



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

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Department of Health & Social Care

Exiting the EU: supplying the health and social care sectors

Report by the Comptroller and Auditor General

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Gareth Davies
Comptroller and Auditor General
National Audit Office

25 September 2019

This report records the progress made by the Department of Health & Social Care, working with others, to secure continuity of supply for health and social care sectors should the UK depart the EU without a deal on 31 October

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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.

Part One

Introduction

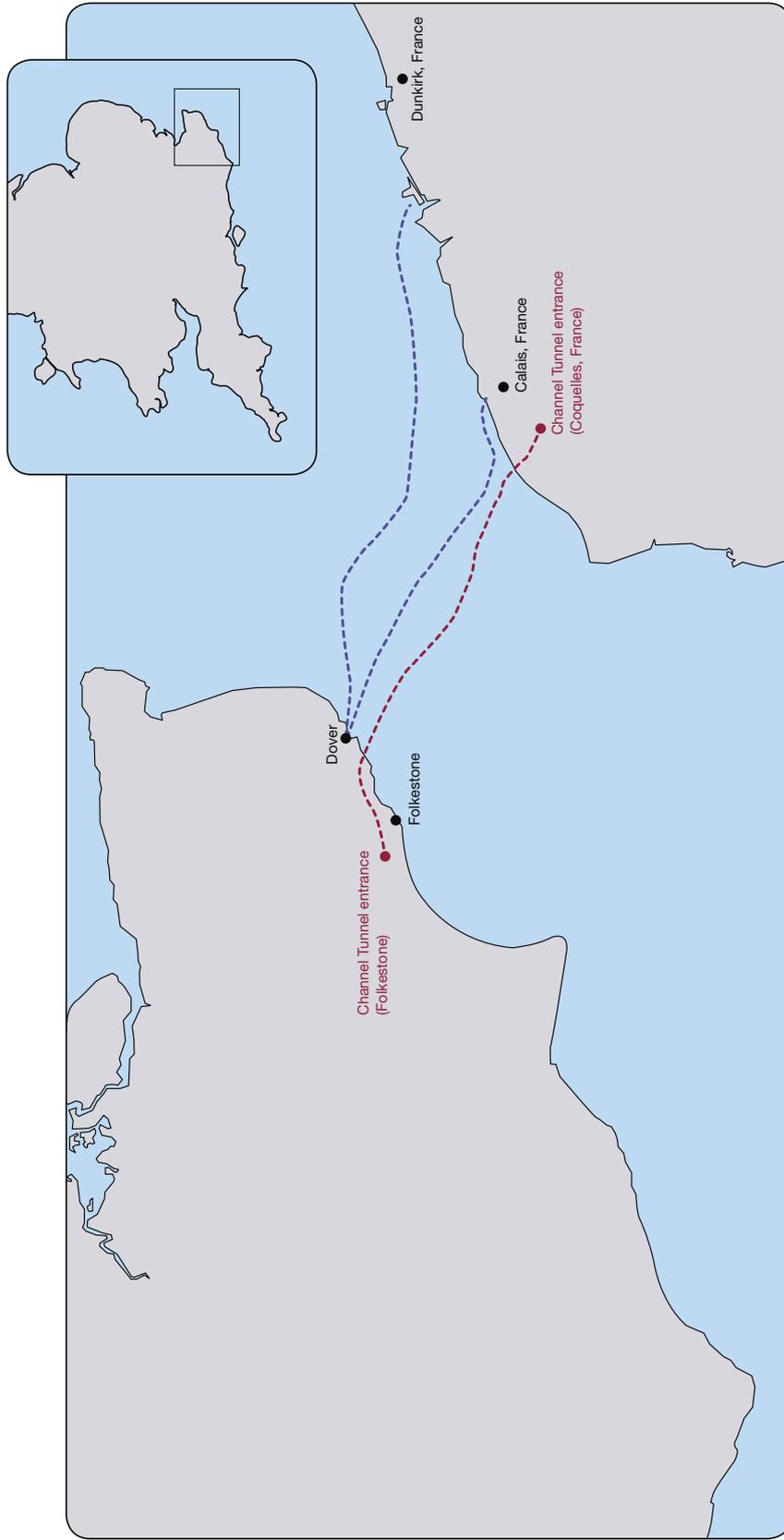
1.1 Following the EU membership referendum in June 2016, the government asked departments to begin preparing for all eventualities, including a ‘no-deal’ exit from the EU. The National Audit Office has, to date, published more than 20 reports examining various aspects of government preparations for the UK leaving the EU including, for example, arrangements being made at the UK/EU border.

1.2 The government is seeking to design its customs, agri-food and other control arrangements to ensure goods can flow through the UK border without significant delays, but if there is no-deal it assumes that EU member states will impose third country controls on UK goods entering the EU. This has the potential to create significant delays for goods flowing through short Channel crossings in both directions (**Figure 1**).

1.3 Departments are working to a common set of agreed assumptions about expected flows across the short Channel crossings. These assumptions cover a range of possible scenarios, including a ‘reasonable worst-case scenario’. The government has revised its assumptions over time following updates to the underlying assessments and continues to keep them under review.

- Until autumn 2018, the government’s initial ‘reasonable worst-case’ planning assumption was that a no-deal exit from the EU would result in two to four weeks of disruption at the border. Departments therefore planned for six weeks’ disruption to allow time for any queues to dissipate.
- At the end of October 2018 the government revised its ‘reasonable worst-case’ assumption. The new estimate was for an 87% reduction in the current flow of goods across the short Channel crossings, with the most severe disruption lasting for up to six months.
- In June 2019, the government again updated its agreed planning assumption for a ‘reasonable worst-case’ scenario. It now considers that the flow of goods could reduce to 40%–60% of current levels from day one, with the flow of goods improving to 50%–70% of current flow after three months and return to close to current levels within 12 months. This improvement to the flow rate assumptions was attributed, in part, to improvements to port infrastructure on the French side of the Channel.

