Comptroller and Auditor General
Special Report

Emergency procurement of ventilators by the Health Service Executive

Report number 114 December 2022

Report of the Comptroller and Auditor General

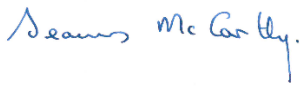
Emergency procurement of ventilators by the Health Service Executive

I have, in accordance with the provisions of Section 9 of the Comptroller and Auditor General (Amendment) Act 1993, carried out an examination of the emergency procurement of ventilators by the Health Service Executive in the context of the Covid-19 pandemic in 2020.

This report was prepared on the basis of information, documentation and explanations obtained from the public bodies and persons referred to in the report. The draft report was sent to the chief officers of the Health Service Executive, the Department of Health, the Department of Public Expenditure and Reform, IDA Ireland and the Health Products Regulatory Authority. Where appropriate, responses were incorporated in the final version of the report.

The purpose of this report is to examine the use of public resources with respect to the emergency procurement of ventilators by the Health Service Executive. The sole focus of this report is on the performance of public bodies, not on staff members of those bodies or any third parties. For the avoidance of doubt, this report does not make any criticism or comment or present any view, whether express or implied, with respect to staff members of public bodies or third parties, and should not be understood as doing so.

I hereby submit the report for presentation to Dáil Éireann in accordance with Section 11 of the the Comptroller and Auditor General (Amendment) Act 1993.



Seamus McCarthy
Comptroller and Auditor General

7 December 2022

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Summary

The World Health Organisation determined in early 2020 that ventilators would be a critical medical device in the treatment of patients severely affected by Covid-19 infection.

By early March 2020, the Health Service Executive (HSE) identified that additional ventilators were urgently needed to deal with the expected surge in demand for critical care. The majority of decisions made by the HSE in respect of the emergency procurement took place over a four-week period between March and April 2020.

The HSE purchased 581 ventilators at a cost of €20.5 million from its established suppliers.

The HSE identified, through a variety of means, a number of potential suppliers of ventilators that it had not previously done business with. These included both manufacturers of devices and intermediaries. In order to secure orders, the HSE made advances to the new suppliers totalling €81 million.

Following the subsequent cancellation of orders, the HSE received a number of refunds of advance payments, totalling €50.5 million.

The HSE did not receive benefit or use from expenditure of €30.5 million, which therefore represents a loss of value. The HSE is pursuing refunds of €22.3 million for orders that were cancelled or where the ventilators received were deemed not fit for purpose. Expenditure of a further €8.1 million is considered to be unrecoverable. The majority of this (€6.8 million) relates to ventilators purchased that the HSE ultimately did not need. These have since been donated to health authorities in India.

Assessment of ventilators needed

The HSE identified that, in March 2020, it had a total of 533 ventilators available for use for adult patients.

Under an arrangement with 18 private hospitals, it was estimated that an additional 55 ventilators (48 ICU grade and seven transport ventilators) would be available to the health service for the three months April to June 2020. These were not taken into consideration when determining the number of ventilators on hand and available for use.

By late March 2020, HSE clinical staff had estimated as part of its ‘surge capacity planning’ that an additional 326 ventilators would be needed. This number was based on the maximum extent by which critical care capacity in the Irish health system could be increased to deal with the expected influx of Covid-19 patients.

Through purchases from its established suppliers of ventilators, the HSE was able to procure 581 ventilators — nearly twice the estimated number clinically required, and that could be used.

Although the HSE sought initially to purchase ventilators similar to models typically used in ICUs in Ireland, it subsequently decided to purchase models that had a lower technical specification but that met the WHO specification for the treatment of patients with Covid-19.

In response to a proposal from the HSE, the Department of Health on 21 March 2020 sanctioned the purchase of 1,900 ventilators at an estimated cost of €73.5 million — an implied average unit cost of €38,700. This examination was unable to find a business case prepared by the HSE to support the requirement for 1,900 ventilators. Instead, the quantity for which sanction was requested appears to have been based on the orders that the HSE had already placed with potential suppliers and orders that were at an advanced stage of negotiation.

Between 3 March 2020 and 14 April 2020, it can be identified that the HSE placed orders for almost 3,500 ventilators at a total cost €129 million — nearly twice the number approved by the Department and over ten times the estimated number clinically required.

Sourcing suppliers

The HSE approached its established suppliers in the first instance to enquire for availability of ventilators. Due to HSE concerns around their capacity to meet the demands, the HSE then began investigating other potential suppliers, with the assistance of IDA Ireland. Direct approaches were also received by the HSE from a variety of sources with offers of assistance.

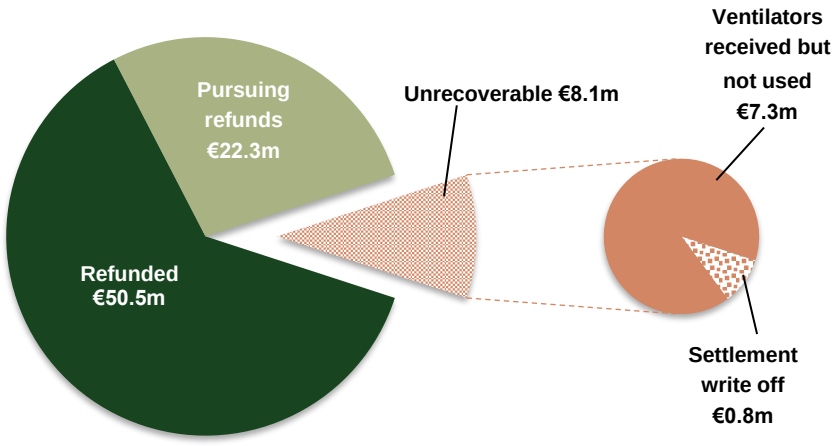
Most of the new potential suppliers identified were not directly involved in the manufacture of ventilators and had little or no experience in the supply of those devices but represented they had connections to manufacturers of devices.

No due diligence checks were carried out for four of the ten new potential suppliers to whom the HSE made advance payments. The extent of checks completed for the other six varied from commercial research to a high-level risk assessment.

Advance payments

Between 24 March 2020 and 14 April 2020, the HSE made combined advance payments of €81 million to the ten new suppliers to secure almost 2,200 ventilators. A total of €50.5 million has been recovered, but as at May 2022, the remainder was still being pursued, or was being treated by the HSE as unrecoverable (see Figure 1).

Figure 1 Status of advance payments to the new suppliers at May 2022



Source: Analysis by the Office of the Comptroller and Auditor General. Any inconsistent totals are due to rounding.

Quality of ventilators purchased

The usual clinical and technical support provided by suppliers of ventilators was not available from the new suppliers. The HSE also had no previous experience using any of the ventilator models being offered by those suppliers. Orders were placed with the new suppliers on the basis of a 'desk review' by HSE staff of documentation provided by the prospective suppliers, and the attendance by HSE senior clinicians and clinical engineering staff at a demonstration of two sample ventilator models provided by one of the new suppliers.

However, quality issues emerged quickly after the first deliveries of devices from some of the new suppliers, including a number of devices delivered directly to some of acute hospital sites. Performance tests completed by a third party on behalf of the HSE found that of 100 ventilators tested, 41 failed. A further desk-based review by the Health Products Regulatory Authority of supplier documentation found that two models did not comply with the EU regulatory framework and that three models required further investigation.

In light of the significant quality issues identified coupled with the risk to patient safety, the acute hospitals were advised by the HSE's Head of Clinical Engineering, as agreed with the Head of Critical Care, not to put the ventilators into use. HSE Procurement was also advised to cease accepting delivery of the ventilators sourced from these suppliers. However, the HSE did not cancel the remaining orders it had placed with two suppliers for 365 ventilators at a cost of €6.8 million. This followed advice from the IDA that the deliveries from the suppliers, who were manufacturers of devices, were on schedule and that as these were 'sensitive' supply lines, no intervention should be made to the orders.

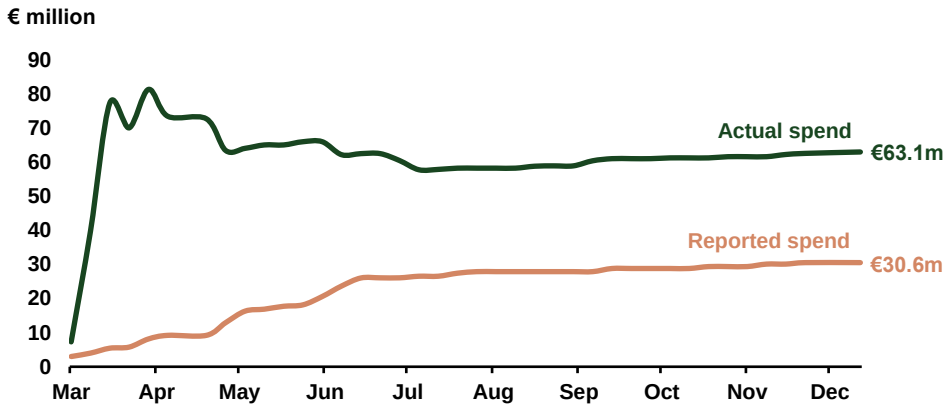
None of the total of 467 ventilators received from the new suppliers were put into clinical use in Ireland.

Cost and deployment

On 20 March 2020, the HSE wrote to the Department of Health and to the Department of Public Expenditure and Reform (DPER) requesting approval to contractually commit for up to 1,900 ventilators at an estimated cost of €73.5 million. The letter stated that further approval would be sought in writing for any ventilators purchased beyond this number.

In accordance with the conditions of the sanction for the purchase of ventilators, the HSE sent a weekly expenditure report to the Department and to DPER. The report only included expenditure for ventilators that had been delivered and did not include the payments in advance and refunds received from cancelled orders (see Figure 2). This was seriously misleading and negated the effectiveness of the Departments' oversight of the expenditure.

