be possible to have all the freight capacity available from 31 October. It therefore split the procurement into two mini-competitions and expects to award the contracts on 12 October, less than three weeks before the UK is scheduled to leave the EU. Both competitions aim to provide 1,273 HGV spaces per week. The first competition places greater priority on those operators who can deliver capacity by 31 October. This approach aims to bring capacity with a short mobilisation time (for example, tickets on existing services) online quickly. The planned capacity of 2,546 HGVs per week reflects the total freight capacity requested by government departments to secure supply of priority goods, for example certain chemicals. The government has not defined food as a priority good. The capacity requested by the Department of Health & Social Care amounts to 91% of the total (paragraphs 2.12, 2.17, 2.18 and 2.25).

18 The Department of Health and Social Care has also started procurement of its own dedicated courier service and expects the service to be ready for testing by 24 October. The Department expects that this courier service will enable transportation of particularly urgent goods, for example if a supplier's own arrangements fail. The service will include customs and excise support services. It will provide capacity for 50 pallets and an additional 35m³ for specialist goods or any goods required urgently to be transported each day. The contracts will run for an initial period of 12 months, with the option to extend for a further 12 months. The Department estimates the total value of its dedicated freight service contracts at £25 million. It expects to pay £3.9 million of this, with the rest of the cost met by companies using the service. The service is expected to be available from 1 November 2019 (paragraphs 2.12 to 2.24).

19 Despite recent efforts across government, there is still a risk that suppliers are not sufficiently aware of new border processes. In June 2019, the government estimated that 50%–85% of HGVs using the short Channel crossings might not be ready by October for new French customs arrangements. Trade bodies operating in the pharmaceutical sector told us, in September, about continuing concerns among their members about the quality of practical information from government on the precise border processes that will operate after 31 October, as well as the need for clarity about how the government-secured freight capacity will operate. On 1 September 2019, the government launched a communications campaign to support individuals and businesses to prepare; however, the time available to businesses to prepare is now short. On 30 August, DfT announced a new fund of £30 million for upgrades to both port infrastructure and connecting road and rail links. DfT plans to spend about half of this fund to support no-deal EU Exit planning (paragraphs 2.25 to 2.28).

Enhancing the Department's ability to respond if its plans are activated

20 The Department is taking action to strengthen its ability to address shortages if disruption begins to occur. The action includes the following (paragraphs 3.2 to 3.6):

- **Strengthening the Department's usual processes for managing potential shortages.** The Department and NHS E&I already have processes in place to manage shortages of medicines as part of business-as-usual day-to-day operations. At any one time, the Department estimates that about 100 medicines are likely to be experiencing some form of shortage. It categorises shortages into one of four tiers in line with their significance, and each receives escalating tiers of management attention and action. The Department told us that it has expanded its teams to manage these processes, for example recruiting additional pharmacist advisers.

- **Improving the timeliness and quality of information on local impacts.**

The Department is planning to create daily situation reports using information reported by the NHS and, via the Ministry of Housing, Communities & Local Government, Local Resilience Forums (LRFs). LRFs manage local civil contingencies and comprise members drawn from organisations that deliver local services, for example, local government, health, police and fire services. The NHS National Co-ordination Centre (NCC) will receive reports on how the NHS is operating at the front line.

- **Improving the Department's ability to respond to emerging issues.**

The Department has established a National Supply Disruption Response command centre. It will be available to all health and social care stakeholders. It will receive information from the NCC and LRFs as well as information on stockpile levels. It will also be the gateway through which suppliers can access the freight capacity secured by the Department and DfT – providing suppliers with access codes which will allow them to purchase tickets with freight operators.

21 The Department recognises that it may need to manage a number of financial risks. These include increased price volatility on goods if supplies become constrained and/or exchange rates change. There is a claw-back mechanism which caps health expenditure on medicines that are still within patent. However, other items supplied to the NHS and social care sectors are not subject to price regulation and prices will change to reflect supply and demand (paragraph 3.7).

Overall assessment

22 The Department has done a great deal of work to prepare for a no-deal exit. It identified several high-risk areas and took steps to fill gaps in the information it held, for example on the reliance of supplies on the short Channel crossings. It worked effectively with stakeholders in the medicines industry to understand the challenges they face in the event of a no-deal exit and to address them, for example by providing additional warehouse capacity. However, there remains a significant amount to do before 31 October, in particular to ensure that:

- government has a full picture of preparedness across the supplier base;
- sufficient cross-government freight capacity is in place; and
- social care providers such as nursing homes are fully prepared.

In the event of a no-deal exit, the Department would be working in a highly uncertain environment and operating all the elements of its plan would be a hugely demanding task.