Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

An overview of national approaches to stockpiling of medical countermeasures for public health emergencies

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About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.

- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.

- **Regulating health services —** Regulating medical exposure to ionising radiation.

- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.

- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.

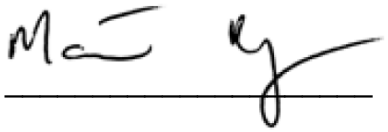
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

Foreword

The World Health Organization (WHO) has identified strategic health stockpiles as a resource that may be deployed as part of a national response to health threats, emergencies and disasters. Health threats which have been outlined at EU level include: pathogens with a high pandemic potential; chemical, biological, radiological and nuclear threats (CBRN); and threats resulting from antimicrobial resistance (AMR). Countries take these health threats into consideration and include medical countermeasures (MCMs) such as vaccines, medicines, medical equipment and diagnostics in their national stockpiles.

National approaches to stockpiling of medical countermeasures for public health emergencies vary from country to country based on a number of factors including country location, infrastructure, and perceived and or assessed threats. Gaining an understanding of national approaches to MCM stockpiling will help inform the development of a national medical countermeasure stockpiling strategy in Ireland. This report therefore contains an overview of national MCM stockpiling strategies for public health emergencies in selected countries, conducted at the request of the Health Security Unit in the Department of Health.

Work on this report was undertaken by an Evaluation Team from the Health Technology Assessment Directorate in HIQA. HIQA would like to thank its Evaluation Team, the key representatives who participated in interviews, and all who contributed to the preparation of this report.



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Conflicts of Interest

None reported.

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List of abbreviations used in this report

AMR	antimicrobial resistance
CBRN	chemical, biological, radiological and nuclear
COVID-19	coronavirus disease 2019
EEA	European Economic Area
EU	European Union
EU FAB	EU network of vaccine producers for public health emergencies
HERA	Health Emergency Preparedness and Response Authority
HIQA	Health Information and Quality Authority
HTA	health technology assessment
ICU	intensive care unit
MAH	marketing authorisation holders
MCM	medical countermeasure
NATO	North Atlantic Treaty Organization
PPE	personal protective equipment
RescEU	Part of EU civil protection mechanism
USAID	United States Agency for International Development
WHO	World Health Organization

Key points

- This report provides an overview of national approaches to stockpiling medical countermeasures (MCM) for public health emergencies in selected countries and was requested by the Health Security Unit in the Department of Health.
- Interviews were conducted with key representatives from five countries: France, Latvia, Lithuania, the Netherlands and Norway.
- Thematic analysis was conducted on interview summaries. The following seven themes were identified: past stockpiling approaches; scope and current stockpiling approaches; threat identification, risk assessment and product identification; cost considerations and efficiency; management and governance; national, EU and international coordination and collaboration; and future approaches.

Past stockpiling approaches:

- All five countries reported previous experience in stockpiling, with stockpiles generally evolving over time from a focus on mass casualty incidents to also covering the following: anti-microbial resistance; chemical, biological, radiological and nuclear threats; and pandemic threats.
- The COVID-19 pandemic influenced changes in stockpiling approaches. These included the addition of general medicines and personal protective equipment to the stockpiles, and the review of sources of medical countermeasures to ensure access to further stock in times of crises.

Scope and current stockpiling approaches:

- All five countries reported having physical stockpiles that focused on national and cross-border threats. These were mainly held by governments, with four countries stating that medical institutions also held their own stockpiles.
- The majority of stockpiles involved stock rotation, that is, stock was rotated for use prior to its expiry date.
- Stockpiles varied in size from a six-week supply to a six-month supply.
- Countries noted that their national stockpiles included products such as: anti-viral medicines, personal protective equipment, intravenous antibiotics, medical devices, and medical countermeasures for chemical, biological, radiological and nuclear threats.

- Stockpile locations varied in all five countries. Locations were influenced by factors such as security, required speed of deployment, and stockpile distribution.
- All five countries had national legislation related to stockpiling. Three countries had regulations requiring wholesalers to hold stockpiles of general medicines while two countries had legislation regulating stockpiles held by government and other public bodies.
- Three countries reported using either national procurement mechanisms or international joint procurement agreements depending on the products required and time constraints.
- Procurement challenges reported included:
    - acquiring sufficient supplies given global shortages of certain products
    - long lead-in times for products such as vaccines
    - concerns regarding suppliers' capacities to honour advance purchase agreements in the event of a crisis.
- In two countries, stockpile procurement was the responsibility of national agencies with experience in stockpiling and preparedness. In another country, a hospital procurement group was involved in the process.

Threat identification, risk assessment and product identification:

- All five countries reported completing risk assessments or analyses to determine what risks warranted stockpiling. Two countries reported using formal scoring or evaluation methods to rank health risks or needs.
- Advice from expert groups was used by all five countries to identify threats, assess risks, and to assist decision-making regarding what products to stockpile and in what quantities.
- All countries indicated that costs and previous stockpiling experience influenced what was included in their stockpiles. Two countries used international documentation to inform the types and quantities of products stockpiled.

Cost considerations and efficiency:

- None of the five countries reported using a formal methodology to assess the costs and benefits of stockpiling approaches.

- Four countries cited budget as a limiting factor when deciding on what to include in stockpiles, and three countries noted challenges in agreeing contracts with industry stakeholders to hold stockpiles.
- All five countries highlighted waste as a challenge, but acknowledged that it must be managed or minimised, as it cannot be avoided entirely. Examples of strategies used to minimise waste included: stockpile rotation; sale, auction or free transfer of expiring products to medical and defence services; and donation to other countries as humanitarian aid.

Management and governance:

- All five countries reported that government ministries were ultimately responsible for the governance of national stockpiles.
- Stockpile management was the responsibility of the associated governing body in most countries. However, one country employed a national stockpile management group, financed by their Department of Health.
- Operational delivery, including stockpile distribution, took place through mechanisms such as ministries of health and inter-ministerial collaboration, wholesaler distribution networks, and the national emergency medical service.

National, EU and international coordination and collaboration:

- Two countries aligned their stockpiling approaches with national pandemic preparedness plans.
- Five countries participated in EU stockpiling initiatives and four countries reported participation in the European joint procurement agreement. All EU countries stated that having a national stockpiling was the highest priority, and that EU stockpiling initiatives complement, rather than replace, national stockpiles.
- Two countries reported collaborating with neighbouring countries to share certain MCMs.
- A lack of oversight or coordination of national stockpiles at EU level was noted as a gap in international coordination.

Suggested future approaches:

- A number of future approaches were outlined including:
  - a national independent expert group or national security board to assess risks

- an active stockpile management group
- decentralised stockpiles.

Overall:

- National MCM stockpiles are a key resource that may be deployed as part of a response to health emergencies and disasters. The themes identified, along with their associated sub-themes, may represent areas for consideration when developing a national MCM stockpiling strategy in Ireland.