Figure 2 Cumulative actual and reported spending on ventilators, March to December 2020[a,b]



Source: Analysis by the Office of the Comptroller and Auditor General

Notes:
a Some units purchased from established suppliers were delivered in quarter three and quarter four of 2020.

b The HSE received a refund of €500,000 in August 2021, and a further refund of €11.6 million in early December 2021. This reduces the outlay at year end 2021 to €51 million.

Emergency procurement of ventilators by the Health Service Executive

Section 1

Introduction

1.1 In early 2020, the World Health Organisation (WHO) determined that ventilators would be a critical medical device in the treatment of patients severely affected by Covid-19.

1.2 In March 2020, the Health Service Executive (HSE) commenced the emergency procurement of additional ventilators to treat patients suffering with respiratory symptoms associated with Covid-19. The majority of decisions relating to the procurement took place within a four-week period between March and April 2020.

1.3 The HSE purchased 581 ventilators at a cost of €20.5 million from its established suppliers (see Appendix A).[1] A further 467 ventilators were purchased from new suppliers that the HSE had not previously done business with. Advance payments were made to the new suppliers totalling €81 million to secure orders (see Appendix B).

1.4 A number of State bodies assisted the HSE with the emergency procurement process (see Figure 1.1). A subgroup of the National Public Health Emergency Team (NPHET), called the Medical Devices Criticality Assessment Group (MDCAG), was tasked with overseeing the response to medical device supply issues and shortages as a result of Covid-19. The terms of reference for this group are set out at Appendix C.

Emergency procurement

1.5 The primary objective of good public procurement is to ensure that goods and services of the required type, quality and quantity are acquired in a timely way, and in a manner that complies with relevant public procurement rules. This should result in the achievement of economy in the use of scarce public funds, while also ensuring fairness to all potential interested suppliers.

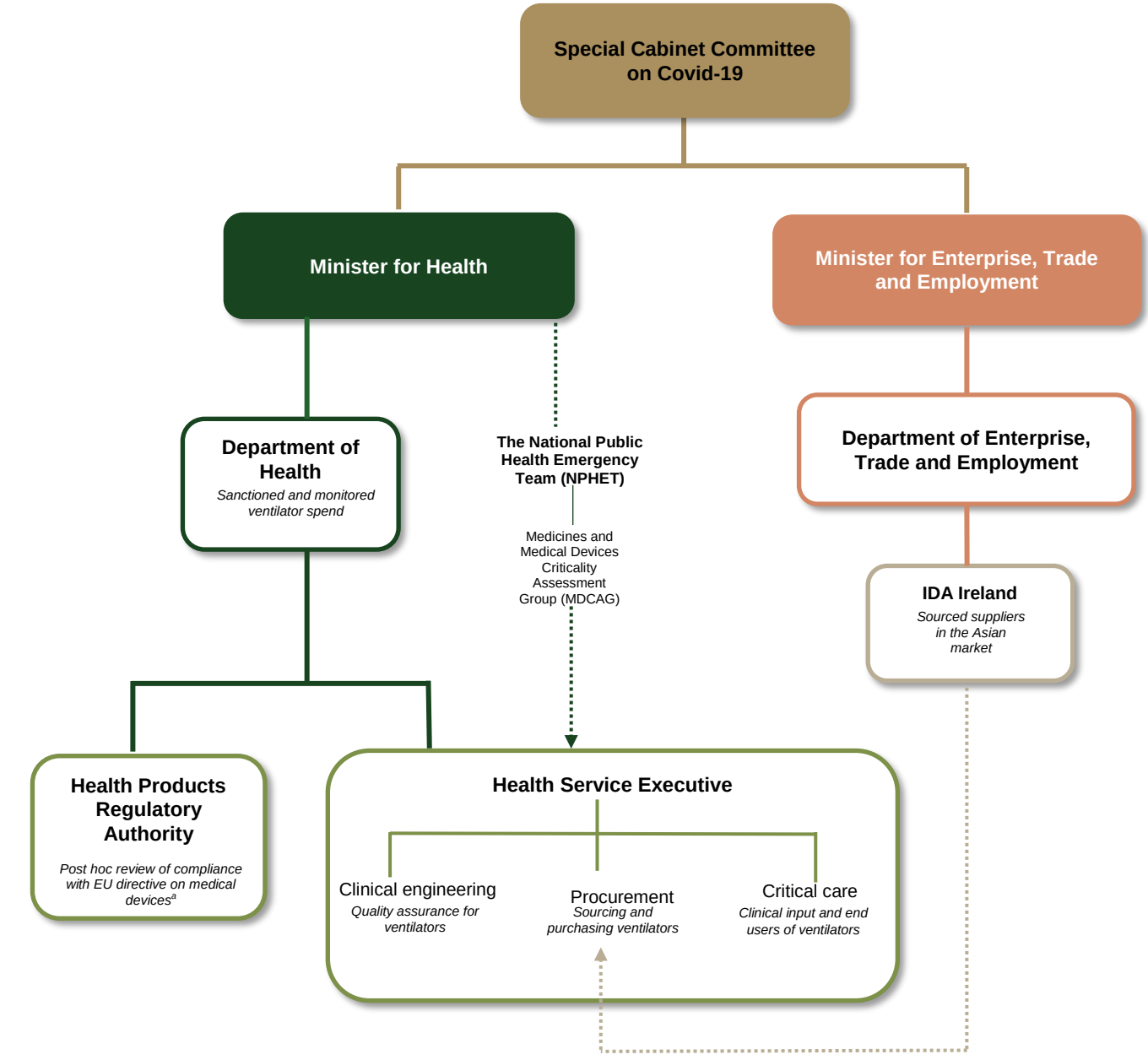
1.6 EU procurement law recognises that circumstances may arise where it is not possible or appropriate to follow the normal procurement procedures. The exceptions provided for include procurement of goods and services in an emergency situation, when a procuring public authority is permitted to dispense with standard competitive tendering processes.

1.7 In April 2020, the EU Commission provided guidance to member states on how to use the flexibility provided by the EU's public procurement framework to respond to the Covid-19 emergency. The framework permits purchasing bodies to negotiate and contract directly with suppliers in cases of extreme urgency brought about by unforeseeable events.[2]

1 Five acute hospitals separately directly purchased a total of 34 ventilators costing €1.13 million (including VAT) — St Vincent's University hospital €626,700; St. James's hospital €285,500; Wexford General hospital €108,900; Clonmel hospital €73,200 and Tullamore hospital €36,300. The last three of these are directly run by the HSE.

2 Article 32 of Directive 2014/24/EU on public procurement.

Figure 1.1 Overview of the State bodies involved in emergency procurement of ventilators



Source: Office of the Comptroller and Auditor General

Note: a Medical Devices Directive 93/42/EEC.

Focus of this report

1.8 This examination was undertaken to review the HSE's management of the emergency procurement of ventilators. In particular, it sought to examine

- whether the HSE was effective in obtaining the required number of ventilators of the required quality
- whether the HSE identified and managed the risks associated with the emergency procurement effectively
- whether the HSE had a robust system in place for checking the ventilators purchased
- how the costs incurred during the emergency procurement were monitored and evaluated, and the extent to which the ventilators purchased were effectively deployed.

Methodology

1.9 The examination team interviewed staff from the HSE, the Department of Health (the Department), the Department of Public Expenditure and Reform (DPER), IDA Ireland, and the Health Products Regulatory Authority (HPRA).

1.10 A range of documentation relating to the emergency procurement was provided to the examination team. This included

- e-mail correspondence and contemporaneous notes
- official minutes of meetings and meeting papers
- relevant invoices and purchase orders
- multiple spreadsheets recording orders, delivery timelines, number of ventilators on hand etc.
- contracts and legal correspondence
- internal reports and memos.

1.11 The HSE has stated that time constraints and supply chain issues meant that the usual procurement records were not fully maintained during the emergency response to the pandemic.

1.12 The examination team also engaged with the HSE's internal audit division and reviewed the findings of an internal audit report on the procurement of ventilators completed in June 2021.

Section 2

Assessment of the need for ventilators

2.1 Typically, public procurement begins with the assessment of the business need. In doing so, the intended use of the goods along with the available budget are taken into consideration. Based on that assessment, the technical specification and required quantity of the goods are usually determined.

Required specification

2.2 Ventilators are medical devices used to deliver medical gas comprising of varying concentrations of oxygen into the lungs of critically ill patients, assisting them to breathe. The devices are regulated under an EU framework that includes a range of measures to ensure their safety and efficacy.[1] A wide range of ventilator models is available, with different technical specifications for different models. Critical care ventilators are intended for use in specialised healthcare environments and can only be installed and operated by trained professionals.

2.3 When purchasing a ventilator, the standard process in the HSE to identify the clinical need for the device and to determine the technical specification required usually takes up to 12 weeks. The process includes an assessment of

- the clinical speciality of the critical care unit requesting the ventilator
- the type of patient (e.g. adults/children)
- the type of respiratory conditions typically treated in the critical care unit
- the experience and training of critical care staff with particular ventilator models
- technological developments
- compliance with EU regulatory standards.

2.4 In early 2020, the WHO set out the minimum technical specification of a ventilator to be used to treat Covid-19 patients.[2] In early March 2020, the MDCAG noted that ventilators used in intensive care units (ICUs) in Irish hospitals were of a higher technical specification than the specification set by the WHO.

2.5 Initially, the HSE sought to purchase ventilators of a similar make, model and specification as those typically used within its ICUs for safety, and ease and speed of commissioning. However, by 22 March 2020, the HSE had decided that it would also be prepared to purchase ventilators that met the WHO specification.

Number of ventilators on hand

2.6 The HSE does not have a centralised asset register. Therefore, in order to establish the number of ventilators on hand, the HSE relied on a medical devices database maintained by HSE clinical engineering for equipment maintenance and replacement purposes.

1 Medical devices within the EU are currently regulated by one Regulation and three Directives: Regulation (EU) 2017/745; Council Directive 90/385/EEC; Council Directive 93/42/EEC; Directive 98/79/EC.