Figure 1
 Most supplies to the health and social care sector enter the UK using the short Channel crossings
 The short Channel crossings comprise the Dover to Calais and Dover to Dunkirk ferry routes plus the Channel Tunnel crossing



- Short Channel crossing ferry routes
- Channel Tunnel route

Note

1 Health and social care sector supplies into the UK are also imported from outside the EU and from the EU by air freight.

Source: National Audit Office analysis of departmental and published documents

The scale of the challenge

1.4 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. These items are distributed across the UK to hospitals, GP and dental practices, care homes, community pharmacies and directly to recipients at home. Some items can remain in storage for long periods but others, such as radioisotopes, have a limited shelf-life. Some items must be transported and stored in temperature-controlled facilities while some are subject to specific regulatory requirements, for example regulations governing the transport and storage of hazardous materials and controlled drugs.

1.5 The Department of Health & Social Care (the Department) does not usually have direct involvement in the different supply chains, nor information about the extent to which these might depend on goods crossing the UK border from the EU. It has undertaken a significant amount of work to map out the supply needs. Its work suggests that supplies are significantly reliant on finished products or raw materials coming into the UK via the EU:

- 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 of those use the short Channel crossings.
- More than half the clinical consumables used in the UK 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.

1.6 The Department has varying degrees of influence over these supply chains:

- **Manufacturers** – Most supplies (other than substances of human origin) are made by private companies. The Department has good working links with some suppliers, for example drug companies, but usually has little or no direct contact with most of the others. In planning for EU Exit, it has had the most contact with suppliers with the largest market share: 28 suppliers provide around 80% of medicines (by volume) and 189 suppliers provide around 80% of medical devices and clinical consumables.
- **Logistics companies** – These move supplies from the point of manufacture in the UK, and elsewhere, to wholesalers and then on to front-line providers. The Department had no contractual relationships and very limited interaction with logistics companies before it started planning for EU Exit.

- Wholesalers – These companies buy products from manufacturers and sell them to front-line health and social care providers. Most but not all wholesalers are private sector companies: NHS Supply Chain acts as a wholesaler for some medical devices and clinical consumables, primarily to hospitals. NHS Blood and Transplant is the supplier of substances of human origin. Some private sector wholesalers have contracts with front-line services (for example, hospitals or care homes), rather than with the Department.
- Front-line service providers – These take the purchasing decisions that help maintain stocks for immediate needs and ensure service users receive the treatment and care they need. There are 7,454 GP practices in England, 225 NHS Trusts and NHS Foundation Trusts providing hospital care, and 24,000 social care providers registered with the Care Quality Commission.

The Department's Continuity of Supply Programme

1.7 The Department started work planning for the UK's departure from the EU in July 2016 and the preparations began to accelerate in summer 2018. **Figure 2** on pages 16 and 17 provides an overview of the key dates in the Department's planning for the UK's departure.

1.8 In December 2018, the Department brought all its preparations for maintaining supplies for the health and social care sectors under a single Continuity of Supply Programme (the Programme), and appointed the Department's chief commercial officer as the senior responsible officer. The Programme forms one of five core areas of work being taken forward by the Department as part of its preparations for the UK's exit from the EU. The other core areas focus on the NHS and social care workforce; reciprocal healthcare; research and clinical trials; and data-sharing, processing and access.

1.9 The Department's programme 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 objective does not explicitly mention supplies for social care. The Department has, however, stated that "contingency plans for 31 October will cover NHS, social care and the independent sector".

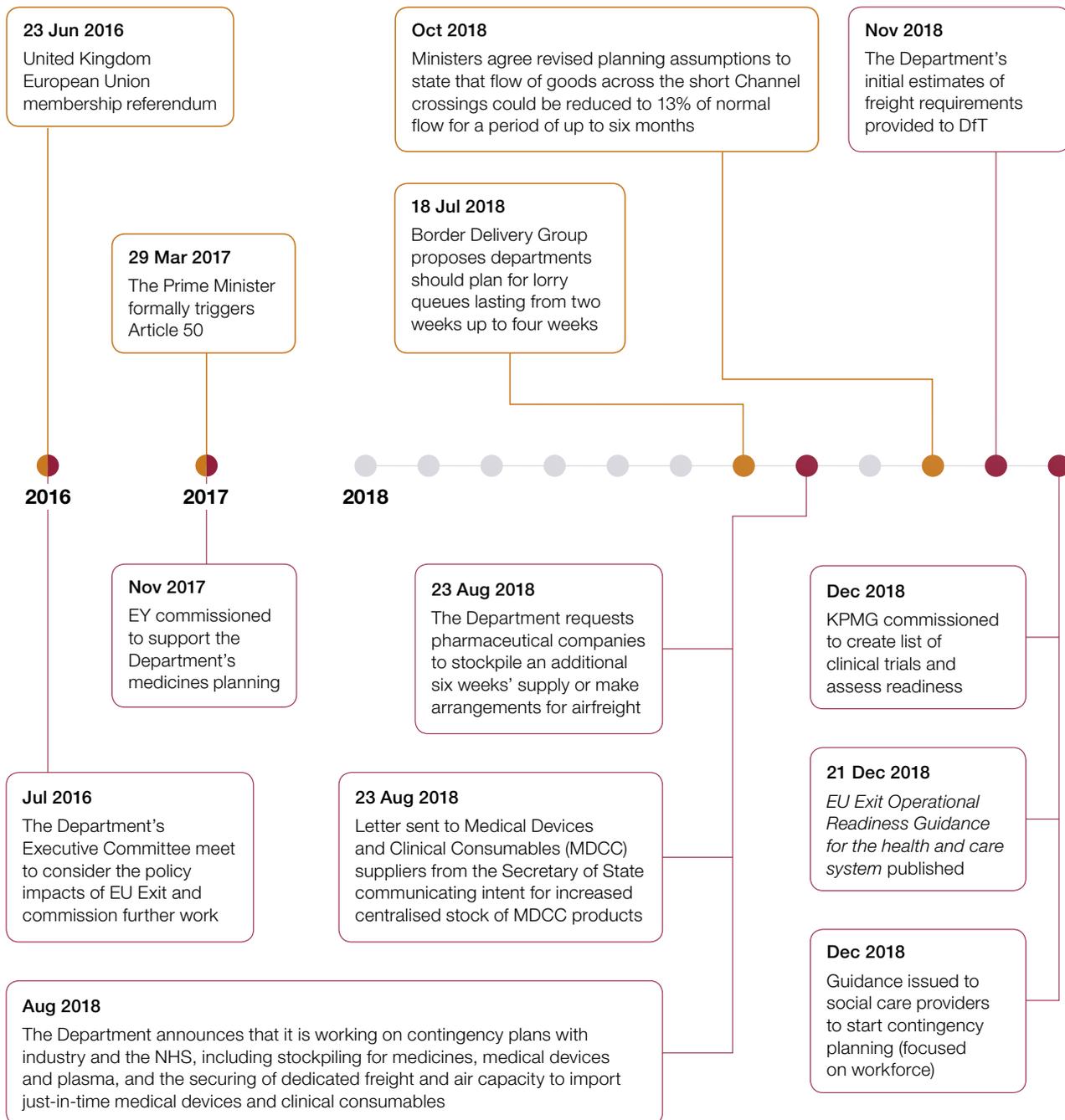
1.10 The Department developed a plan to ensure supplies remain unhindered. The key elements of the plan, known as 'the multi-layered approach', comprise:

- building up stockpiles and procuring additional warehouse space;
- re-routing priority supplies away from the short Channel crossings and improving supplier readiness;
- making changes to regulations to facilitate the movement of supplies; and
- taking action to strengthen its ability to address shortages should disruption begin to occur, for example by improving the timeliness and quality of information from front-line services.

Figure 2

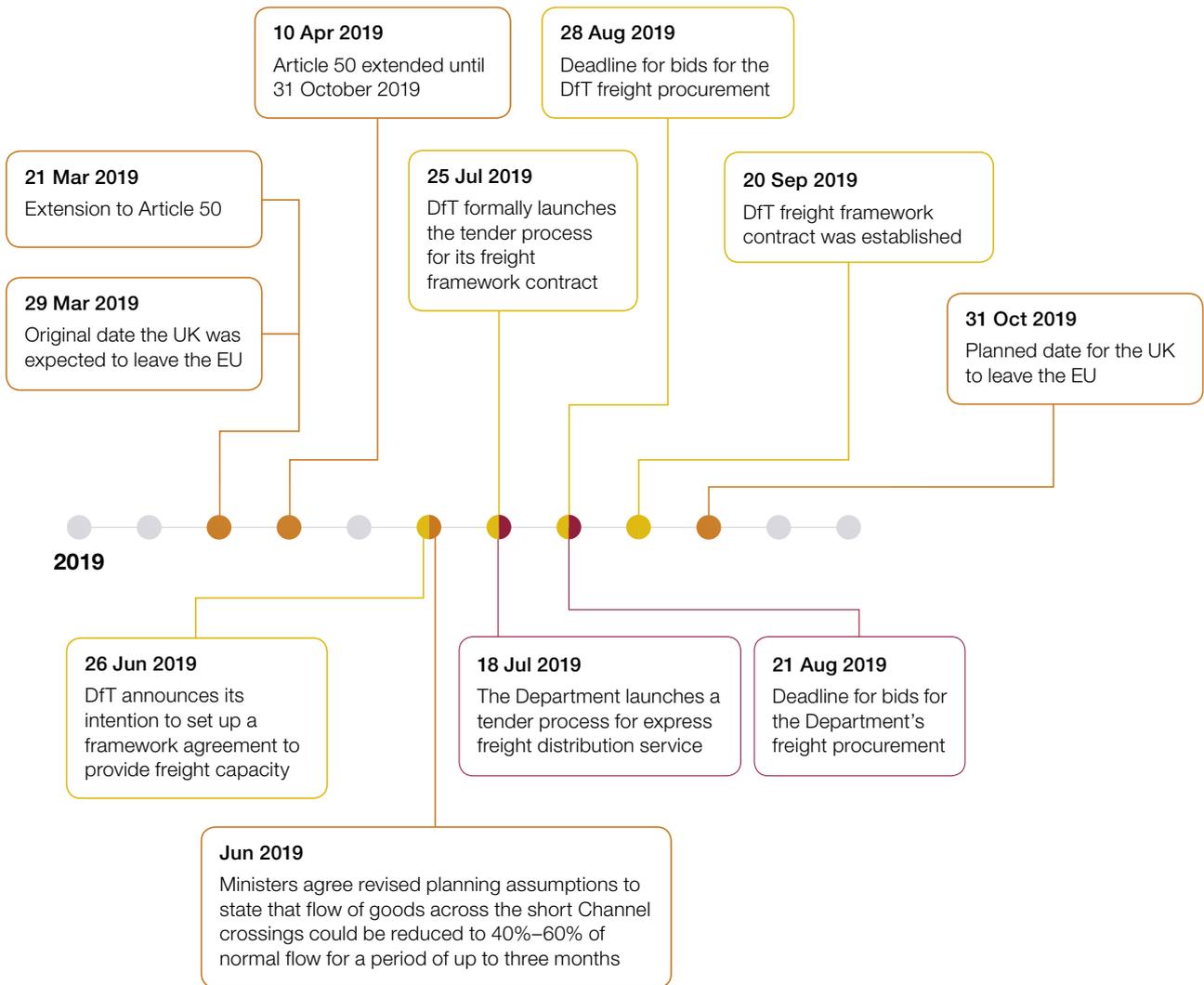
Timeline of preparations for a no-deal exit

Since June 2016 the Department of Health & Social Care (the Department), Department for Transport (DfT) and wider government have taken several actions to prepare for EU Exit



□ Department of Health & Social Care □ Department for Transport □ Wider government

Source: National Audit Office analysis of departmental and published documents



1.11 Since 2018, the Department estimates it has spent £50.1 million on the Continuity of Supply Programme, comprising £35.3 million in 2018-19 and £14.8 million to date in 2019-20. The latter amount includes warehouse costs of £8.2 million, spending on medicines of £2.5 million and other administration and staffing costs. The Department has committed to spend a further £37.2 million by 31 March 2020. It has also set aside a further £281.5 million as a contingency fund in case of need.