Plain Language Summary

Stockpiling involves storing a large supply of items in case they are needed in the future. This report looked at stockpiling for public health emergencies in five countries: France, Latvia, Lithuania, the Netherlands and Norway. 'Public health emergencies' are events like the COVID-19 pandemic, where supplies of certain items such as medicines or healthcare equipment may be needed quickly. We interviewed experts from each of the five countries to find out how they approached stockpiling in their countries. We asked them what they stockpiled in the past, what type of stockpiles they currently have, and how they decide what items to include in their stockpiles. We also asked them how they manage their stockpiles, how they review the cost of stockpiling and how they are linked with European stockpiles.

All of the countries included in this study had stockpiles that were put in place by the national government. In the past, these stockpiles were set up so that countries could respond to accidents that involved a large number of people. Over time they also started to stockpile for public health emergencies, such as pandemics. Items that are now stockpiled for public health emergencies include vaccines, medicines, medical equipment, chemical antidotes, laboratory supplies, and personal protective equipment (for example facemasks and gloves).

The COVID-19 pandemic changed what some countries include in their stockpiles. Some countries started stockpiling items such as facemasks, gloves and ventilators during the pandemic, but are now deciding if they should keep doing this due to the high costs involved. Another change since the pandemic was that some countries now stockpile day-to-day general medicines to avoid items going out of stock.

All five countries use what they call physical stockpiles. Physical stockpiles mean that items are stored in a warehouse and can be sent to wherever they are needed quickly, in case of an emergency. The other option is a virtual stockpile. Virtual stockpiling means that companies that make or sell items store a certain amount of stock that the government can buy if needed in an emergency. The countries in this report were not using virtual stockpiles, as they cost a lot of money and there is a risk that stock may not be available very quickly.

All five countries used experts to guide them in deciding what items they needed to stockpile and how much of each item to stockpile.

All five countries reported that waste due to unused stock was a challenge. While it is not possible to avoid having any waste, it can be reduced. Most of the countries rotated stock to make sure it did not go out of date. Rotating stock means that when items are close to their expiry date they are either sold or given away to hospitals or charities, so that they are not wasted.

Government ministries were responsible for stockpiling in all five countries. One country also had a specific team of people that was responsible for managing the stockpile. Four of the countries said that they took part in buying stock with other countries in the EU (joint procurement) with one country stating that EU joint procurement only contributes to a very small part of their stock of medicines. However, all of the countries said there was not enough coordination on stockpiling between the EU countries.

Some countries had suggestions for how Ireland should go about stockpiling. These suggestions included having a group to decide what threats to stockpile for, and having a group to manage the stockpile on a day-to-day basis. Another suggestion was that stockpiles should be stored in different locations in case access to a particular location is not possible in an emergency situation.

The information in this report will be used to help develop a stockpiling strategy for Ireland.

1 Background

In 2001, the European Commission established the European Union (EU) Civil Protection Mechanism,[1] with an aim of protecting EU citizens through the coordination of responses to natural and man-made disasters and crises. This mechanism was further upgraded in 2019 with the creation of rescEU, a reserve of assets, hosted in 10 EU countries (Belgium, Croatia, Denmark, Germany, Greece, Hungary, Romania, Slovenia, Sweden, and The Netherlands), which may be deployed in response to crises in Europe.[1] This reserve includes shelters, transport and logistics assets, energy supply items, and a stockpile of medical countermeasures (MCMs), (such as vaccines, medicines, medical equipment and diagnostics),[2] to be used in response to health emergencies.

However, the COVID-19 pandemic further highlighted the need to improve preparedness for emerging health threats. At EU level, the Health Emergency Preparedness and Response Authority (HERA) was developed in September 2021 to prevent, detect, and rapidly respond to health emergencies; this has included increasing medical, or MCM stockpiling capacity.[3] At a national level, the World Health Organization (WHO) has identified strategic health stockpiles as one of the resources that may be deployed as part of a national response to health emergencies and disasters.[4] Furthermore, both the WHO and HERA have recommended that individual countries develop national MCM stockpiling strategies.[5]

To facilitate MCM stockpile strategy development a list of the top three health threats was developed by HERA and includes: pathogens with a high pandemic potential; chemical, biological, radiological and nuclear threats (CBRN); and threats resulting from antimicrobial resistance (AMR).[6] The WHO has also published policy advice on national MCM stockpiles for radiological and nuclear emergencies, including considerations for establishing and managing such a stockpile. However, this policy advice relates only to stockpiling of MCMs for the diagnosis, prevention, or treatment of radiation injuries. It does not address generic MCMs used in other health emergencies, such as biological products (for example, vaccines, blood products and antibodies), other medicines (for example, antibiotics, antivirals, painkillers, and fluids) and medical devices (for example, other diagnostic tests and personal protective equipment).[7]

Gaining an understanding of national approaches to MCM stockpiling will help inform the development of a national MCM stockpiling strategy in Ireland, through supporting the work of the Health Security Unit in the Department of Health. This report therefore contains an overview of national MCM stockpiling approaches for public health emergencies in selected countries.

2 Methods

A detailed summary of the methods used for this overview is provided in the *Protocol for an overview of national approaches to stockpiling of medical countermeasures for public health emergencies* (found here). In brief, this report presents a summary of national MCM stockpiling approaches for public health emergencies in five countries: France; Latvia; Lithuania; the Netherlands; and Norway. The countries included were selected based on their varying levels of experience with MCM stockpiling.

2.1 Data collection

Data collection was carried out via semi-structured interviews with key representatives in selected countries. In a deviation from the protocol piloting of the interview topic guide was not undertaken due to lack of key expert availability. However, the interview topic guide was refined as necessary following each interview (see Appendix 1). The focus of the interview was to understand the national level approach taken in each country to stockpiling of MCMs for public health emergencies.

Key representatives in selected countries were identified and were initially contacted via email by the Department of Health with an invitation to participate. Those who responded with an expression of interest in participating were subsequently sent the interview topic guide, a participant information leaflet (see Appendix 2) and a consent form (see Appendix 3) by a member of the evaluation team in HIQA, and a suitable date and time for the interview was arranged. Informed consent was obtained from each participant prior to each interview. For those who did not respond to the initial invitation, three reminder emails were sent by the evaluation team.

The interviews were conducted remotely via Microsoft Teams or Zoom. Three team members were present during the interview: one interviewer and two note takers. All of the interviews were conducted by the same interviewer to ensure consistency. Interview data were recorded as written notes only; neither audio nor video recordings were made.

2.2 Data verification and analysis

Following each interview, each team member's written notes were combined to form a single summary interview note. Each participant was provided with the summary note of their interview and asked to verify it and, where necessary, to provide

clarifications. Participants were requested to complete this verification within five working days of receiving the interview note.

Interview summaries were then pseudonymised, that is, country names and or information which may identify a key representative and or their associated country (such as, organisation titles or named public officials) were removed and replaced with values that do not allow participants or countries to be directly identified.