2 The 'disease commodity package' for Covid-19 was initially published on 29 January 2020 and updated on 6 March 2020. This is a disease-specific datasheet that lists the technical specification of each key commodity needed to allow healthcare systems to respond quickly and effectively.

2.7 The medical devices database captures information such as the location of the device, the manufacturer, the model and the installation date. It does not contain a unique device identifier, such as the serial number or an asset number. Each acute hospital has more detailed information including serial numbers and the service history of each ventilator. Therefore, the acute hospitals were also surveyed to confirm the number of ventilators on hand (see Figure 2.1). This revealed a small discrepancy in the reported numbers of devices, which was attributed to duplicate records and misclassifications.

Figure 2.1 Ventilators on hand at 1 April 2020

Source	Number of ventilators	HSE explanation for difference
Clinical engineering medical devices database	725	
		Duplications and misclassifications
Acute hospitals survey response	710	
		Exclude neo-natal equipment and equipment not capable of ICU level therapy
Ventilators on hand in acute hospitals	533	

Source: Health Service Executive

2.8 Based on this assessment, the HSE concluded that acute hospitals had a total of 533 ventilators available for adult use in March 2020.

2.9 On 30 March 2020, the HSE entered into an agreement with 18 private hospitals. The agreement provided for full hospital capacity and services within the private hospitals to be used for the treatment of public patients on behalf of the HSE. The agreement was in place until 30 June 2020. The MDCAG at a meeting on 14 April 2020 noted that there were a further 48 ICU grade ventilators and seven transport ventilators within the private hospitals. These were not taken into consideration when determining the number of ventilators on hand and available for use in the public hospital system.

Projected additional number of ventilators clinically required

2.10 Throughout March and April 2020, the HSE was assessing the maximum extent to which critical care capacity (beds, medical equipment, staffing, oxygen etc.) could be increased to deal with the potential influx of Covid-19 patients. This exercise was referred to by the HSE as 'surge capacity planning'. By 23 March 2020, the HSE estimated that an additional 326 ventilators would be needed to support maximum surge capacity. This estimate was not revised when new information became available on the number of ventilators on hand (e.g. in the private hospitals, or following deliveries) or when subsequent revisions were made to surge capacity plans.

2.11 By the end of March 2020, clinicians on the MDCAG began flagging the need for an exercise focused on predicting ICU patient numbers along with ventilator demand, prior to any more ventilators being ordered. However, such information was not available until the middle of April 2020.[1]

1 The Irish Epidemiological Modelling Advisory Group was formed on 11 March 2020 to provide statistical and mathematical modelling to the Chief Medical Office and the National Public Health Emergency Team. Minutes of the group indicate that modelling information including potential ICU demand was available to the HSE by 15 April 2020.

2.12 On 30 March 2020, the Chair of the MDCAG e-mailed the HSE's Head of Critical Care informing him that it was the Department's view that as many ventilators as possible should be purchased (extract from e-mail below).

> ***30 March 2020 — E-mail from Chair of MDCAG to Head of Critical Care***
>
> *"I had a discussion with the Department last week in relation to the demand for ventilators and I was told in no uncertain terms to get what we can and in the event it is too many in a few weeks' time then we will have no shortage of takers. So on this basis I am going to review this in a week's time."*

2.13 The Department has stated that their records do not indicate that there was ever a formal instruction or advice to purchase as many ventilators as possible. However, the Department acknowledges it is possible that there were conversations between individual MDCAG members along these lines, particularly as there was very limited access to modelling data at that time to inform purchasing requirements. The Department acknowledges there was also a broad assumption among Department staff that any surplus ventilators could potentially be sold or donated to other EU member states, or third countries, if it transpired that they were not needed in Irish hospitals.

Approval for expenditure

2.14 A submission to Cabinet in the week beginning 15 March 2020 referred to an additional 500 ventilators being sought.

2.15 On 20 March 2020, the HSE wrote to the Department and to DPER requesting approval to commit contractually for up to 1,900 ventilators at an estimated cost of €73.5 million. The letter stated that the HSE would seek in writing further Departmental approval for any ventilators purchased beyond this number.

2.16 There was no business case provided by the HSE to support the purchase of 1,900 ventilators. The quantity proposed appears to have been based on the orders already placed by the HSE as at 20 March 2020 (i.e. 900 units) plus orders at an advanced stage of negotiation (i.e. 1,000 units).

2.17 The HSE's letter of request for approval implies an average unit price for ventilators of just under €38,700. Prior to approving the expenditure, the Department confirmed that this projected unit cost was in line with the cost range of €19,000 to €38,000 set out in a report completed by a consultant in 2016.

2.18 On 21 March 2020, the Department confirmed in a letter to the HSE that 'funding of €73.5 million only' would be provided to the HSE for the purchase of 1,900 ventilators. The letter of sanction noted that the commercial and contractual details of the transaction would be a matter for the HSE. The Department also directed the HSE specifically to ensure that value for money would be achieved in the procurement.

2.19 The Department confirmed that DPER had sanctioned the funding amount, but that it (DPER) had stipulated that the expenditure was to be closely monitored to ensure that the sanctioned level of expenditure was not exceeded.

Orders placed

2.20 This examination has been unable to establish the total number of ventilators actually ordered by the HSE. A spreadsheet was used by the HSE to track purchase order placement, and the subsequent cancellation of some orders. However, information in the spreadsheet was overwritten as orders were reduced or cancelled.

2.21 An audit trail does exist for orders placed with established suppliers and orders with new potential suppliers that were secured with payments in advance. On 6 February 2020, the HSE placed its first order for ventilators (12 units). No further orders were placed until 3 March 2020. By 20 March 2020, orders had been placed for 900 units, and by 14 April 2020, the HSE had committed to orders for a total of 3,429 units at a total cost of €129 million. This comprised orders for 1,231 units from the HSE's established suppliers costing €48 million[1] and 2,198 units from new suppliers costing €81 million. This was almost twice the number of ventilators approved by the Department (1,900) and over ten times the number clinically estimated as needed (326).

2.22 The HSE has stated that any risks considered or identified that could arise as a result of an oversupply of ventilators were negated by the clinical/direct risk to life in the event that sufficient ventilators were not available in hospitals. However, this assertion is inconsistent with the surge capacity planning work carried out by the HSE which indicated that there was a practical limit to the number of ventilators that could be used.

1 Includes orders for 650 ventilators at a total cost of €27 million that were subsequently cancelled by agreement with two of the established suppliers. The total cost is based on the unit prices quoted at the time the orders were placed. No financial losses were incurred in respect of these orders.

Section 3

Sourcing suppliers

3.1 In the first instance, the HSE sought to secure ventilators from its existing panel of medical device suppliers. Prior to the declaration of the pandemic, a national framework agreement was in place with these suppliers following a competitive procurement process carried out in 2018 for the provision of medical devices.

3.2 The established suppliers were contacted for information on the availability of new ventilators on 29 January 2020 and again on 3 March 2020. During the intervening period, availability had declined significantly (see Appendix D). The majority of orders were placed with these suppliers over a three-week period, from 3 March 2020 to 25 March 2020. All of the orders placed were for ventilators with a similar specification to those already being used within ICUs in Irish hospitals.

3.3 In late March 2020, due to concerns the orders would not be available in time or in sufficient quantities to meet the expected demand for critical care, the HSE began exploring alternative supply chains. The assistance of IDA Ireland was sought in this regard. IDA Ireland's role was to identify credible potential suppliers and to put them into contact with the HSE. In all cases, the decision whether or not to proceed with an order was made by the HSE. Direct approaches with offers of assistance were also received. In many of these cases, the companies making the offers had little or no experience in the supply of medical devices, but represented they had connections to manufacturers of such devices. Figure 3.1 outlines the sources of the ten potential suppliers of ventilators with whom the HSE subsequently entered commercial deals.

Figure 3.1 Sources of new potential suppliers, where advance payments were made by the HSE

Source	No. of suppliers	Detail
IDA Ireland — direct channel	3	IDA staff based in China contacted manufacturers of ventilators, directly focusing on original equipment manufacturers with export licences approved and authorised by the Chinese government. Negotiations were conducted by IDA staff in China.
IDA Ireland — secondary channel	2[a]	Companies, including some existing IDA Ireland and Enterprise Ireland client companies, contacted the IDA with offers of ventilators for sale. A team was set up within the IDA to identify credible leads and to pass on the contact details to the HSE.
Political	1	One supplier contacted a TD directly with an offer of assistance. This lead was forwarded to the HSE National Director of Procurement via e-mail.
Department of Foreign Affairs/Bank of China	1	The Department of Health, with the assistance of the Department of Foreign Affairs, liaised and arranged for the Bank of China to contact the HSE with an offer to supply ventilators.
Direct approach to Department of Health	3	One supplier contacted a Department official with an offer of ventilators and other emergency medical supplies available for urgent delivery. This offer was passed on to the HSE National Director of Procurement. One supplier was introduced to the HSE National Director of Procurement by a Department official who had a contact in the UAE Embassy with business connections to the supplier. One supplier was passed on to HSE Procurement having contacted the Department directly offering assistance.

Source: Analysis by the Office of the Comptroller and Auditor General

Note: a Excludes one supplier sourced through the IDA 'secondary channel'. The HSE signed a contract for 350 ventilators with the supplier but subsequently decided not to proceed with the order. No payments were made to this supplier. The supplier has claimed loss of earnings and the case is currently in arbitration.

Due diligence

3.4 Due diligence checks enable public bodies to identify and mitigate the risks associated with doing business with third parties, including ensuring that a supplier

- is who they claim to be
- has the financial ability to deliver
- has the necessary capacity and capability to deliver the required goods/services over the life of any contract.

3.5 Figure 3.2 sets out typical areas where due diligence checks are completed as part of standard procurement procedures. The extent and type of due diligence checks completed will vary according to the procurement characteristics and should be proportionate to the risks involved.