1.12 The Department for Transport (DfT) has received an additional £150 million from HM Treasury to secure freight capacity from October onwards, which will be mostly used to meet health and social care needs. DfT has also allocated a further £30 million for upgrades both to port infrastructure and connecting road and rail links, about half of which is planned to support no-deal EU Exit planning. It estimates that the 2019-20 administration cost of its freight capacity work so far has amounted to £1.7 million, with £0.8 million forecast to be spent by 31 March 2020. By 29 March 2019 it had incurred nearly £85 million in procuring ferry freight capacity – £51.4 million in cancellation fees and £33 million in an out-of-court settlement with Eurotunnel.

1.13 The Programme is supported by officials from NHS England and NHS Improvement (NHS E&I), NHS Blood and Transplant, and Public Health England as well as officials from across the Department. By August 2019 the Department estimated that it had approximately 90 full-time equivalent officials working on the programme with another 48 full-time equivalent staff working within NHS E&I.

1.14 The Department has a direct influence over how the NHS operates but its relationship with the social care sector is much more complex and its influence less direct. The chief executive of NHS E&I reports to the Board of NHS England and, as Accounting Officer for the NHS, is accountable to Parliament. For social care, which includes care homes, domiciliary care in people's own homes and other care services, the Department sets social care policy, secures funding and is accountable to Parliament and the public for the performance of the system as a whole. However, where social care is funded by the public sector, it is commissioned by local authorities, which do not have direct accountability to the government – instead they are accountable to the local population. Other social care is paid for directly by the people who use it, although this is still regulated by local authorities, who have a responsibility for safeguarding, and by the Care Quality Commission, which is accountable to the Department.

1.15 The Department reports on the programme's progress to the EU Exit Operations (XO) Committee.² It works closely with the Border Delivery Group and is also represented on the Freight Capacity Utilisation Board, which is chaired by DfT and coordinates requirements across government for freight capacity.

Scope of this report

1.16 This report examines the progress made by the Department in implementing its Continuity of Supply Programme. It sets out the Department's plan and records 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. The report sets out:

- progress against the Department's plans to build stockpiles and re-route supplies (Part Two); and
- other action taken to secure continuity of supplies before and after EU Exit (Part Three).

² The EU Exit Operations (XO) Committee is a Cabinet Committee that meets every week day to consider matters relating to the effective delivery of plans for an orderly exit from the EU.

Part Two

Putting the plans into action

2.1 This Part examines the progress made by the Department of Health & Social Care (the Department) in putting its plans into action:

- Building up stocks and procuring additional warehouse space.
- Re-routing supplies and procuring freight capacity.

Building up stockpiles and procuring additional warehouse space

2.2 The Department divided the range of supplies into six product category work streams (**Figure 3**). Each work stream has a designated responsible official within the Department. The Department, working with NHS England & NHS Improvement (NHS E&I), undertook work to understand:

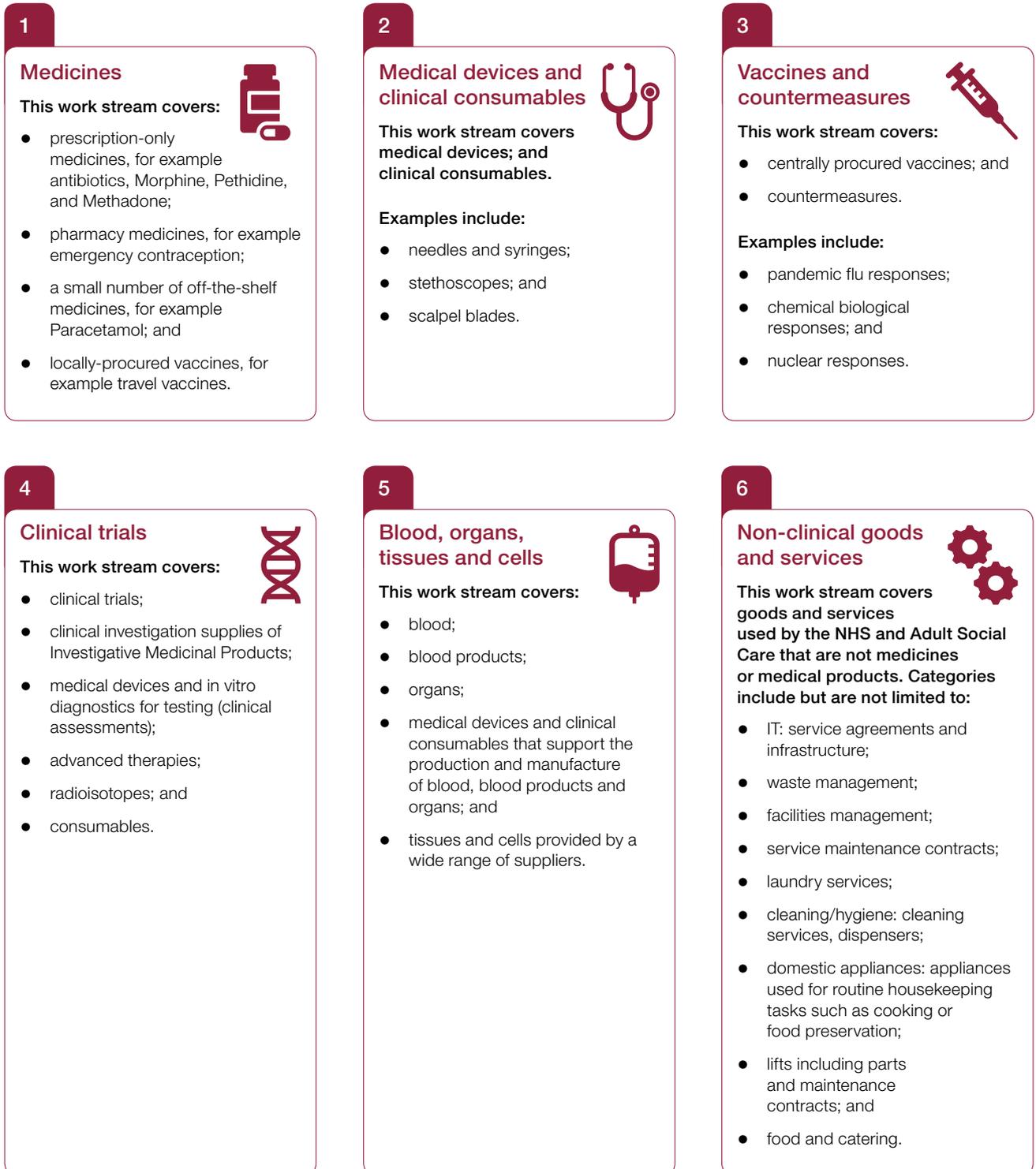
- the nature of products supplied in each work stream;
- their importance to daily operations; and
- the supplier market and their reliance on EU imports and the short Channel crossings.