Thematic analysis was conducted to analyse the verified interview data. A deductive approach was taken, with themes pre-determined based on the topics of interest. Thematic analysis was conducted according to the six-step process described by Braun and Clarke:[8]

- Step 1 — Familiarisation: Three researchers familiarised themselves with the interview data, through reading and re-reading of the data collected.
- Step 2 — Coding: The researchers independently generated initial codes. These initial codes were discussed and then finalised to create a codebook, which subsequently facilitated data coding.
- Step 3 — Theme development: Using a deductive approach, initial themes were identified based on the interview topic guide. All researchers sorted coded data into these initial themes. Additional themes and or sub-themes were also identified by the researchers during this step, where relevant.
- Step 4 — Theme review: All themes were reviewed in detail, modified and refined to ensure they were accurate.
- Step 5 — Theme refinement: All themes were defined and further refined to derive the finalised set of themes and to identify sub-themes and categories (where required).
- Step 6 — Write up: A descriptive report was prepared in which findings were summarised and compared across the selected countries.

3 Findings

Six interviews were conducted across the five countries, with one country providing two separate key representatives for interview. The average duration of each interview was approximately 45 minutes. All of the key representatives interviewed were working within their associated Department of Health (or equivalent), or a government affiliated public health agency. While one country provided written answers to the interview questions prior to the interview being undertaken, these answers were then confirmed and further elaborated on during the interview. For

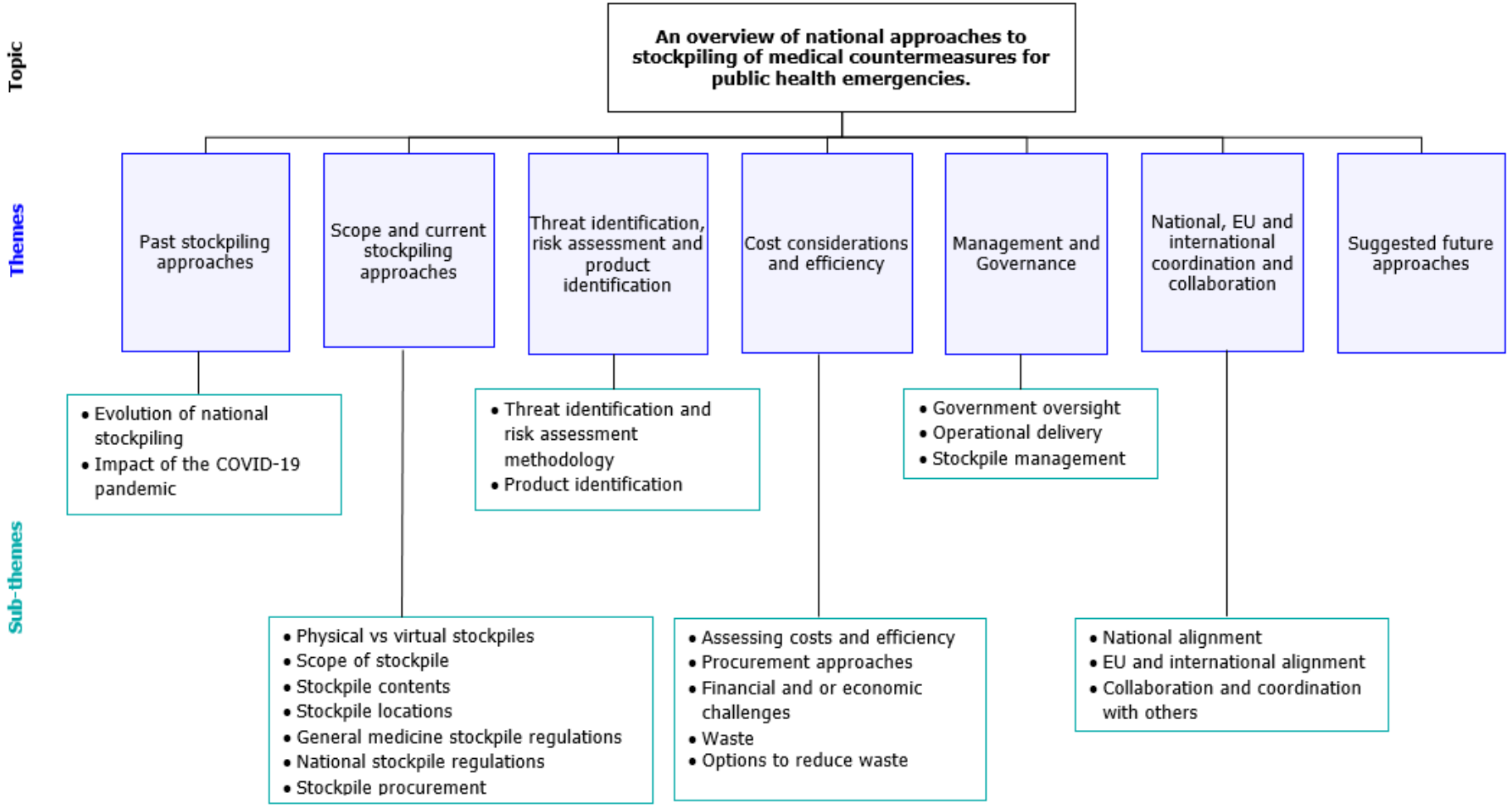
analysis, the information provided by the country with two key representatives was combined and treated as one country.

Additionally, a number of supporting documents (both publicly available and not publicly available) were provided by key representatives following interview completion (see section 3.2).

3.1 Interview thematic analysis

A number of themes and sub-themes were identified across the interviews. Themes identified were: past stockpiling approaches; scope and current stockpiling approaches; threat identification, risk assessment and product identification; cost considerations and efficiency; management and governance; national, EU and international coordination and collaboration; and future approaches (see Figure 3.1).

Figure 3.1. Flow diagram outlining the topic, themes and sub-themes identified from interviews with key representatives.



Key: COVID-19: coronavirus disease 2019; EU: European Union.

3.1.1 Past stockpiling approaches

Evolution of national stockpiling

All five countries reported previous experience with stockpiling. However, the approaches taken towards stockpiling, and the products stockpiled have evolved over time, and vary from country to country. Two countries had a longstanding tradition of stockpiling due to geographical and political reasons. Both countries reported that work is currently ongoing to modernise the stockpiling approach.

In one country, historically, the previous state owned wholesaler was required to hold a physical stockpile to cover the entire country. This system was reviewed in 2012 and legislation in relation to a new stockpiling approach was enacted in 2015. This legislation mandated that stockpiles for a few critical medicines should be held by commercial wholesalers on behalf of the government. Hospitals and outpatient services were also required to look after their own stockpiling needs. This legislation also put an end to non-rotating stockpiles as they were found to be associated with large amounts of waste. As a result from 2021 products in the national stockpiles are now rotated for use in hospitals and outpatient services prior to their expiry date and this has significantly reduced the amount of waste related to stockpiling.

Another country developed their stockpiling approach in the 1970s, with an initial focus on emergency medicine. This originated from the need to be prepared for mass casualty events, such as major road accidents or industrial incidents. There was a realisation of the need for a fast response and stockpiles were generally linked to emergency services in the main hospitals. This evolved into the development of a centralised national physical stockpile in the 1980s, which also covered CBRN and pandemic threats. This country now has national non-rotating stockpiles held by the government, which are mainly centralised.