Figure 3.2 Typical due diligence checks

- **Legitimate business**
- **Trustworthy**
- **Economic and financial stability**
- **Professional and technical capacity**
- **Past track record**
- **Capacity to meet need**
- **Tax compliance**
- **Insurance**
- **Understand contractual obligations**

Source: Office of the Comptroller and Auditor General

3.6 In the case of the seven established suppliers with whom the HSE had previously done business, due diligence was carried out as part of the standard procurement procedures completed in advance of purchasing. This had been completed prior to the pandemic.

3.7 The examination found that no due diligence checks had been carried out for four of the ten new potential suppliers referenced in Figure 3.1. These four suppliers had been introduced to the HSE through the Department of Health or political or diplomatic contacts. In the case of the other six suppliers (including all five of the introductions via the IDA), the extent of due diligence testing varied (see Figure 3.3).

Figure 3.3 Due diligence completed for six new suppliers

Due diligence		Performed by	Supplier source	No. of suppliers
Rapid due diligence	Restricted to commercial assessment, publicly available information and the IDA's knowledge of the companies' track records.	IDA	Direct IDA	3
Third party commercial research	Assessor noted that due to time constraints and urgency, only high level commercial research was possible and that this did not constitute due diligence.	Third party engaged by HSE	Secondary IDA	2
Risk assessment	The assessment considered commercial and quality risks.	HSE	Supplier approached Department directly	1

Source: Health Service Executive and IDA Ireland

Rapid due diligence

3.8 Due diligence checks were completed as part of the IDA's sourcing of potential suppliers for the HSE. This involved

- speaking to all possible suppliers recommended by the Foreign Affairs Ministry of China and the Shenzen government
- checking the EU assurance (CE) certification with potential suppliers[1]
- checking the HSE specifications with potential suppliers
- checking the company's credibility on tianyancha.com (a company credit investigation platform)
- carrying out an on-site visit to the company to establish the credibility of the supplier and to compare the specifications of the ventilators to the HSE requirements.

3.9 From this process, the IDA identified a total of six potential suppliers. The HSE purchased ventilators from three of these (suppliers J, K and N – see Appendix B). The HSE decided not to proceed with the ventilators being offered by the other three suppliers as they did not meet their specifications.

Third party commercial research

3.10 The HSE commissioned third-party commercial research for two of the companies that approached the IDA and Enterprise Ireland with offers to supply ventilators, and whose contact details had been supplied by the agencies to the HSE. The results of the commercial research were provided on 3 April 2020, within hours of the information having been requested by the HSE.

3.11 The research found that one proposed supplier (supplier L) had only been established since 2019 and had no track record to monitor. The HSE had already prepaid $1 million (€925,754) to this company on 2 April 2020.

1 See section 4 Quality of ventilators purchased.

3.12 The research found that another proposed supplier (supplier P) was a small wholesale distributor of personal protective equipment (PPE) with an annual turnover of $6.6 million. The HSE decided to proceed with an order placed with that supplier for ventilators, and prepaid €8.24 million on 3 April 2020, and a further €8.24 million on 7 April 2020.

Risk assessment

3.13 The HSE carried out its own risk assessment in respect of a supplier (supplier H) who had approached the Department directly, and whose contact details were passed on. The risk assessment identified a range of commercial and quality risks associated with the offer of supply, and potential mitigating strategies (see Figure 3.4). However, the HSE has stated that due to the urgency, and its belief that the clinical need for the ventilators outweighed the risks identified, it was not possible for the HSE to implement all of the mitigations identified. It advanced €14.1 million to this supplier.

Figure 3.4 Summary of risk assessment for supplier that approached the Department directly

Risk category	Risk	Mitigation identified	Action taken by HSE
Commercial	Value of transaction (€35 million) is significant — risk of wasted expenditure.	Stagger delivery into stages.	The planned delivery schedule was staggered into stages.
		Department of Foreign Affairs representative to check cargo manifest prior to release of final funds.	As the order did not proceed beyond the first delivery, final funds were not released and this mitigation was not required.
	1,000 ventilators — significant quantity from single source with whom no previous transactions conducted.	Simultaneously pursue other supply sources.	Initial order for 1,000 ventilators subsequently reduced to 328 ventilators. HSE continued to pursue other suppliers.
Quality	Quality may not be to standard specified or expected by HSE.	Engage with Department of Foreign Affairs to source representative with appropriate clinical engineering/medical device background to act as HSE eyes and ears on ground.	The HSE did not pursue this mitigation due to the pace at which the situation evolved, and the restrictions on movement imposed in the manufacturing country.
	Variation in standards due to multiple machines being supplied from multiple manufacturing sites.	Supplier to contractually commit to providing machines to a standard no lower than the sample ventilators reviewed by HSE clinical engineering.	Letter provided by the supplier committing to the standard.
	Machines did not comply with EU standards for ventilators (no CE mark).	HPRA to provide temporary derogation to allow machines to be placed on Irish market during Covid-19 crisis.	Temporary derogation did not materialise as machines provided were not put into clinical use.

Source: Health Service Executive

Payment terms

3.14 The HSE's established financial regulations provide that orders should be placed in writing with suppliers of required goods or services.[1] This is usually done through the issue of a purchase order, the signing of a contract or another written format that has been approved by the HSE Assistant National Director of Finance. The regulations also provide that where there is a need to place orders verbally, confirmation in writing should be issued to the supplier on the next available working day. This procedure should ensure that there is proper authorisation for a procurement, and that all orders placed can be adequately tracked in the event that problems subsequently emerge. Issuing a basic purchase order that identifies the minimum contract information — an agreed product, quantity and price — and that has the appropriate authorisation is not a challenging process.

3.15 In normal circumstances, suppliers are subject to the HSE's standard terms and conditions where a purchase order has been issued or a contract signed.[2] These standard terms and conditions (last updated in January 2013) were prepared by the HSE's legal advisors to provide as much protection as possible to the HSE across all expenditure categories.

3.16 Purchase orders were raised by the HSE for all orders for ventilators placed with the established suppliers. They were already aware of the HSE's standard terms and conditions as part of the normal competitive procurement process.

3.17 While the HSE's standard terms and conditions do not provide for advance payments, the HSE placed two orders with established suppliers for a total of 160 ventilators, and agreed to pay a total of €7.15 million in advance to secure the orders due to the global demand. Both of the orders were fulfilled by the suppliers concerned without any issues arising.

3.18 The proposed new suppliers of ventilators stated that they would require payment in advance, to secure the orders placed with them. Between 24 March 2020 and 14 April 2020, the HSE made advance payments of €81 million to ten new suppliers in order to secure almost 2,200 ventilators. The HSE understood this represented 100% payment of the price agreed for the supply of the devices ordered.

3.19 Figure 3.5 outlines the nature of the agreements in place for the orders issued to these suppliers. The HSE has stated that, although written contracts and/or purchase orders were not in place with four of the new suppliers, verbal contracts were in place and as a consequence HSE terms and conditions were applicable and took precedence.

3.20 The HSE stated that the decision to proceed with advance payments was an operational matter for the HSE, and that there are a number of circumstances where the HSE is bound by the terms of contracts to make payments in advance. Examples of these include payments for rent, subscriptions and software licences. The HSE noted that payments in advance are subject to the usual controls over payment processing, purchase orders and approvals.

1 The HSE's national financial regulations (NFRs) provide the framework within which the internal financial control system of the HSE operates.

2 The HSE's standard terms and conditions for services supplies can be found at https://www.hse.ie/eng/about/who/healthbusinessservices/procurement/hsestandardtermsforservicessupplies.pdf

Figure 3.5 Basis of agreement for orders of ventilators with new suppliers

Agreement type	No. of suppliers	Total advance payments €
Contract	2	12,956,997
Purchase order	4	26,824,154
Verbal contract	3	24,749,500
Certificate of empowerment[a]	1	16,480,000
Total	**10**	**81,010,651**

Source: Health Service Executive

Note: a The certificate dated 16 April 2020 authorised the supplier to identify and purchase 300 ventilators on behalf of the HSE.

Guidance available for public bodies on advance payments

3.21 Advance payments are risky by their nature as the goods may not be delivered, or the goods delivered may not be to the required specification or fit for use.

3.22 The decision to proceed with advance payments was an operational matter for the HSE, and it did not seek guidance or approval from the Department or from DPER prior to making the advance payments to purchase ventilators.

3.23 In its published rules for management of and reporting on financial management for central government departments and offices, DPER acknowledges that the making of advance payments may be necessary in certain circumstances (see Figure 3.6). The instructions do not provide any advice on how to mitigate the risks where advance payments are made.

3.24 There is therefore currently no practical guidance available to public bodies on the use of advance payments. Concerns about the use of advance payments were previously highlighted in a C&AG report which recommended that DPER consider the need for additional guidance about their use by public bodies.[1]

Figure 3.6 Department of Public Expenditure and Reform guidance on management of advance payments

To ensure the integrity of the appropriation account, all due payments (i.e. matured liabilities) should be settled at year-end and payments that are not matured should not be brought forward into the current accounting period. ***This instruction does not preclude the making of advance payments in cases where it is necessary under the terms of a contract to make payments in advance (e.g. in the case of an overseas supplier)****. Departments and Offices should be aware that the circumstances under which they may enter into an Escrow or Letter of Credit arrangement are very limited. Any agreement to use these forms of payment requires the prior sanction of the Department of Public Expenditure and Reform.*

Source: Department of Public Expenditure and Reform, *Public Financial Procedures*, Section C5 Payments and Receipts

1 *Chapter 18 Government Accounting*, Report on the Account of Public Services, 2010.

3.25 The Committee of Public Accounts (the Committee) raised a concern about the use of up-front payments in 2017.[1] It recommended that DPER develop appropriate guidance in relation to up-front payments for procured services as part of general procurement procedures. The recommendation was accepted by the Minister for Finance and Public Expenditure and Reform.[2] DPER advised that its Government Accounting Unit would work with DPER's specialist Office of Government Procurement (OGP) to clarify its formal position on the use of advance payments.