The Department developed plans to secure continuity of supply for each work stream, drawing on the elements of the multi-layered approach where appropriate.

2.3 In August 2018, the Department asked pharmaceutical suppliers to stockpile up to six weeks' worth of medicine stock above business-as-usual levels for those medicines coming via the EU. These stockpiles are owned by suppliers. NHS bodies usually keep sufficient stock to meet immediate needs but do not have capacity to maintain significant stocks. For the planned no-deal exit date of 31 October 2019, the Department wrote to suppliers in June and asked them to ensure continuity of supply for their products through a combination of stockpiling and securing alternative routes into the UK. The Department advised suppliers to determine for themselves the appropriate balance between these strategies but suggested creating a stockpile of six weeks' worth of supplies as a default.

Figure 3

The Department's six product work streams for continuity of supply



2.4 The Department launched a survey of pharmaceutical suppliers at the beginning of July and is seeking further information from suppliers about their stockpiles and re-routing plans. As at 20 September, it had received responses from 69% of medicines suppliers in scope for the Continuity of Supply Programme (the Programme), which it estimates represents 90% of the market. The responses confirmed that at that point stockpiles of at least six weeks were in place for 72% of medicine product lines and suppliers reported that they had secured freight capacity away from the short Channel crossings for 25% of medicine product lines. In mid-February 2019, six weeks in advance of a potential 29 March 'no-deal' exit from the EU, it had received responses from 95% of medicines suppliers with stockpiles of at least six weeks in place for 91% of medicine product lines.

2.5 For supplies of medical devices and clinical consumables to the NHS, the Department worked with NHS Supply Chain to create a central stockpile of six weeks' worth of high-volume medical devices and clinical consumables, with a value, as of 20 September, of around £85 million, with a further £10 million worth of goods already ordered and due to be delivered before 31 October. NHS Supply Chain is a limited company, wholly owned by the taxpayer, that provides supplies to NHS Trusts and other healthcare organisations. It also asked suppliers of medical devices and clinical consumables to create their own stockpiles. It launched a survey of suppliers of medical devices and clinical consumables on 27 August to establish their readiness. As at 20 September, 109 of 189 priority suppliers (58%) confirmed plans to stockpile at least six weeks' worth of goods; 26 (14%) planned to stockpile less than six weeks of goods; and 54 (29%) had not yet responded to the survey.

2.6 In December 2018, the Department wrote to social care providers, for example nursing homes and domiciliary care providers, to ask them to ensure they have fully up-to-date and robust contingency plans for the possible implications of a no-deal EU Exit. As the NHS supplies the medicines for people in social care they are already included in the Department's planning for medicine supplies. But social care providers also rely on non-medicine supplies which in most instances, are not bought via the NHS. The Department does not have its own stockpiles of non-medicine items for social care. It has advised social care providers not to stockpile medical devices or clinical consumables, for example rubber gloves, but instead to ensure they are ready to deal with any disruption.

2.7 At present, the Department does not know what proportion of social care providers have followed its advice, what preparations providers have made with their suppliers and whether suppliers can 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 services provided by 24,000 regulated providers. Many providers are small and operate at a very local level: 80% of care home providers only operate one home. In terms of numbers of beds, for example, it is also much bigger with more than 400,000 beds compared with around 100,000 NHS beds. This makes planning for continuity of supply more difficult. During 2019 the Department issued guidance for the health and social care sectors about 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. The Department currently lacks reliable information on the extent to which its advice was followed by the social care sector.

2.8 The Department adopted a variety of approaches to building stocks of more specialist items, depending on the level of business-as-usual stocks, and whether it has direct responsibility for the activity and its assessment of priorities:

- **Vaccines** – The Department shares responsibility for vaccines with Public Health England (PHE). Vaccines procured by local health providers are factored into the wider medicines stockpiling programme overseen by the Department, while PHE leads on contingency planning for centrally procured vaccines and countermeasures. PHE usually holds four to six months' supplies of vaccines to support national immunisation programmes as part of its business-as-usual activities. In addition, PHE has brought forward some deliveries and worked with suppliers to ensure that contingency plans for re-routing are in place. The manufacture of the seasonal flu vaccine is dependent on decisions made by the World Health Organization about which virus strains it includes in the vaccine. As such, supplies are therefore not usually ready until autumn. The Department expects most winter flu vaccines to already be in the UK before 31 October. However, some adult flu vaccines are due to enter the country in the weeks after 31 October. The supplier has informed the Department that it has already taken steps to ensure the November delivery of the vaccines by moving its supply routes away from the short Channel crossings.
- **Clinical trials** – The Department has no direct day-to-day involvement in clinical trials. It estimates that 25% of supplies for clinical trials enter the UK via the short Channel crossings. As the organisations running clinical trials are responsible for ensuring continuity of supply, including making contingency arrangements, the Department asked the sponsors of clinical trials to consider their supply chains and put in place contingency measures. However, the Department has since decided that sponsors of clinical trials can use its additional warehousing capacity if they decide to create stockpiles. The Department has launched a survey of clinical trial organisers to find out the current state of readiness.