A history of a reactive approach to stockpiling was described by another country. In this country, stockpiling was focused on the most serious threats identified, and they described this past approach as being fragmented. Stockpiles were mainly focused on threats as they arose, but this reactive approach resulted in large amounts of unused stocks. In this country, work is reportedly underway to develop a new approach to stockpiling of MCMs as well as general medicines.

Impact of the COVID-19 pandemic

All five countries reported that the COVID-19 pandemic influenced their stockpiling approach:

- one country noted that the pandemic increased political motivation to ensure adequate stockpiles were in place
- two countries started to stockpile new MCMs as a result of the COVID-19 pandemic. This included items such as ventilators, syringe drivers, intensive care unit (ICU) medicines and personal protective equipment (PPE). One of these countries is reviewing whether or not to continue to stock these items in the future
- two countries decided to stock general medicines as a result of the pandemic. One country introduced legislation in 2021 which requires the pharmaceutical industry to hold between two to four months of routine stock. The second country developed a list of critical medicines for chronic diseases but has not implemented a general medicine stockpile as yet.
- from 2020 onwards, one country implemented a new system where rotating stockpiles were held by contract with wholesalers, covering three to six months of day-to-day general medicines for both hospitals and outpatient sector to prevent shortages.

3.1.2 Scope and current stockpiling approaches

Physical vs virtual stockpiles

Two main types of stockpiles were reported by key representatives: physical (stock held in warehouses) and virtual stockpiles (available stock held by industry which can be potentially mobilised when required). Physical stockpiles were also further categorised as being rotating (stock is rotated for use prior to expiry date) or non-rotating. Four countries used rotating stockpiles, with only one using non-rotating stockpiles. However, all countries had some non-rotating stockpiles for rare threats. Stockpiles varied in size from a six-week supply to a six-month supply. All five countries reported the use of physical stockpiles, with all of these stockpiles, apart from one, held by national governments.

The use of virtual stockpiles was previously considered by four countries, but none of the countries had implemented this. At the time of interview, these countries were still assessing how this might be implemented. However, a significant number of barriers have been identified, namely cost and storage space. One expert discussed the challenges with implementing virtual stockpiling in their country to date. They explained that the costs quoted by industry for providing a virtual stockpile were prohibitive unless they had a system for rotating the items in the stockpile through their own businesses. This would be possible for a small stockpile of routine items but it would not be feasible for specific countermeasures addressing rarer threats. Another consideration for the feasibility of virtual stockpiles is the quantities required. For example, one country tried to implement a virtual stockpile for

facemasks. However, it was not possible as the quantities that needed to be stockpiled were deemed too high by industry. Another expert also described a similar challenge in finding suppliers in their country who were able to offer virtual stockpiling in the quantities required. The likely need for importation of virtually stockpiled products when required, due to a limited number of domestic suppliers, was also noted as potentially challenging in a global crisis.

Scope of stockpiles

All five countries reported that their stockpiles focused on national threats, but also covered cross-border threats. However, one country highlighted that national and cross-border threats are often the same (such as tuberculosis and AMR). Three countries reported having stockpiles in place which covered general medicines, while one country was in the process of implementing a stockpile of general medicines.

One country described the scope of their stockpile as diverse. Their national stockpile mainly addressed national threats, but also covered some cross-border threats. Its main focus was to respond to public health crises such as epidemics, pandemics, CBRN threats and industrial incidents. This country mainly used non-rotating physical stockpiles as they have noted complexities in donating or selling unused stocks due to EU trade policy. Their national stockpile also had the capability to take charge of purchasing and regulation of certain products when shortages occur. This happened during the COVID-19 pandemic and also in specific circumstances where there were severe shortages of different medical products. Regulations in this country also required wholesalers to keep sufficient levels of general medicines in stock to cover a period of two to four months depending on the specific medication.

In another country, separate stockpiles were reported for hospitals and primary care. Hospitals were required to have their own rotating stockpiles as well as some non-rotating stockpiles for certain threats such as CBRN and AMR. In this country a national rotating stockpile for general medicines was also held by the pharmaceutical wholesalers. Contracts with multiple wholesalers, who cover different geographic regions, are in place for stockpiling of general medicines for primary care. This approach ensures coverage of the entire country. In addition to a legislative requirement for wholesalers to hold a stockpile of at least two months for a specific list of medicines. At the time of the interview, the quantity of stock held as a legislative requirement was in the process of being increased from a two-month supply to a six-month supply. The intention is that this increase in the legislative requirement will replace the contract based stockpiling.

The third country interviewed noted that the scope of their national stockpile included nuclear accidents, smallpox, diphtheria and antidotes for poisoning. This

stockpile was held by the government and rotation of stock was implemented when possible. Difficulties with rotating stock were reported due to EU policy and contracts made with suppliers. In addition to the national stockpile, wholesalers and marketing authorisation holders (MAH) were required to keep a six-week stockpile for general medicines. This country highlighted that they were currently reviewing their stockpiling approach and were focusing stockpiles on responding to the early phase of a crisis where procuring stocks can be challenging and an agile response is required.

The fourth country included had a rotating physical stockpile, which was focused on mass casualty incidents, CBRN threats and pandemic threats. They specified that it did not include general medicines or countermeasures aimed at AMR. This country had a list of general medicines that wholesalers will be required to stockpile in the future, but at the time of being interviewed there was no stockpile for general medicines in place.

The final country stated that their rotating physical stockpile was focused on all possible threats for the national health system, such as: pandemics, military threats, nuclear incidents, natural disasters, fires and other possible threats. This country did not have a stockpile for general medicines, however, medical institutions were required to have stockpiles in place that would last for at least one month, although some institutions reportedly had stockpiles for a period of up to three months.

Stockpile contents

The question of what specific items each country stockpiled was not addressed in this work. However, items which were specifically mentioned as being included in national stockpiles were the following: anti-viral medicines, PPE, intravenous antibiotics, medical devices and ICU medications. Examples of threats which were stockpiled for included:

- AMR
- CBRN
- tuberculosis
- industrial accidents
- nuclear accidents
- diphtheria
- small pox mass casualty incidents
- natural disasters.

All five countries reported stockpiling PPE, with two countries only including PPE since the COVID-19 pandemic. Two countries reported stockpiling ventilators, however this was under review in one country (see section 3.1.3). Another had

decided to include ventilators in hospital stockpiles only, to allow for easy rotation. All of the countries stated that their stockpiles include MCMs for CBRN threats, with one specifically mentioning that they have a stockpile of iodine tablets for nuclear incidents.

Two countries reported stockpiling vaccines. The first country reported that they stockpiled a six-month rolling safety stock for childhood vaccines and a four-month safety stock for other vaccines. They also held specific vaccines which were required for infectious disease threats, such as anthrax. Another country stated that while COVID-19 vaccines were included in the national stockpile, vaccines were not generally stored in their national stockpile. However, there was a separate government agency in this country which was tasked with the procurement of vaccines, and ensuring an adequate stock of vaccines was maintained. One country outlined that they had previously included vaccines in their national stockpile, but had stopped this practice ten years ago due to the high levels of waste related to the short shelf life of vaccines.

One country stated they did not stockpile blood products or lab equipment as part of the national stockpile, but there were other agencies within the country with a remit for these items.