3.26 In 2018, the Committee again raised concern about the appropriate use of advance payments.[3] It noted that where a public body enters into an arrangement to prepay for goods or services, there is potential for the loss of public funds if the goods or services are not delivered. It further noted that, while the financial stability of companies was assessed at the point of contract, there did not appear to be any ongoing monitoring of a company's financial status and its ability to deliver on its commitments.

3.27 As part of its review of prepayments and procurement guidelines, the Committee recommended that DPER consider how this risk can be managed over long-term contracts with recurring prepayments. The Minister for Finance and Public Expenditure and Reform accepted the recommendation.[4]

3.28 In its response to the Committee, DPER noted a range of safeguards included as part of the contract process and that responsibility for contract implementation rests with the contracting authority. It also noted that contracts should be actively managed and monitored by the contracting authority and that it is the responsibility of each contracting authority to adhere to the prepayment guidelines in *Public Financial Procedures* and also in the *Public Spending Code*.

3.29 The OGP did not refer to the management of advance payments in its subsequently published *Guidelines on the Procurement of Goods and Services* (2019).[5] Instead, it emphasises that for public procurement "payment is due when the goods or services have been provided satisfactorily and the supplier has submitted their account". This implies, but does not clearly say, that advance payments should be avoided where possible.

3.30 In the circumstances, the HSE did not have the benefit of considered central and/or specialist external guidance when it was confronted with requests for advance payments during the Covid-19 pandemic. Figure 3.7 sets out a possible outline framework for the matters that should be considered by a public body considering making a substantial advance payment.

1 Committee of Public Accounts report on *The Examination of Financial Statements in the Third-Level Education Sector*, July 2017.

2 *Minute of the Minister for Finance and Public Expenditure and Reform in response to the Committee of Public Accounts Report on the Examination of Financial Statements in the Third Level Sector*, December 2017.

3 *Committee of Public Accounts Periodic Report No. 4, May – July 2018*, published December 2018.

4 Circular 11/2019 *Minute of the Minister for Finance and Public Expenditure and Reform in response to the Committee of Public Accounts Periodic Report No. 4 May – July 2018.*

5 Version 2 of the *National Public Procurement Guidelines for Goods and Services* published in January 2019.

Figure 3.7 Key elements of a potential guidance framework for public bodies considering making advance payments

- A definition of an advance payment, clearly distinguishing such payments from progress payments.
- Set out the circumstances when advance payments can be made.
- Provide a methodology to enable public bodies to determine when it is appropriate to include an advance payment within a contract.
- Set out the steps a public body should follow before negotiating or agreeing to an advance payment clause within a contract including
    - setting out the business rationale for issuing an advance payment
    - an assessment of the risks associated with paying for goods and services before they are received, for example, viability of the supplier and non-performance of the contract
    - consideration of the financing and interest costs to the Exchequer
    - ensuring that the value of the advance payment does not exceed the value of the goods and services received in a suitable fiscal period (e.g. no advance payment to exceed the value of six months/one year's supply).
- Explain when specific approval from DPER should be sought for a proposed advance payment agreement, for example where the amounts are above a specified threshold or are being made outside the usual circumstances.

Source: Office of the Comptroller and Auditor General

Section 4

Quality of ventilators purchased

4.1 The HSE took delivery of significantly fewer ventilators than it had ordered (see Figure 4.1). Almost half of the ventilators ordered from the established suppliers were supplied. The remaining orders were cancelled by the HSE because it determined that a sufficient quantity of ventilators had already been received.[1]

4.2 Just over a fifth of the ventilators ordered from the new suppliers were delivered, with the remaining orders being cancelled by the HSE for a number of reasons including

- quality-related issues in the first batch of ventilators delivered that were considered to pose a serious risk to patient safety
- suppliers not being able to fulfil orders
- a sufficient supply of ventilators having been secured from the established suppliers
- the effectiveness of public health measures in preventing the worst case scenario from materialising.

Figure 4.1 Number of ventilators ordered, cancelled and received

Supplier source	No. of suppliers	Number of ventilators Ordered	Cancelled	Received
Established suppliers				
Existing framework	6	1,221	650	571
Contacted HSE directly[a]	1	10	—	10
Total	**7**	**1,231**	**650**	**581**
New suppliers				
Direct IDA	3	600	200	400
Secondary IDA	2	320	320	—
Political	1	100	100	—
Department of Foreign Affairs/Bank of China	1	200	200	—
Approached Department directly	3	978	911	67
Total	**10**	**2,198**	**1,731**	**467**
Total	**17**	**3,429**	**2,381**	**1,048**

Source: Analysis by Office of the Comptroller and Auditor General

Note: a A specialised company (supplier G) engaged (pre-Covid) by acute hospitals to repair and replace medical equipment offered ten reconditioned ventilators for sale to the HSE.

1 Includes orders for 650 ventilators at a total cost of €27 million that were subsequently cancelled by agreement with two of the established suppliers. The total cost is based on the unit prices quoted at the time the orders were placed. No financial losses were incurred in respect of these orders.

Quality issues with ventilators from new suppliers

4.3 In accordance with the EU regulatory framework for medical devices, medical device suppliers in EU member states have the obligation to ensure that their medical devices conform with essential requirements for safety and performance (see Figure 4.2).[1] Typically, ongoing clinical and technical support is also sought by the purchaser of medical devices in order to ensure their safe deployment within the health system.

Figure 4.2 Key measures that ensure safety and performance of medical devices

CE marking of conformity

The Conformité Européenne (CE) mark is defined as the mandatory conformity marking for regulating goods sold within the European Economic Area (EEA) since 1985.

Conformity assessment

Process demonstrating whether the requirements of the EU legislation have been fulfilled.

Instructions for use and labelling

Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users. The manufacturer should be clearly identified.

Clinical evaluation

Systematic and planned process to continuously generate, collect, analyse and assess the clinical data of a device in order to verify safety and performance.

Registered on the European Database on Medical Devices (EUAMED)

Central European database allowing all stakeholders to access basic information on medical devices.

Source: EU regulatory framework for medical devices

4.4 In the case of the new suppliers, the usual clinical and technical support was not available to the HSE. The HSE also had no previous experience of using the models being offered.

4.5 In order to assess the technical specification of the ventilators being offered, HSE clinical engineering performed a desk based review of documentation provided by each supplier. The HSE stated that, given the timescales involved and the urgency of demand, a desk based review was the only option available.

4.6 The review sought to establish that models being offered at a minimum met the WHO specification and found that on paper they did. One of the new suppliers also arranged for two sample ventilator models to be delivered in advance. HSE clinical staff attended a demonstration of these models in late March 2020.

4.7 The first delivery from the new suppliers, of 100 ventilators, arrived in early April 2020 — 65 from supplier H,[2] and 35 from supplier K.[3] The HSE arranged for a third party to carry out the necessary performance tests (usually carried out by the supplier) and 41 of the 100 ventilators failed the tests. HSE clinical engineering and critical care staff agreed that the high failure rate represented a risk to patient safety and advised the acute hospitals to delay clinical use of these batches of ventilators.

1 Medical Device Directive 93/42/EEC was in place at the time of the emergency procurement. It was replaced by Regulation (EU) 2017/745 in May 2021.

2 In addition to the 65, supplier H had also provided two sample ventilators to the HSE prior to the order being finalised.

3 Just over half of the 100 ventilators were delivered to acute hospitals and were tested on-site. However, they were not installed in ICUs and were not made available in the hospitals for clinical use.

Health Products Regulatory Authority review

4.8 During March and April 2020, the HPRA provided regulatory support to the HSE and the Department in respect of the ventilator procurement.[1] This was limited to a desk-based review of documentation provided by the suppliers for some of the models. The HPRA noted that while this review provided a degree of confidence, it did not fully mitigate the risk of supply of non-genuine or non-compliant ventilators.

4.9 The HPRA review examined the documentation provided by the new suppliers for compliance with the Medical Devices Directive as well as consistency in labelling, and a review of company websites — typical market surveillance activities. As shown in Figure 4.3, based on the information available at that time, the review found that two of the models did not comply with the Medical Devices Directive (and should therefore not be placed on the Irish market) and that three required further investigation. The HPRA concluded that the devices should not be put into service in Irish hospitals pending resolution of these issues.

Figure 4.3 Summary of the HPRA review findings

	Ventilator model				
	Eternity SH300	**VG70**	**Prunus 2000D**	**PA700**	**Booray 5000D**
Documents					
EC certificate	🔴	🔴	🔴	🟢	🟢
Declaration of conformity	🔴	🔴	🔴	🔴	🔴
Sample product labelling	🟢	🟡	🟡	🟡	🟢
User manual	🟢	🔴	🔴	🔴	🔴
Overall conclusion	Further investigation required	Does not comply with medical devices directive and should not be placed on Irish market	Futher investigation required	Does not comply with medical devices directive and should not be placed on Irish market	Futher investigation required

Source: Health Products Regulatory Authority post hoc review

Key:

- 🟢 Document provided by supplier and no issues noted by HPRA
- 🟡 Document provided by supplier and issue/s noted by HPRA
- 🔴 Document not provided by supplier

Actions taken by the HSE

4.10 In early May 2020, the Head of Clinical Engineering as agreed with the Head of Critical Care advised the relevant acute hospitals that all ventilators from the new suppliers should not be put into clinical use. The HSE procurement unit was also advised to cease accepting delivery of ventilators sourced from these suppliers. The HSE has stated that this instruction was based on the risk the ventilators might present to the safety of patients, and the fact that they were not required anyway because a sufficient number had been received from the established suppliers.

1 The HPRA is the designated competent authority for medical devices in Ireland. The competent authority is the body which has the authority to act on behalf of the government of an EU member state to ensure that the requirements of the medical devices directives are carried out in that particular member state. The regulatory role of the HPRA involves monitoring the safety of medical devices in Ireland after they are placed on the market.

4.11 The HSE did not cancel orders with two of the three suppliers that had been sourced through the IDA's direct channel. This was following communication from the IDA (21 May 2020) stating that delivery of the ventilators was confirmed and on schedule, and advising that "as these supply lines are sensitive, no intervention should be made to these orders".