- **Bloods, organs, tissues and cells** – The UK makes most of these products, but a small amount of blood products and equipment come from the EU. NHS Blood and Transplant now has purchased eight to 12 weeks' worth of EU-sourced products, for example blood bags. It has more than the usual six-week stockpiles (paragraphs 2.3 and 2.4) in other areas because these goods have a long shelf-life and because it is the lead procurer for these supplies for the UK, as well as being the supplier of last resort to the Republic of Ireland, supplies for which are routed through the UK.
- **Products that can't be stockpiled** – For products with a short shelf-life or where production constraints mean stockpiling is not possible, for example radioisotopes, suppliers can use the freight capacity procured by the Department should they need to. The largest suppliers, responsible for at least 80% of radioisotope doses, have confirmed to the Department that they have plans in place to air freight stock into the UK after 31 October, to avoid delays at the short Channel crossings.

Additional warehouse space

2.9 In September 2018, the Department identified warehouse space as a barrier to pharmaceutical suppliers building the additional stockpiles of medicines referred to at paragraph 2.3 – in particular, space for products requiring storage at controlled temperatures. The Department therefore decided to procure additional space. It signed contracts with three companies in December 2018 and January 2019. It secured an additional 58,850 pallets of storage space (of which 5,000 are refrigerated, and 850 can hold controlled drugs). The space is available for a 12-month period.

2.10 Demand for space from pharmaceutical suppliers ahead of March 2019 was less than the Department had expected, and one of the three warehouses was not used. During the summer of 2019 the Department reassessed likely demand ahead of 31 October, and as a result it has reduced its requirements for additional warehouse space to a maximum of 48,000 pallets. It decided to terminate one of the three contracts, while keeping the other two contracts in place until the end of December 2019. It is keeping the situation under review. The Department pays the cost of preparing the warehouses for use. The space is let out by the storage companies to suppliers at normal commercial rates. The total contract costs are £10.9 million, of which the Department had paid out £8.2 million by the end of August 2019.

Re-routing supplies and procuring freight capacity

2.11 In autumn 2018, the government decided that maintaining additional stocks of ‘priority’ goods may not be sufficient to maintain supplies under its revised assumption for a ‘reasonable worst-case’ scenario (paragraph 1.3). It therefore decided to encourage the re-routing of supplies of priority goods away from the short Channel crossings ahead of 29 March and procure freight capacity to carry priority goods. In January 2019 it agreed with the devolved administrations that it would include capacity for the total amount imported into the whole of the UK. In February 2019 we reported on the procurement of ferry freight capacity to prepare for a possible no-deal exit on 29 March 2019.³ The contracts with the ferry companies were cancelled on 1 May.

2.12 The government has defined priority goods, known as Category One goods, to be those “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 and are therefore eligible for transport via the government-procured freight capacity. The definition does not encompass all supplies to the health and social care sectors – it excludes non-clinical goods and services and the government has not defined food as a priority good.

2.13 In December 2018, the Department estimated that it would need sufficient ferry freight capacity to accommodate 2,164 heavy goods vehicles (HGVs) per week at the end of March. This represented the estimated weekly volume of priority supplies for the health and care sectors.

2.14 The Department used a variety of methods to determine the need for freight capacity. For example:

- it surveyed medicines suppliers to understand how many medicines entered the UK via the EU and in what volumes; and
- it drew upon sales data from NHS Supply Chain to understand volumes. The Department estimates that 40% of hospital spend on medical devices and clinical consumables is through NHS Supply Chain. It did not have ready data on the supplies used for social care. It estimated the volume of goods used by the social care sector by taking the amount used by the hospital sector and doubling this amount to cover social care.

2.15 For 31 October 2019, the Department has increased its estimate of its freight capacity requirement by 7% to 2,326 HGVs per week. This mostly reflects an increased allowance for raw materials for medicines produced in the UK and a reduction due to some suppliers already securing alternative supply routes. The Department concluded that seasonal factors would not affect the amount of freight it needed. The figure includes a 30% contingency allowance, as advised in HM Treasury’s Green Book.⁴ The Department would like all of this capacity to be available from 31 October.

³ Memorandum to the House of Commons Committee of Public Accounts, *The award of contracts for additional freight capacity on ferry services*, National Audit Office, February 2019.

⁴ HM Treasury, *The Green Book: central government guidance on appraisal and evaluation*, 2018.

Procurement of government-wide freight capacity

2.16 DfT is in the process of securing freight capacity for 31 October. It 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 will now depend on how smoothly the rest of the procurement process runs, and how quickly the successful operators can respond. It is seeking to procure capacity on available freight services, which could include “vessels, trains or aircraft”. Eligible suppliers will be able to buy tickets from freight operators at a commercial rate. The ticket income will help offset the costs to the taxpayer.⁵ The procurement is in two stages. First, DfT ran a competition for a framework agreement. This created a pool of providers who can supply freight services. The framework was established on 20 September 2019. Second, following on from the establishment of the framework, the 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.

2.17 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. Both competitions aim to provide 1,273 HGV inbound and outbound 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 total 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 capacity requested by the Department of Health & Social Care amounts to 91% of the total.