Stockpile locations

Stockpile location varied from country-to-county, with all five countries outlining this was mainly due to security of supply, speed of deployment and stockpile distribution:

- two countries suggested that security of supply was a concern, particularly after the invasion of Ukraine in 2022. This resulted in one country holding national stockpiles in multiple locations and reinforced the need for physical stockpiles in another.
- two countries reported that speed of deployment impacted their stockpile location, with four countries requiring hospitals and healthcare institutions to have their own stockpile for items that they would require. This was intended to ensure that items were near to the user for fast deployment. In another country, speed of deployment also impacted whether stockpiles were held centrally or locally.
- one country also outlined that wholesalers stored stockpiles for hospitals and for primary care. This allowed for geographical coverage of the entire country and the use of pre-existing distribution channels.

General medicine stockpile regulations

All five countries reported having national legislation related to stockpiling. Legislation related either to national stockpiles for emergency response or to general medicines. Three countries outlined that they had regulations requiring wholesalers to have stockpiles in place for general medicines. The time periods for these stockpiling requirements varied from six weeks in one country to four months in another. Another country advised that they were planning to implement regulations to allay manufacturers concerns of parallel distribution by wholesalers. *Parallel distribution occurs when products originally placed on the market in one member state by the market authorisation holders (MAH) are marketed in another country by another wholesaler, independent of the MAH.*[9] *This occurs outside of the distribution channels established by the manufacturer and can generate profits to independent wholesalers when products are sold on to other countries which have higher prices for pharmaceutical products.*

National stockpile regulations

Two of the countries had legislation relating to national stockpiles held by government and other public bodies for emergency response. The first of these countries introduced legislation in 2019 which placed the responsibility for stockpiling on individual government ministries. Individual ministries in this country are required to conduct risk assessments for their own areas of responsibility and to stockpile accordingly. The second country had legislation that set out the procedures for national stockpiles as well additional stockpiles that must be held by individual municipalities. Furthermore, in this second country, the relevant government minister issued an order to medical institutions obliging them to hold their own stockpiles equivalent to one month's supply, with many reportedly choosing to keep a three-month stockpile in warehouses.

Stockpile procurement

Three countries reported adopting a flexible approach, using either national procurement mechanisms or international joint procurement agreements; this depended on the products required and time constraints involved. These three countries noted some advantages of national procurement over international joint procurement mechanisms, for example, control over choice of products and or suppliers, and more timely access to products. One country specifically expressed a preference for national suppliers or European suppliers since the COVID-19 pandemic; this was due to challenges experienced in securing timely, reliable access to products manufactured outside the EU during the pandemic. Joint procurement was noted to reduce costs, and was reported to be the sole means of procuring certain products at certain times (for example, antiviral medicines during the COVID-19 pandemic). One country reported that when using EU joint procurement, they

review the particular brand chosen by the EU, and on occasion have procured their own products if they favour another brand.

Four countries reported difficulties related to procurement. These difficulties included acquiring stockpiles with an adequate shelf life, in the required quantities, due to the current shortages in the global market for medicines and medical devices. This was further supported by another country who noted that over the past few years they have observed an increase in medicine shortages, and this was linked to just-in-time delivery of products. Procurement of vaccines was also noted to take a long time, with a lead-in time of up to two years. This meant that advanced planning was crucial. Two countries also highlighted concerns with advance purchase agreements. They outlined that if manufacturers have multiple agreements in place with several countries they may not be able to deliver the required products when a cross-border crisis occurs.

Three countries also outlined who was responsible for stockpile procurement. One country reported a hospital procurement group which took on the role of purchasing pharmaceuticals, diagnostic tools and PPE, while the two remaining countries outlined that the government gave responsibility for stockpile procurement and tendering to the national agencies with experience in stockpiling and preparedness.

3.1.3 Threat identification, risk assessment and product identification

Threat identification and risk assessment methodology

All five countries reported that they completed a risk assessment or an analysis, in some form, to assist in deciding what risks to stockpile for. Expert group advice to decide which risks should be stockpiled for and or to identify threats to their respective health system, was reported by all five countries. In general, these experts groups were composed of representatives from a number of different bodies or agencies including: federal institutions (such as ministries or departments of health); the health-care system (such as doctors and pharmacists); independent agencies, public health experts, scientists, chemical experts and or authorities located across the domains within which threats may occur (such as health and the environment); and the armed forces. One country also outlined that a separate working group was used to risk assess for hospitals, compared to primary care. Two countries reported they conduct risk analysis or threat review every three years, with one country indicating this can be conducted in the interim when events such as the emergence of new dangers or changes in legislation occur. Another country reported that threat assessment was conducted, by law, independently within each Ministry, with each Ministry therefore involving their own expert group. One country also

acknowledged that when using an expert group, conflict of interest must be considered, and that they rarely use industry representatives.

Two countries also outlined formalised scoring or evaluation methodologies used by expert groups or ministries of health to rank health risks or needs. This included one country reporting the use of a risk matrix to aid in the identification of stockpile resources, while another reported the use of an evaluation form by the expert group to prioritise what products should be held in the rotating stockpile (see section 3.2). This evaluation form was developed based on experience, and considers the development of new products. While the remaining countries acknowledged that there can be scoring and or risk assessments conducted, no detailed information was provided as to what these may entail. Lastly, one country also reported that national risks were largely in line with international risks, with EU risk mapping and North Atlantic Treaty Organization (NATO) guiding documents considered during risk assessment.

Product identification

The majority of countries reported difficulty in deciding what to stockpile, and in what quantity products should be stockpiled. A number of factors were reported to impact this decision including expert group advice, previous experience and stockpile review, cost and political will, and international guidance.

All five countries reported that expert group advice was not only used to assess or evaluate national risks but also to guide what kind, and what quantity, of products were included in their respective stockpiles. In one country, when smaller quantities of products were considered, the quantity required was decided by their Ministry of Health. However, when larger quantities were required, that incurred increased costs, the expert group was then asked to provide advice. One country specified that expert group advice was of particular importance when considering the quantity of MCMs needed for products which are not used on a daily basis.

All five countries indicated that previous experience influenced the inclusion of products in their respective stockpiles. This included experience in the stockpiling of facemasks. Two countries indicated that, previously, surplus facemasks were stockpiled due to the anticipation of a pandemic. In the context of such a pandemic not occurring and or in the context of stockpiles ultimately deemed surplus to requirements during the COVID-19 pandemic, stockpiling approaches were reconsidered. Both countries suggested these surplus quantities led them to revaluate how they assess product inclusion, particularly in relation to products required in large volumes. Additionally, one country reported that previous experience of medicine shortages impacted what was included in their stockpiles. This experience, combined with the risk of shortage at any given time point,

facilitated product identification as it helped estimate when a medicine shortage would become a threat for certain illnesses and or indications. One country also indicated that the quantity of everyday drugs and or medical devices used on a monthly basis by their ambulance service or hospitals was used to calculate the amount required for a rotating stockpile. Here, one month's use was deemed as a reference amount to calculate the quantity required for two to three months' use.