4.12 The IDA stated that this advice reflected the challenge associated with opening a supply chain of such complexity and scale in a short time frame. This involved discussion, communication and negotiation across the Chinese government system, Chinese private and state-owned companies, manufacturers and distributors, customs regulators, logistics companies in Ireland and China, airport authorities in Ireland and China, airlines and many others. As the contracting party with full access to all of the pertinent facts, including IDA's advice, the HSE's decision to proceed or not with the order that they had placed and paid for, was one for the HSE.

4.13 Over the period May to September 2020, the HSE took delivery of a further 365 ventilators from these two suppliers (215 ventilators from supplier K and 150 ventilators from supplier N) at a total cost of €6.8 million.

Section 5

Cost of ventilators

5.1 The HSE paid a total of €101.5 million to the suppliers of ventilators under the Covid-19 emergency procurement programme, including advance payments of €81 million to the newly identified suppliers.[1] By the end of January 2022, the HSE had received refunds of €50.5 million from some of those suppliers, resulting in a net outlay of €51 million.

5.2 The HSE obtained a total of 1,048 ventilators. As of December 2021, 572 ventilators[2] were available for clinical use in Ireland — 468 deployed to hospitals and 104 held in storage for surge capacity management. These were all obtained from the HSE's established suppliers of ventilators at a total cost of €20.3 million — an average unit cost of just under €35,500.

5.3 The difference between the net outlay and the expenditure on ventilators deployed or held for future use — €30.5 million — represents spend where value has not been obtained by the HSE (see Figure 5.1).

Figure 5.1 Analysis of spend on ventilators for which value has not yet been obtained

	€m
Refunds being pursued by HSE	
Cancelled orders	19.5
Ventilators failed performance tests[a]	2.9
	22.3
Irrecoverable expenditure	
Ventilators received and later donated	6.8
Written off in final settlement with supplier I	0.8
Ventilators failed performance tests and refund not being pursued[a]	0.5
	8.1
Total	**30.5**

Source: Health Service Executive. Any inconsistent totals are due to rounding.

Note: a 102 ventilators were deemed unfit for clinical use in Ireland as a result of 41 units failing performance tests. The total cost of these 102 units was €3.4 million — 67 for which refunds of €2.9 million are being pursued; and 35 costing €0.5 million for which refunds are not being pursued.

5.4 In May 2021, 365 ventilators that cost €6.8 million (an average of €18,582 per unit) were shipped to India. The technical specification of the ventilators matched the request from the health authorities in India and they were provided in their original packaging, at no cost to the authorities there. In June 2021, a further nine ventilators purchased from the HSE's established suppliers, at a cost of €202,554, were donated to health authorities in Nepal.

5.5 The HSE is pursuing refunds from a number of suppliers and has incurred legal costs in the region of €505,000 as of 13 April 2022. In addition, the HSE has also incurred transportation costs of €305,000, and costs associated with performance testing of ventilators sourced from new suppliers (€63,000).

1 Excludes orders for 650 ventilators at a total cost of €27 million that were subsequently cancelled by agreement with two of the established suppliers. The total cost is based on the unit prices quoted at the time the orders were placed. No financial losses were incurred in respect of these orders.

2 Excludes nine ventilators purchased from established suppliers that were donated to Nepal in June 2021.

Unit prices of ventilators (excluding VAT)

5.6 The price per unit agreed to by the HSE for ventilators ranged between €12,850 and €37,900 for the established suppliers and between €13,800 and €65,000 for the new suppliers (see appendices A and B). The HSE stated that the price per unit depended on a number of factors, including the type of ventilators purchased, the technical specification of the ventilator, the date of the order, the country of origin of the ventilator and the condition of the ventilator (whether it is new or re-conditioned).

5.7 Benchmarking of price per unit is a useful tool in non-competitive procurements as it helps provide assurance that the price paid is reasonable. The HSE did not complete any such analysis before placing orders with the new suppliers.

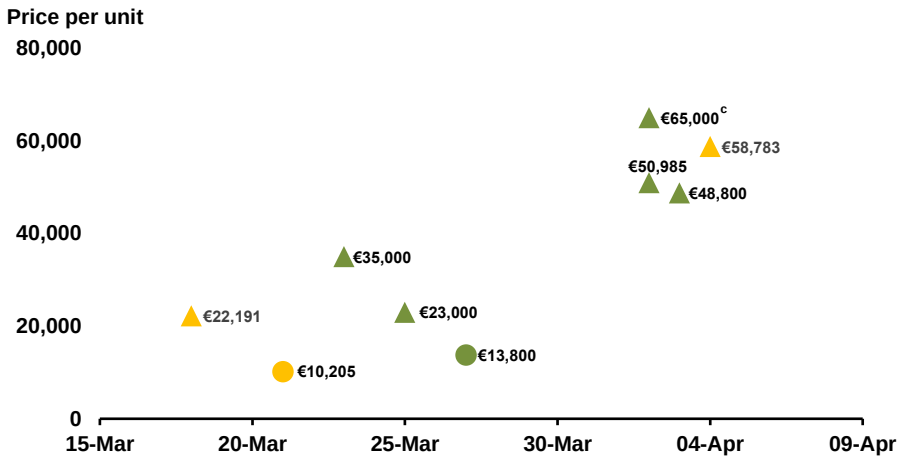
5.8 It is also not clear if the HSE had set a maximum price per unit that it was willing to pay when it entered negotiations with the new suppliers. The HSE had issued orders for almost 3,500 ventilators at one point — over ten times the clinically estimated need — while the price of ventilators increased in response to the increased demand.

5.9 The HSE has noted that, like other countries and health authorities, they were competing to secure a supply of medical devices and had become price takers in the market.

Unit price comparison for VG70 model

5.10 The HSE placed a number of orders for VG70 ventilators directly with the manufacturer (supplier J), and with five other suppliers who were acting as intermediaries. At around the same time, the Department of Health and Social Care in the UK also purchased VG70 ventilators. The prices paid by the UK and Irish authorities provide evidence of the market response to significantly increased demand (see Figure 5.2).

Figure 5.2 Price per unit comparison for VG70 model, March to April 2020[a,b]



Source: Analysis by Office of the Comptroller and Auditor General

Key:

- Price per unit paid by HSE to manufacturer
- Price per unit paid by HSE to intermediary
- Price per unit paid by UK Department of Health and Social Care to manufacturer
- Price per unit paid by UK Department of Health and Social Care to intermediary

Notes:

a UK prices paid were sourced from the UK National Audit Office (NAO) report on an investigation into how the UK government increased the number of ventilators available to the National Health Service (NHS) in response to Covid-19. £STG prices converted to euro equivalents using central bank exchange rates on the date of order.

b Prices shown are exclusive of VAT.

c Supply only. Transport and importation costs would bring this to €75,800 per unit.

5.11 A comparison of the price per unit for orders placed indicates that

- There was an increase of about one-third in the manufacturer's supply price between 21 March and 27 March 2020.
- Prices agreed with intermediaries more than doubled between 25 March and 3 April 2020.
- Prices agreed with intermediary suppliers were two to two and a half times higher than the manufacturer's supply price around the same time.

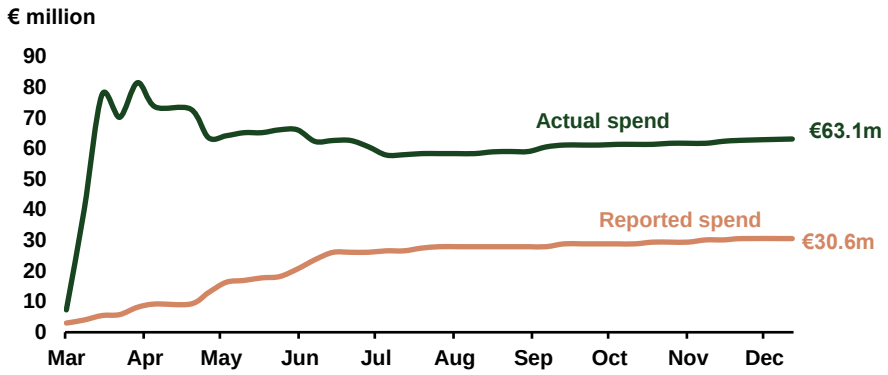
5.12 The comparison between the manufacturer's supply price and the intermediaries' prices may not be on a fully like-for-like basis, since the manufacturer's price was for supply only, and did not include transport/delivery, any required local market modifications, and support arrangements. The extent to which these were included in the various intermediary supplier prices is unclear, since these were not experienced suppliers of the devices. In one case, additional invoiced transport and importation charges would have resulted in a combined cost of €75,800 per device.

Monitoring and oversight of ventilator spend

5.13 A condition of the sanction for the purchase of ventilators — and of other Covid-related emergency expenditure, such as PPE — was that the HSE was to report regularly to the Department and to DPER on the expenditure, so that the Departments could monitor the situation as it evolved.

5.14 HSE Finance sent a weekly report to the Department and to DPER on its expenditure on ventilators. This examination found that the expenditure reported was only for ventilators that had been delivered and did not include either the payments in advance, or the value of refunds received following cancelled orders (see Figure 5.3). This was misleading, and effectively negated any meaningful oversight by the Department and DPER of the level of expenditure incurred by the HSE on the purchase of ventilators.

Figure 5.3 Cumulative spend and reported spend, March to December 2020[a,b]



Source: Analysis by the Office of the Comptroller and Auditor General

Notes:
a Some units purchased from established suppliers were delivered in quarter three and quarter four of 2020.
b The HSE received a refund of €500,000 in August 2021, and a further refund of €11.6 million in early December 2021. This reduces the outlay at year end 2021 to €51 million.

Section 6

Conclusions and recommendations

6.1 The emergency procurement of ventilators during the pandemic cost the HSE a net total of €51 million. Of this amount, €20.5 million represents payments for ventilators received from suppliers of medical devices that the HSE had done business with prior to the declaration of the pandemic. These devices met the required standards for use in Ireland (and in the EU), and have been deployed to hospitals, or are held in reserve for future use.