2.18 DfT expects to award the contracts following the mini-competitions on 12 October, just less than three weeks before the UK is scheduled to leave the EU. The successful bidders of the mini-competitions will be responsible for providing transportation services for driver-accompanied or unaccompanied freight vehicles between the UK and the EU, as well as the supporting services needed to make them work, for example ticketing services and other operations. This means that until the mini-competitions are complete, DfT cannot advise companies about the details of the services to be operated. For both mini-competitions, DfT is looking to procure three broad types of freight service:

- Optimising the use of existing capacity, by booking tickets on existing services.
- ‘Sweating’ existing capacity, for example where a ferry usually does three return journeys per week, an operator might offer to add additional journey legs.

5 See footnote 3.

- Procuring additional capacity that is not currently available. For example, by contracting with an operator to bring a larger vessel onto routes outside the short Channel crossings.

2.19 DfT has indicated it is confident that the freight capacity procurement will be successful. However, the Ministry of Defence was requested to make available one of its freight vessels as a contingency measure. The vessel has capacity for approximately 150 unaccompanied HGV trailers per sailing and DfT and the Ministry of Defence are working together to operationalise the vessel for use if necessary.

Procurement of additional courier services by the Department

2.20 For 29 March 2019, in addition to the DfT-procured freight capacity, the Department procured its own ferry and air freight capacity. This arrangement, known as the Dedicated Shipment Channel, provided for 15 HGVs of sea freight and 0.7 HGVs worth of air freight per day. The Department wanted an arrangement in place to transport urgent supplies, if needed, and a means for transporting products usually supplied in smaller batches. The arrangement included a centre in Antwerp to consolidate packages into freight loads.

2.21 For 31 October 2019, the Department is – in a different approach to that used for March – procuring courier services that will collect consignments from the manufacturer at their European address and deliver them into specified addresses in the UK. The service will include customs and excise support services. It expects this service to be a contingency measure. Suppliers, who will pay for the service, will only draw on this contract where their own arrangements fail. The service is expected to be in place from 1 November.

2.22 The procurement is divided into three lots:

- Lot one provides for a delivery service for small parcels: up to 30m³ of parcels per day, to be delivered within 24 hours.
- Lot two provides for a shipment service for pallets: up to 50 standard European pallets per day, with a delivery time of one to four days. Most of these pallets will not require special conditions, for example temperature control, although some may do so.
- Lot three provides for goods that must be transported under special conditions, for example goods requiring temperature-controlled storage, compressed gases or biohazard materials. The Department is seeking to procure 5m³ of capacity for medicines each day, and an additional service for other goods as required, all with a delivery timescale of 24 hours.

2.23 All three contracts are for an initial period of 12 months, with the option to extend for a further 12 months. The Department estimates the total value of the contracts to be £25 million. It expects to pay £3.9 million of this, with the rest of the costs met by companies using this service, provided the service is fully used.

2.24 The Department launched the procurement on 23 July 2019. The deadline for bids was 21 August. The Department expects to sign the contracts on 8 October and for the services to be in place for testing by 24 October. The Department then has one week to test the services and resolve any issues before it expects to begin operating on 1 November.

Practical challenges for suppliers

2.25 Evidence collected by the Department suggests suppliers are taking different views on the need to re-route away from the short Channel crossings. A survey of pharmaceutical suppliers undertaken by the Department from the beginning of July – which by 20 September had a response rate of 69% of suppliers, accounting for 90% of the market – showed:

- suppliers of 25% of medicine product lines had secured capacity on alternative routes into the UK;
- suppliers of 20% of medicines product lines plan to use an alternative route but had not yet secured capacity;
- suppliers of 33% of medicines product lines had either decided against re-routing or had not yet made any plans to do so; and
- suppliers of the remaining medicine product lines have not provided a response to the Department.

2.26 In June 2019, the government estimated that across all economic sectors 50%– 85% of HGVs using the short Channel crossings may not be ready for new French customs procedures. In September, we consulted with the trade bodies that supply the health and social care sectors. They were very supportive of the assistance they had received from the Department, but their members had concerns about cross-government delays in issuing detailed information on how the border would work after 31 October, without which it would be difficult to put plans fully into place. In addition, the trade bodies told us that there remained a lack of clarity about how government-secured freight capacity will operate in practice, and how their members and logistics providers will access this.

2.27 The Department, working with the Border Delivery Group, is seeking to improve awareness of new border processes among suppliers in the health and social care sector. The Department established an industry working group to share information with the sector, to inform the development of the Programme and to support central government planning. The Department used this group to work with the sector and to try to influence and support central government planning. Members of the group signed non-disclosure agreements to enable the Department to share information with them. On 22 August 2019, it was announced that these agreements would only be maintained when government feels it is strictly necessary. The Department has told us that non-disclosure agreements are no longer in use for this group. On 1 September 2019, the government launched a communications campaign to support individuals and businesses to prepare. In addition to advertising widely, the campaign includes face-to-face business readiness events and forums across the UK and a weekly bulletin providing the latest guidance.

2.28 Keeping the flow of HGVs going also depends on adequate port infrastructure and keeping connecting road networks open. On 30 August DfT announced a new fund of £30 million for upgrades both to port infrastructure and connecting road and rail links. The plans include:

- £10 million for ports across England to help deliver upgrades which will enhance capacity and maintain the flow of HGVs;
- £5 million for four Local Resilience Forums to help build infrastructure improvements to minimise any potential traffic disruption at the UK border; and
- £15 million for longer-term projects to boost road and rail links to ports.

Part Three

Other action to secure continuity of supply

3.1 The Department of Health & Social Care (the Department) is taking a range of other action to strengthen its ability to secure supplies. For example:

- making changes to regulations to facilitate the movement of supplies;
- strengthening its process for managing potential shortages;
- improving the timeliness and quality of information it receives on local impacts and strengthening its ability to respond; and
- strengthening its monitoring of market and pricing behaviours.