Stockpile review was also reported by three countries. One of these countries reported that if stockpile losses, such as waste, were observed, they reviewed the necessity and effectiveness of stockpiling the associated product. The stockpiling of high cost medical devices, such as ventilators, was of particular concern to this country, as they had previous experience of ventilator waste.

All five countries also indicated that cost and or the budget allocated to stockpiling influenced the inclusion of products in their respective stockpiles. Three of the countries described the funding of national stockpiles. In the first country this was through central government funding, the second country had interministerial funding which was approved by the prime minister and in the third country it was funded by the Department of Health. One country outlined that a national centre coordinated their stockpile budget, while another outlined a cost framework within which there was a limit to what could be spent. The remaining countries indicated their stockpile budget was based on government approval. Three countries reported that the high costs associated with MCM stockpiling often resulted in decisions surrounding product inclusion becoming a political issue. One country reported that, following the COVID-19 pandemic, political will to fund national stockpiles may have increased; however they were unsure this increased support would persist over time.

Lastly, two countries indicated that they used international documents and resources, such as those provided by WHO, HERA and NATO, to help decide on product inclusion in their respective stockpiles.

3.1.4 Cost considerations and efficiency

Assessing costs and efficiency

None of the five countries reported using a formal methodology to assess the costs and benefits of stockpiling. However, four countries commented on how challenging it is to assess the efficiency of a specific stockpiling approach, or to compare the efficiency of alternative approaches.

Despite this lack of formal assessment, three countries cited examples of how they observed inefficiencies in their stockpiling approaches and made changes in response. Examples provided included switching from static to rotating stockpiles or

changing the stockpile locations of very high cost medical devices to facilitate more frequent rotation. In addition, one country reported that the ministry responsible for coordinating their national stockpiles is also currently undertaking a project to evaluate different approaches in European countries, with the aim of preparing suggestions for how to improve approaches to stockpiling.

Examples of assessments of stockpiling effectiveness – that is, the extent to which the stockpiling achieves its intended outcomes – were reported by two countries. One of these countries reported assessing the adequacy of their stockpiles based on regional, national and international exercises and requests for international humanitarian aid, while the other monitored their annual usage of stockpiled products to respond to medicines shortages.

Three countries reported that costs were not the main factor influencing their choice of stockpiling approach; stockpiling was considered necessary by their national governments due to factors like their country's size and or geographical location.

Procurement approaches

While current approaches to stockpile procurement were outlined in section 3.1.2, four countries also commented on cost and efficiency considerations in relation to procurement. As previously outlined, it was noted that there are potential cost savings associated with entering into joint procurement agreements, compared to procuring on a national basis. In addition, one country noted that national procurement may be less efficient than joint procurement for smaller countries in certain cases, such as where suppliers' minimum required purchase volumes for their products are excessive in relation to the country's needs.

Financial and or economic challenges

All five countries made reference to the challenge of managing stockpiling within a limited budget allocation. Four countries specified that the available budget was a limiting factor when deciding what to include in national stockpiles; while threat identification and risk assessment processes were used to develop a prioritised list of products to stockpile, the budget may not be available to procure all products (as outlined in section 3.1.3).

Three countries noted challenges associated with agreeing contracts with industry stakeholders for stockpiling. Two of these countries were examining the possibilities of implementing stockpiles held by the market authorisation holders (MAHs) or wholesalers. Both countries highlighted the potential challenges of financing this type of stockpiling approach; one country specified that the challenge would be agreeing the budget to make available for this purpose, whereas the other country

noted the challenge of agreeing a fair compensation amount with industry stakeholders. The third country had national legislation in place requiring wholesalers to maintain certain stockpiles for a few medicines. Although this legislation was in place for a number of years, they reported that it was an ongoing and time-consuming challenge to agree contracts with wholesalers, particularly with respect to the level of financial compensation they should receive for maintaining these required stockpiles. For that reason legislation to hold stocks for an extended time period will be implemented which will replace the contracts.

Aside from these financial challenges, one country also highlighted the potential for national stockpiling to contribute to market distortion, specifically where governments or other public bodies seek to purchase large quantities of scarce products. The cited example of this was the purchasing of PPE and other MCMs during the COVID-19 pandemic.

Waste

All five countries highlighted waste as a challenge associated with stockpiling, both in reference to the waste of products and the waste of public finances. All countries particularly emphasised static stockpiling approaches as being associated with waste. Four countries cited examples of having to destroy stockpiled products that reached their expiry dates, remained unused, and where it was not possible to sell, donate or recycle them. Examples of such products included: antibiotics and vaccines with short shelf lives; high cost medicines and medical devices that are not frequently used; MCMs stockpiled for emergencies with a negligible probability of occurring but potentially catastrophic impact, such as smallpox vaccines; and excessively large quantities of MCMs stockpiled during the 2009 influenza A (H1N1) and COVID-19 pandemics. One country highlighted the challenge of dealing with negative media attention and or public opinion relating to waste. For example, if stockpiles are unused, they may be perceived as being a waste of money. Conversely, if waste is minimised, there is a risk of having too little stockpiled should an emergency occur.

Despite the issues of cost and waste, three countries noted that physical stockpiling remains important to ensure timely access to MCMs in the event of an emergency. Two countries described viewing national stockpiling as a form of insurance and, as such, certain costs are deemed necessary and acceptable to incur in order to mitigate risks with a high likelihood and or high impact.

Options to reduce waste

All five countries referred to waste as an aspect of stockpiling to be managed or minimised, rather than avoided entirely. Four countries provided examples of how they minimised waste. These examples included approaches taken to improve

efficiency, as mentioned in *Assessing costs and efficiency*; for example, reviewing wasted products and either revising the need to stockpile them or changing the approach to stockpiling them to prevent future losses.

Three countries described various methods of rotating stockpiled products to reduce waste, and one further country noted that they would like to implement stockpile rotation for this purpose. Of the countries that used rotation, one country implemented rotating stockpiles held by wholesalers, whereas two countries had arrangements for rotating physically stockpiled products into other settings as they approached their expiry dates. Two of the countries currently implementing stockpile rotation described how this approach requires active management to be effective. One of these countries outlined that they had established a group dedicated to actively managing their rotating stockpiles and keeping waste below a certain target level (0.5% of the total value of the stockpiled products).

Two countries noted that demand for certain MCMs that are routinely used in healthcare can be predicted; this facilitates stock rotation and waste minimisation. Examples provided of MCMs that lend themselves to this approach were vaccines used as part of national immunisation programmes, and medicines and medical devices commonly used by hospitals or ambulance services.

Two countries stated that they had legislation in place that made provisions for low cost sales or free transfers of physically stockpiled products as they approach their expiry dates. Both countries had arrangements to sell or auction products to healthcare institutions at a defined time prior to their expiry dates; for example, one year before expiry. Both countries reported that these sales resulted in some financial losses, since the products were usually sold below market rates. Both countries also had systems in place to donate products that are close to expiry to other national services without cost to those services, for example, to ambulance services, hospitals, or the military. One country noted that they selected certain products for national stockpiling that aligned with those used by these other services in order to facilitate the donation or sale of these products when they were approaching the end of their shelf lives.