Loss of value for money

6.2 The HSE is currently pursuing refunds of €22.3 million paid in advance for orders that were cancelled or where the ventilators received were deemed not fit for purpose. In addition, expenditure of €8.1 million is irrecoverable with the majority of this (€6.8 million) relating to ventilators that the HSE ultimately did not need and that have since been donated to health authorities in India. On this basis, the HSE did not receive value for expenditure totalling €30.5 million.

6.3 Purchasing bodies are permitted within the EU's public procurement framework to negotiate and contract directly with suppliers in cases of extreme urgency brought about by unforeseeable events such as the Covid-19 emergency.

6.4 Even in emergency situations, good established procurement practices can assist in achieving value for money. They will require speedy recognition of the key risks to achieving value for money, and help in identification of strategies to mitigate those risks e.g. the importance of involving users and specialists in product specification; the utilisation of established forms of contract and contract terms where possible; and adherence to established procurement authorisations to ensure that managers with the appropriate knowledge and experience are involved in the decision making.

6.5 While procurement in an emergency situation may not always result in optimal value for money outcomes, it is important to learn lessons and to improve processes so that in similar challenging situations subsequently, better outcomes may be achieved.

Assessment of ventilators needed

6.6 In March 2020, the HSE identified an urgent need for ventilators and commenced an emergency procurement. Due to the emergency situation, the HSE was permitted under EU procurement rules to dispense with standard competitive tendering processes and to negotiate directly with suppliers. However, the HSE did not follow all of the routine procurement steps in a direct negotiation process. The HSE did not set out the number of ventilators it required prior to orders being placed. In addition, the technical specification of the ventilators required was not determined by an assessment of business need.

6.7 HSE Procurement commenced ordering and purchasing ventilators before a target number of devices required was determined. By late March 2020, clinical staff had estimated that an additional 326 ventilators would be needed. This was based on the maximum extent that critical care capacity could be increased to deal with the expected influx of Covid-19 patients, referred to as surge capacity planning. In the event, the HSE was able to procure from the established suppliers nearly twice the number of ventilators estimated to be clinically required.

6.8 Although the HSE sought initially to purchase ventilators similar to models used in ICUs in Ireland for safety, and ease and speed of commissioning, it subsequently decided also to purchase models that had a lower technical specification but that met the WHO specification for the treatment of patients with Covid-19.

6.9 On 21 March 2020, the Department approved the purchase by the HSE of 1,900 ventilators at an estimated cost of €73.5 million — an implied average cost of €38,700. The request for this sanction appears to have been based on orders the HSE had already placed or that were at an advanced stage of negotiation.

6.10 Between 3 March 2020 and 14 April 2020, the HSE placed orders for almost 3,500 ventilators at a total cost of €129 million — almost twice the number approved by the Department and over ten times the number the HSE estimated could be clinically used.

6.11 The HSE has stated that any value for money risks arising from the excess purchases of ventilators were negated by the clinical and direct risk to life of not having a sufficient number available in hospitals.

6.12 This assertion is not consistent with the concept of surge capacity planning. If that planning was correct, then the health system would have been unable to deploy any additional devices beyond the projected requirement of around 326 machines. Even if double that number could have been deployed in the most extreme situation, the level of orders placed by the HSE would have been excessive.

Sourcing suppliers

6.13 The HSE sought to secure ventilators from its established suppliers in the first instance. Due to concerns it had around the capacity of those suppliers to meet its demand, the HSE also began exploring potential new suppliers. Assistance was provided by the IDA in this regard. In addition, some suppliers approached the HSE and the Department directly with offers to supply.

6.14 The HSE had not previously done business with any of the new potential suppliers. Most of the new suppliers were acting as intermediaries, and were not involved directly in the manufacturing of the medical devices and had little or no experience in the supply of those devices.

6.15 In the normal way, due diligence checks of new suppliers provide assurance that they are who they claim to be and have the financial ability and necessary capacity to deliver the required goods or services. Standard procurement procedures contain a range of due diligence checks normally completed as part of a competitive procurement process.

6.16 No due diligence checks were completed for four of the new suppliers. The extent of checks completed for the other six varied, ranging from commercial research to a high level risk assessment. These checks flagged various financial and quality risks with the new suppliers. Nevertheless, the HSE considered that its need for additional supply of ventilators outweighed the risks.

6.17 Between 24 March 2020 and 14 April 2020, the HSE made advance payments to new suppliers of €81 million to secure almost 2,200 ventilators. The HSE's standard terms and conditions do not include provisions in relation to advance payments and were not altered in light of these payments. There is currently no practical guidance available to public bodies on the use of advance payments.

Recommendation 6.1 to Department of Public Expenditure and Reform/Office of Government Procurement

The Department of Public Expenditure and Reform/Office of Government Procurement should consider developing practical guidance for public bodies on the use of advance payments including

- defining an advance payment
- setting out the circumstances when advance payments can be made
- providing a methodology to assist public bodies in determining when it is appropriate to include an advance payment within a contract
- setting out the steps a public body should follow before negotiating an advance payment clause within a contract
- clarifying when approval should be sought from DPER, for example, where amounts are above a specified threshold or are being made outside the normal circumstances.

Accounting Officer's response

Agreed.

The Department notes the particular circumstances of the emergency procurement of ventilators and the finding that the EU public procurement framework allows for direct negotiation with suppliers in cases where unforeseeable events such as the Covid-19 emergency arise. The Department also notes the finding that procurement in emergency situations may not always result in optimal value for money outcomes.

While it is not likely that any general guidance could have dealt with the particular context arising in the emergency procurement of ventilators, the Department accepts that in general the processes for the payment for procured goods and services can be assisted through wider availability of advice in relation to the issues set out in the recommendation. Accordingly, the Department and the OGP will work to provide further high level advice to public bodies on steps to manage the use of advance payments within contracts.

Quality of ventilators purchased

6.18 The usual clinical and technical support was not available to the HSE from the new suppliers and the HSE had no previous experience using any of the ventilator models being offered by the new suppliers. Orders were placed with the new suppliers on the basis of a desk-based review by HSE staff of documentation provided by the suppliers, and the attendance by HSE senior clinicians and clinical engineering staff at a demonstration of two sample ventilator models provided by one of the new suppliers.

6.19 However, quality issues emerged quickly after the first delivery of devices from the new suppliers, including direct delivery to some acute hospital sites. Performance tests completed by a third party on behalf of the HSE found that of the 100 ventilators tested, 41 failed. As the high failure rate was deemed to represent a risk to patient safety, the hospitals that had received ventilators were advised to delay using them.

6.20 A further desk-based review by the HPRA of the supplier documentation found that two models ordered did not comply with the EU medical devices directive and that three models required further investigation. In light of the significant quality issues identified coupled with the risk to patient safety, the acute hospitals were advised by the HSE's Head of Clinical Engineering as agreed with the Head of Critical Care not to put these ventilators into use. HSE Procurement was also advised to cease accepting delivery of the ventilators sourced from these suppliers.

6.21 Orders with two suppliers for a further 365 ventilators, at a cost of €6.8 million, were not cancelled by the HSE following confirmation from the IDA that delivery of the ventilators was on schedule and advice that, as these supply lines were sensitive, no intervention should be made to these orders. The devices were subsequently received by the HSE, but were not deployed. In May 2021, these ventilators were donated to the health authorities in India as the technical specifications met the requirements there.

Cost and deployment

6.22 The price per unit for ventilators ordered by the HSE ranged between €12,850 and €65,000. The price varied significantly depending on the supplier (established or new), whether the supplier was a manufacturer or an intermediary, when the order was placed, and the specification of models being offered (new or reconditioned).

6.23 A comparison of the unit prices paid for one ventilator model (VG70) shows that prices increased significantly in a very short period (just over a week) and that the price per unit paid to the intermediary suppliers was significantly higher than that paid directly to the manufacturer.

6.24 We received no evidence that the HSE completed any form of benchmarking analysis prior to placing orders with the new suppliers to confirm that the unit prices being offered were reasonable. The HSE noted that as competition to purchase resulted in inflated prices, it had become a price taker.

6.25 Where a significant level of unplanned expenditure occurs in a short period, it is important that the oversight and accountability arrangements continue to operate. Although the HSE was providing the Department and DPER with weekly reports of expenditure in response to Covid-19, the reports did not include information on the advance payments made. This was seriously misleading and negated the effectiveness of the Departments' oversight of the expenditure.

Appendices

Appendix A Purchases from established suppliers of ventilators

Order date (2020)	Supplier	Ventilator model	Number of ventilators			Price per unit[a,b]	Total paid[a]
			ordered	cancelled	received	€	€
06-Feb	Supplier A	Hamilton T1	12		12	21,615	319,042
03-Mar	Supplier B	Servo U	30		30	24,130	890,397
06-Mar	Supplier A	Hamilton T1	30		30	22,603	834,065
09-Mar	Supplier B	Servo-I Base unit	3		3	26,976	99,541
10-Mar	Supplier C	V800 ventilator	40		40	33,452	1,645,838
10-Mar	Supplier D	LTV ventilator	20		20[c]	18,485	450,121
10-Mar	Supplier A	Hamilton C6	72		72	34,807	2,506,089[d]
10-Mar	Supplier A	Hamilton T1	15		15	22,672	340,076[d]
11-Mar	Supplier E	Puritan Bennett Model 980	15		15	24,500	452,025
12-Mar	Supplier E	Puritan Bennett Model 980	36		36	24,540	1,086,621
12-Mar	Supplier D	Vyarie Avea ventilator	13		13	29,385	469,860
13-Mar	Supplier D	Vyarie Avea ventilator	7		7	28,429	244,770
18-Mar	Supplier E	Puritan Bennett Model 980	8		8	24,500	241,080
18-Mar	Supplier F	Nihon Kodhen NKV-550	600	450	150	37,900	6,992,550[e]
20-Mar	Supplier F	Nihon Kodhen NKV-550	20		20	37,900	758,001[d]
20-Mar	Supplier E	Puritan Bennett Model 980	300	200	100	24,500	3,013,500
25-Mar	Supplier G	Servo-i Base unit	10		10	12,850[f]	158,055[e]
Total			**1,231**	**650**	**581**		**20,501,631**

Source: Analysis by Office of the Comptroller and Auditor General

Notes:

a The price per unit excludes VAT and the total paid is inclusive of VAT where applicable (see footnote d).

b The price per unit is calculated based on the total paid and the number of ventilators received. The price per unit for each model may not be directly comparable due to the following factors: discounts were applied in some cases and not in others; and some invoices included additional charges associated with ancillary items, freight charges and crating costs.

c Nine of these units at cost of €202,554 (including VAT) were included in the medical equipment donated to health authorities in Nepal.

d There was no VAT charged on the purchase of these units. Revenue permitted the temporary application of the zero VAT rate to certain supplies of medical devices acquired by the HSE, between 9 April 2020 and 30 June 2022, for use in the delivery of Covid-19 related health care services. The zero rate was applied to these three orders.

e Immediate payment terms were in place for these two orders. All other orders had normal payment terms whereby the goods were paid for after delivery.

f The price per unit reflects the fact that these were re-conditioned units.