Making changes to regulations to facilitate the movement of supplies

3.2 The Department has introduced three statutory instruments to amend the regulations governing the supply of medicines, medical devices and supplies for clinical trials. These changes are intended to ensure that supplies can continue to enter the UK in the event of the UK departing the EU without a deal. The main provisions include:

- automatically converting EU product licences into UK licences at no cost to industry;
- confirming that medicines can continue to be imported into the UK from the EU under the Parallel Importation Scheme for one year after exit day. At present, because the UK is part of the EU's single market, medicines sold by wholesalers into one part of the EU can be bought and sold on in another country. This is known as parallel importation. For parallel imports to continue beyond the first year, EU regulators will need to agree to share the required information with the Medicines and Healthcare products Regulatory Agency; and
- confirming that medical devices and clinical consumables approved for sale in the EU are automatically approved for sale in the UK, for a limited period, to allow manufacturers to complete any necessary additional registration. The UK will continue to recognise batch certification that takes place in the UK, EU and EEA until the government considers any further change is necessary. The UK will also recognise batch testing from the UK, EU, EEA and third countries with whom the EU currently has arrangements in place in this regard.

Strengthening procedures for managing shortages

3.3 As part of normal day-to-day operations, the Department and NHS England and NHS Improvement (NHS E&I) have processes in place to manage shortages of medicines. Shortages can be caused by a range of factors, for example manufacture and supply problems and unexpected spikes in demand. When the Department is notified of a shortage, usually by the supplier, the problem is assessed by the Department and NHS E&I against a range of criteria and the incident assigned to one of four risk tiers. The Department may then undertake a range of actions to address the issue. The four risk tiers are:

- Tier 1 – Low patient risk and assessed as no further action required;
- Tier 2 – Additional work needed to create a supplier resolution and mitigation plan. For example, the Department might ask suppliers to share out supplies among NHS organisations, rather than fulfilling large orders for some hospitals and leaving others without supplies;
- Tier 3 – Requires exploring clinical or other therapy substitutions; and
- Tier 4 – An emergency situation requiring emergency planning support.

On average, the Department estimates that there are around 100 medicine shortages at any one time and most of these are assessed by the Department as Tier 1.

3.4 Ahead of EU Exit, the Department has strengthened its procedures. It has recruited a network of pharmacists so that, should the number of shortages increase, there is a cohort of staff to manage and support the process. This extended team was in place for March 2019 and additional pharmacists are due to be recruited for October. The Department informed us that it has also put in place a medicines shortage response group and strengthened its communication routes to general practices and community pharmacists.

3.5 In early 2018 the Department also introduced a Serious Shortage Protocol. The Protocol allows community pharmacists to fill a prescription with a different medicine to the one prescribed, under certain circumstances, with a very specific product direction based on clinical advice. There are a number of safeguards around the process: pharmacists can only prescribe from a number of specified alternatives that are included in a list following a review by senior clinicians.

Improving the timeliness and quality of information on emerging local issues

3.6 In the period following a no-deal exit, the Department plan to gather information to create daily reports on how the health and social care sectors are operating. It would receive information through several channels:

- The **National Co-ordination Centre (NCC)**, which is run by NHS E&I and usually convened to manage events that require a national NHS response. The centre would review reports about how the NHS is operating at the front line and deal with enquiries from NHS staff. The NCC is supported by regional boards, which would receive reports from the designated senior responsible officers for EU Exit in each NHS organisation. In addition to receiving information from the front line, the NCC would provide advice and support to NHS organisations via a call centre. Where hospital suppliers need to access government freight capacity, the NCC would refer them to the National Supply Disruption Response (see below).
- **Local Resilience Forums (LRFs)** would feed information to central government about how local services are operating. LRFs are responsible for civil contingency planning at local level and comprise representatives from organisations delivering essential local services, for example the emergency services and local government. There is one LRF for each of the 43 police force areas in England and Wales. Consolidated information from LRFs would then be reviewed by the Resilience and Emergencies Division in the Ministry of Housing, Communities & Local Government (MHCLG). This would include any urgent supply issues impacting on the provision of social care by a provider. This information would then be shared with the Department by MHCLG.
- The **National Supply Disruption Response** is a command centre run by the Department. It will be available to all health and social care stakeholders, not just NHS providers. The response team would receive information from the NCC, LRFs and other sources on stockpile levels, any pressures on supplies, and other relevant issues. The response team would then provide a daily briefing to ministers on the latest situation. The team would also be the gateway through which suppliers can access the government-procured freight capacity by providing suppliers with access codes which will allow them to purchase tickets with freight operators.

Monitoring and managing financial risk

3.7 The Department recognises that it may need to manage a number of financial risks. These include increased price volatility on goods if shortages begin to be constrained and/or exchange rate risks. There is a claw-back mechanism which caps health expenditure on medicines that are still within patent. However, no similar mechanism exists for other types of supplies.

Appendix One

Our approach and evidence base

Scope

1 This report examines the progress made by the Department of Health & Social Care (the Department) – working with other government departments, NHS England and NHS Improvement, social care providers, and with suppliers – against its plans to mitigate the risk of disruption to supplies. This report sets out the facts relating to:

- the role of the Department in its Continuity of Supply Programme (the Programme) in the health and social care sectors;
- the scope of the Programme and the Department’s multi-layer response;
- the Programme’s governance arrangements;
- the costs to government of planning for a no-deal exit relating to continuity of supply;
- the Department’s progress against the Programme’s objectives; and
- the role of the Department for Transport (DfT) in securing freight capacity.

Evidence base

2 We have produced this report after reviewing evidence collected between 1 August and 23 September 2019. We:

- interviewed officials in the Department involved in implementing the programme to understand the programme’s scope, structure and progress to date;
- reviewed key documentation held by the Department on the supply of medicines and medical devices in the health and social care sectors;
- interviewed officials in DfT;
- reviewed key documentation held by DfT. This included: DfT’s business case; documentary evidence of the procurement process; and the signed contracts; and
- interviewed a selection of third parties. While we have not had time to thoroughly consult third parties who are working with the departments or relying on the mitigations the departments are putting in place, we have spoken to a selection of organisations to understand their perspectives on the task and the actions of departments.

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