Two countries also outlined that they have donated unused MCMs from their national stockpiles to other countries to provide humanitarian aid. However, one country noted that the amount they are permitted to donate for this purpose is limited, so while donation of this type may be a means of reducing waste to some extent, it is not a solution.

Similarly, two countries reported that EU trade policy and legislation may act as a barrier to minimising waste. This included limitations on donating products to other countries, and also to restrictions on donations between public bodies within the

same country. One country noted that they have advocated for change in this regard, but that it is a legally complex matter.

3.1.5 Management and governance

Government oversight

All five countries reported that government ministries were ultimately responsible for the governance of national stockpiles. However, the way in which this occurred differed across the countries:

- two countries outlined that each ministry was responsible for their own stockpile; however, there may be crossover of stockpiles depending on the threat. For example, while the Ministry of Health may stockpile specific MCMs, the Ministry of Infrastructure may also stockpile countermeasures related to CBRN incidents
- one country outlined their respective Ministry of Interior had overall responsibility to coordinate all state stockpiles, despite each individual ministry developing their own stockpile
- one country reported their expert group retained oversight of the national stockpiles and reported back to their respective Department of Health if any problem occurred
- one country outlined overall coordination was retained within an emergency centre located within the national government.

Additionally, for the two countries in which each ministry was responsible for their own stockpile, it was indicated that in the event of a large crisis which extended beyond a single domain, governance would be inter-ministerial.

Stockpile management

While stockpile management was largely devolved to the associated governing body (see *Government oversight*), one country reported that they employed an active national stockpile management group, financed by their respective Department of Health. This management group was responsible for stockpile review, keeping stockpile waste low, and ensuring the correct amount of products were stockpiled. One country also reported that while the Ministry of Interior had overall responsibility for national stockpiles, ongoing management around what was stockpiled, stockpile maintenance, and distribution of stockpiles was retained within the national emergency medical service.

3.1.6 National, EU and international coordination and collaboration

National alignment

Three countries reported that they had or were developing pandemic preparedness plans, with two of these indicating that their stockpiling approaches were aligned with these plans. In one country, this was facilitated by the agency with responsibility for risk assessment and product identification also having responsibility for developing pandemic preparedness plans. One country reported that while stockpiling was mentioned in their pandemic preparedness plans, these plans were overarching and no specific stockpiling requirements were outlined within them.

In addition, one country outlined how close collaboration between all relevant stakeholders involved in national stockpiling enabled them to ensure alignment in relation to stockpile management. They spoke positively about the importance of regular communication, and reported that the group responsible for managing national stockpiles met weekly with experts from the health services and also received weekly status updates from pharmaceutical manufacturers or wholesalers.

EU and international alignment

All five countries were either EU or EEA member states, and all reported positive engagement in EU stockpiling initiatives. Four countries reported participation in joint procurement agreements at European level, particularly during the COVID-19 pandemic. Two countries referred positively to their involvement with HERA, and a further country indicated their intention to become more closely involved. The EU FAB initiative (network of vaccine producers for future health emergencies) was cited by one country as a beneficial development to ensure adequate manufacturing capacity and priority for EU countries with respect to vaccines in case of a future public health emergency. Two countries noted their involvement in the EU Civil Protection Mechanism and or rescEU initiatives, and one further country indicated their desire to contribute further to rescEU stockpiling.

Two countries indicated that knowledge of rescEU stockpiles influenced the contents of their national stockpiles. One country stated that they aimed to align their national stockpiling approach with rescEU stockpiles, while the other country noted that awareness of the types of requests made to the Emergency Response Coordination Centre was helpful to inform their national requirements. However, all of the EU member states also explicitly stated that national stockpiling remains their highest priority, since EU stockpiling initiatives are intended to complement rather than replace national stockpiles.

A number of countries reported various methods of learning from other countries to inform their national stockpiling approaches. For example, two countries stated that they referred to recommendations and other documentation produced by HERA, the WHO and the United States' Centers for Disease Control and Prevention when considering their stockpiling approaches. Two countries noted that they engaged in

discussions with colleagues in other European countries. One country reported that they aligned their stockpiling approach with those of neighbouring countries, as they faced similar threats. Another country stated that they also learned from the experiences of countries outside the EU during the COVID-19 pandemic.

Gaps in and barriers to international alignment were noted by a number of countries. Two countries commented that their national stockpiling approaches were not well aligned with those of other countries, with one expressing a perception that most countries stockpile based on their own individual risk assessments. In addition, two countries expressed queries around the purposes of EU stockpiling initiatives and how they are intended to align with national stockpiles. Both countries observed that current EU stockpiles were focused mainly on civil protection rather than public health emergencies, with one country citing the lack of a distinct budget for HERA as a barrier to improving stockpiling of MCMs. One country noted that there was currently a lack of oversight at EU level of what each country stockpiles, while acknowledging that confidentiality may be a barrier to achieving this. Another country highlighted that differences in clinical practice between countries may present barriers to alignment. The example provided for this was the greater use of narrow spectrum antibiotics in one country compared to other European countries, resulting in different antibiotic stockpiling requirements. Finally, two countries noted opportunities for greater EU alignment, particularly in relation to the establishment of agreements between EU countries to coordinate and or share stockpiles for certain high impact, low probability public health threats, rather than each country maintaining separate individual stockpiles of infrequently-used MCMs.

Collaboration and coordination with others

Separate to formal initiatives that aimed to promote alignment between EU countries, two countries also reported developing other international collaborations. Both countries outlined that they had agreements in place with neighbouring countries to cooperate in case of shortages of certain MCMs. One country noted that these arrangements were used during the COVID-19 pandemic. The other country reported that they had cooperated with other countries to share mpox vaccines, and noted the opportunity for more formal coordination of such arrangements at EU level.

3.1.7 Suggested future approaches

A number of suggestions for future approaches to stockpiling were outlined by key representatives, including:

- the potential for EU stockpiles to focus on specific, low probability threats, such as Ebola, and stockpile MCMs which do not need to be stocked at a national level
- the use of a national independent expert group or national security board to assess risks and provide scientific support around the choice of MCMs stockpiled
- that stockpiles are agreed at the highest level of government to increase the possibility of appropriate budget allocations
- the use of an active stockpile management group and a rotating stockpile to ensure stockpile waste remains low
- decentralised stockpiles, as these may be more efficient, particularly in terms of distribution. However, it was suggested that decentralised stockpiles should not be independent and should remain under centralised coordination to limit waste and ensure appropriate oversight
- to consider the use of the private sector to provide stockpiles
- that stockpiling should complement other measures for prevention and that a focus on the entire preparedness cycle is required.