Appendix B Purchases from newly identified suppliers

Order Date (2020)	Source	Supplier	Type	Legal agreement	Due diligence	Ventilator model	No. of ventilators ordered	No. of ventilators cancelled	No. of ventilators received	Price per[a] unit €	Total payments in advance €	Total refunds received €	Total refunds being pursued €	Total irrecoverable expenditure €
23-Mar	Approached DoH	Supplier H	Intermediary	Purchase order	Risk assessment	Booray 3000			1	35,000	14,120,400	3,816,793	10,303,607[c]	—
						Booray 5000	328[b]	261[b]	13					
						PA700			20					
						SH300			31					
						VG70			2					
25-Mar	Approached DoH	Supplier I	Intermediary	None	None	VG70	450	450	—	23,000	10,350,000	9,550,000	—	800,000
27-Mar	Direct IDA	Supplier J	Original equipment manufacturers	Contract	Rapid due diligence	VG70	200	200	—	13,800	2,760,000	2,759,910	—	—
27-Mar	Direct IDA	Supplier K	Original equipment manufacturers	None	Rapid due diligence	Booray 2000D	100	—	100	14,520	1,452,000	—	—	1,452,000
						Prunus 5000D	150	—	150	21,426	3,213,900	—	—	3,213,900
02-Apr	Secondary IDA	Supplier L	Intermediary	Purchase order	High level commercial research	SH300	20	20	—	46,288	925,754	920,925	—	—
02-Apr	Political	Supplier M	Intermediary	Purchase order	None	VG70	100	100	—	65,000[d]	9,144,000	9,144,000[e]	—	—
02-Apr	Direct IDA	Supplier N	Original equipment manufacturers	Purchase order	Rapid due diligence	Crius V6	50	—	50	17,560	878,000	—	—	878,000
02-Apr	Department of Foreign Affairs/Bank of China	Supplier O	Intermediary	Contract	None	VG70	200	200	—	50,985	10,196,997	3,034,131	7,162,866	—
03-Apr	Secondary IDA	Supplier P	Intermediary	None	High level commercial research	SH300	200	200	—	58,000	11,600,000	11,599,950	—	—
						VG70	100	100	—	48,800	4,880,000	—	4,880,000	
07-Apr	Direct IDA	Supplier N	Original equipment manufacturers	Purchase order	Rapid due diligence	Crius V6	100	—	100	17,560	1,756,000	—	—	1,756,000
14-Apr	Approach DoH	Supplier Q	Intermediary	None	None	SH300	200	200	—	48,668	9,733,600	9,712,554	—	—
Total							**2,198**	**1,731**	**467**		**81,010,651**	**50,538,263**	**22,346,473**	**8,099,900[f]**

Source: Analysis by Office of the Comptroller and Auditor General

Notes:
a For consistency the price per unit is reflected excluding VAT. The total payments include VAT where applicable.
b Initial agreement was for 270 units of SH300 and 30 units of Booray 5000D/3000D. The final order for 328 units does not distinguish between model types.
c Includes the cost of all 67 units received and deemed not fit for clinical use (€2.9 million).
d The unit price quoted on the invoice was €65,000. The invoice also included transportation and import costs which would bring the unit price to €75,800.
e Refund received was in the form of a credit note applied to the purchase of personal protective equipment.
f Excludes €26,015 in respect of exchange rate differences subsequently written off.

Appendix C Medical Devices Criticality Assessment Group (MDCAG) terms of reference

1 Role/Purpose

- The Medicines Criticality Assessment Group and the Medical Devices Criticality Assessment group were set up as subgroups to the Department of Health Brexit operation group, chaired by HSE/HPRA, to work on Brexit related supply issues.
- The groups have now been requested to refocus their efforts on Covid-19 related medicines and medical devices supply issues and shortages.
- For all Covid-19 related work, the groups will be considered subgroups of the National Public Health Emergency Team (NPHET).

2 Term

- This terms of reference is effective from 3rd March 2020 and will be ongoing until terminated by agreement between group member and NPHET.

3 Membership

- The Medicines Criticality Assessment Group will comprise of members from the following organisations, as required:
  - Health Products Regulatory Authority (HPRA) — QSAC, HPAR, Compliance
  - HSE — HBS, Acute Hospital Drugs Management Programme, National Cancer Control Programme, Primary Care Reimbursement Services, National Immunisation Office
  - Department of Health (DoH) — Medicines, Controlled Drugs and Pharmacy Legislation Unit.
- The Medical Devices Criticality Assessment Group will comprise of members from the following organisations, as required:
  - HPRA — Medical Devices
  - HSE — HBS, NCAGL (Clinical and Medical Devices Leads), Laboratory services expert
  - Department of Health (DoH) — Medicines, Controlled Drugs and Pharmacy Legislation Unit.

4 Roles and Responsibilities

- The Medicines Criticality Assessment Group and Medical Devices Criticality Assessment Groups will:
  - a) Establish extent of the availability of medicines and medical devices used in the following:
    - Diagnosis of Covid-19 (as per agreed diagnostic strategies) (including testing equipment).
    - Treatment of Covid-19 (Antivirals).
    - Treatment of secondary bacterial infections in patients with Covid-19 (pneumonia etc.).
    - Supportive Treatments used in patients with Covid-19
      - treatments to manage disease at home
      - treatments to manage disease in hospitals, including in ICU care
      - devices and consumables used.
    - Personal Protection.
  - b) Conduct ongoing horizon scanning activities to ensure that any potential medicines and medical devices shortages caused by Covid-19 related issues and any potential medicines, device or equipment shortages not directly related to Covid-19 but which could have a high impact on patients and healthcare professionals, are identified as early as possible.
  - c) Oversee the response to medicines and medical devices shortages caused by Covid-19 related issues and any medicines, device or equipment shortages not directly related to Covid-19 but which could have a high impact on patients and healthcare professionals.
- In order to carry out a), the groups must be provided with guidance from the HSE's High Consequence Infectious Diseases (HCID Group). The HCID Group should establish a list of essential medicines and medical devices that will be required. It is understood by the criticality groups that this may be an evolving list. Input will also be sought from the HSE's Covid-19 modelling group.
- The groups' work will focus on addressing shortages and investigating availability. Decisions in relation to other issues such as procurement and indemnity will be outside the remit of the group.

5 Meetings

- Meetings to be chaired by DoH representative, where possible.
- Any issues that cannot be resolved at group level are to be raised by DoH Representative at the internal DoH Covid-19 working group. Issues may be escalated via this group to NPHET.

6 Amendment. Modification or Variation

- This Terms of Reference may be amended, varied or modified in writing after consultation and agreement with group members and NPHET.

Source: https://www.gov.ie/en/collection/08242-national-public-health-emergency-team-nphet-covid-19-subgroup-covid-19-medicines-and-medical-devices-criticality-assessment-group/

Appendix D Ventilator stock with established suppliers as of 29 January 2020 and as of 3 March 2020[a,b]

Supplier	At 29 January 2020	At 3 March 2020
A	▪ 40 ventilators in stock in Switzerland. ▪ Can ship immediately on receipt of a purchase order. ▪ Another 100 ventilators available in one week on receipt of a purchase order.	▪ No stock in Europe. ▪ Earliest ship date on receipt of purchase order is 5 April 2020 for multiples.
B	▪ 12 ventilators in stock in Sweden. ▪ Can deliver within ten days of receipt of a purchase order. ▪ Another 30 ventilators available in three weeks on receipt of a purchase order.	▪ 30 ventilators in stock in UK. ▪ Can deliver in ten days on receipt of a purchase order.
C	▪ 50 ventilators in stock in Germany. ▪ Available to ship immediately on receipt of purchase order. ▪ Three week delivery.	▪ No stock in Europe. ▪ Seven week delivery.
D	▪ 20 ventilators in stock in Switzerland. ▪ Available to ship immediately on receipt of a purchase order.	▪ No stock. ▪ Earliest ship date on receipt of a purchase order is 1 April 2020 for 20 ventilators.
E	▪ 14 ventilators in stock in Ireland. These ventilators do not have a compressor.[c] ▪ 15 ventilators that are two years old and are of a lower spec available in Ireland.	▪ No update provided

Source: Health Service Executive — equipment status report

Notes:
a Excludes supplier F, as the HSE had not previously purchased ventilators from this supplier. The HSE had purchased other medical equipment from this supplier and had an established trading relationship with them.

b Excludes supplier G, a specialised company engaged by the acute hospitals to repair and replace medical equipment that offered ten reconditioned ventilators directly to the HSE.

c Compressors filter and supply clean air to the ventilator. They can be separate devices or built into the ventilator. However, the WHO technical specification recommended that ventilators with integrated medical air compressors be used in the treatment of Covid-19.