3.2 Summary of supporting documents

Key representatives from Latvia and Norway provided supporting documents that were publicly available. Latvia provided their *Law on State Material Reserves,*[10] *Disaster Risk Assessment Recommendations*[11] and the report *About the State Civil Defence Plan.*[12] The *Law on State Material Reserves*[10] outlines how state reserves are to be effectively used in the event of disasters, military and other threats, and also outlines the roles of a number of ministries (including the Ministry of the Interior and Ministry of Industry). The *Disaster Risk Assessment Recommendations*[11] report outlines how risks are assessed at national and local or regional levels. The report outlines multiple scoring criteria for determining the probability and reliability of the occurrence of the risk frequency, risk plausibility, and the consequences of the risk. Lastly, *About the State Civil Defence Plan*[12] outlines a description of: the main risks; disaster prevention, preparedness and response measures to address the main identified risks; and information on funding resources and mechanisms. This report also outlines the responsible institutions in terms of type of activity (for example, the Ministry of Health are responsible in the area of health and medicine). Additionally, for each event or risk, the following information is included: the name of the event; deadline; the decision maker; the institution responsible for execution; the performer; and the event designation according to the NATO crisis reaction system manual.

Norway provided a summary of the *National pharmaceutical preparedness: Assessments and recommendations 2019* [13] which outlines the results from the

revision of the 2012 National Medicine Shortage Prevention Plan. This plan focuses on preventing drug shortages due to supply chain failure, as opposed to a sudden onset situation. A number of deficiencies in the plan were outlined around organisation, logistics and procedures, and 29 actions to improve the plan were listed. These actions were grouped under the headings 'international', 'national', 'regional and or local level', and 'all levels', and included:

- develop a unified strategy for Norway's international efforts in the medicine domain (international)
- revise wholesaler regulations and list of medicines that are part of mandatory contingency stock (national)
- prepare list of advice to help to the county governor and municipalities improve their work with medicine shortage prevention (regional and or local)
- establish agreements with relevant medicine manufacturers (across levels).

One country also provided a document which could not be confirmed as publicly available. In brief, this document outlined an evaluation form used by the country's expert group to prioritise what medicines should be held in the rotating stockpile. This evaluation form scored medicines across multiple criteria in categories such as criticality, consequence, and volume and or scope, with a higher overall summed score resulting in inclusion in the stockpile.

4 Discussion

Traditionally, to ensure national security, governments typically invested in areas such as the military and armed forces.[14] However, a 2020 Delphi consultation of EU experts identified that preparedness planning should include the availability of appropriate MCMs to protect the health of the member state's population, as one of its core preparedness principles.[15] Therefore, the ability to develop, and implement population-wide MCMs is key to ensuring national security,[14] and is facilitated through the creation of national MCM stockpiles. However, the approaches which countries take to MCM stockpiling for a particular health threat can vary significantly dependent on factors such as the size of the population affected, the healthcare capacity of the country, and the anticipated treatment duration.[7] Gaining an understanding of how countries approach national MCM stockpiling may help inform the development of a national MCM stockpiling strategy in Ireland. Therefore, a descriptive summary of national approaches to MCM stockpiling for public health emergencies in France, Latvia, Lithuania, the Netherlands and Norway was undertaken. These countries were selected based on their varying level of MCM stockpiling experience.

All five countries reported some experience of stockpiling, and their approaches had evolved over time. Stockpiles were initially set up to respond to mass casualty incidents, but most countries reported focusing now on broader threats, including the top three threats as identified by HERA: AMR, CBRN threats, and pathogens with a pandemic potential.[6] Additionally, the COVID-19 pandemic was identified as having a positive impact on current stockpiling approaches, as it increased political willingness to fund stockpiling and highlighted the importance of stockpiles for preparedness. It also resulted in the introduction of stockpiles for general medicines in two countries.

While rotating stockpiles require planning to ensure the timely distribution of products prior to expiration date or end of shelf life,[16] it is suggested they result in increased pandemic preparedness, and less waste.[17] The current report identified that all countries, bar one, reported some kind of rotating stockpile, although this was dependent on the product stockpiled. This rotation was conducted via methods such as wholesaler rotation, placing stock nearing expiry on the market, and or providing it directly to hospitals, and was deemed by key representatives as essential in keeping stockpile waste low.

The use of virtual stockpiles was also assessed by four countries, but it was not considered to be a feasible option at time of interview. This was due to the high costs which industry would charge for providing this service, as well as the large amount of storage space that would be required. However, the HERA AMR report suggested that an increase in private sector stock was the most feasible way of using stockpiles to avoid supply chain disruptions.[18] The HERA report also suggested that a transparent platform which identified antibiotic shortages and provided information on product availability could be used as a form of virtual stockpiling for AMR threats.[18] In 2022 USAID developed a list of the most commonly ordered items in the COVID-19 pandemic and used this to develop a virtual stockpile.[19] Two European wholesalers were selected to keep a revolving stockpile of essential PPE in China. There was no obligation to purchase unordered stock and this ensured no financial risk to USAID. The USAID advised that the cost of items ordered from the virtual stockpile was between 20-50% higher than usual, however speed took priority over lower price during emergencies.[19]

The current report also identified that all public sector stockpiles were fully funded by public funds from national budgets. However, in three of the included countries, the stockpiles for general medicines were privately owned industry stockpiles. These were either held by wholesalers or the MAHs. This is supported by the HERA AMR report,[18] which outlined that the privately owned stockpiling model is in place for general medicines in several EU countries including France, Finland and the

Netherlands, and this places the onus on the MAHs or wholesalers to maintain an inventory to a certain level.

Stockpile location was identified as an important consideration for the countries interviewed in this report. Ensuring stockpiles were hosted in multiple locations for security purposes was noted, as well as having certain supplies hosted in hospitals for rapid access. This is referred to as "user-managed inventory" and may increase MCM distribution capacity and speed at a local and or regional level, while also being cost-effective.[20]

Appropriate regulation is an important aspect of any stockpiling approach. For general medicines, countries interviewed noted that it is necessary to have legislation in order to ensure industry holds the required amounts of stock and to avoid the issue of parallel export. For countries with established regulatory systems, periodic reviews may be helpful to ensure that systems remain responsive to changes in the health sector over time. For example, Norway's *National pharmaceutical preparedness: Assessments and recommendations* included a recommendation to regularly revise wholesaler regulations and the list of medicines included in mandatory contingency stocks.[13] Legislation is also used in some countries to set out clear structures for national stockpiling and to assign responsibilities to ministries, municipalities or healthcare institutions. An example from the included countries is Latvia's *Law on State Material Reserves,*[10] which assigns coordinating responsibilities to the Ministry of Industry and Ministry of the Interior, and sets out the requirements for individual ministries to establish and manage stockpiles for their respective sectors. Furthermore, pieces of secondary legislation under this law regulate the procedures for use, verification, sale, transfer and write-off of stockpiled products.[21, 22]

Three countries adopted a flexible approach to procurement, using national or joint procurement at different times. While EU joint procurement has considerable public support,[23] research based on the pandemic response in the UK suggested that appropriate regulation and governance for procurement is required in order to ensure transparency.[24] Furthermore, while joint procurement was reported as less costly by countries within the current report, it was also found to be time consuming and may limit the brand of product which can be procured.

All five countries reported using expert advice to perform threat identification or risk assessment, while two countries outlined formalised scoring or evaluation methodologies which these use. Both these methods are in line with the '*Strategic Toolkit for Assessing Risks'* (STAR) published by the WHO in 2021.[25] This toolkit was developed to support countries in adopting an all hazards approach to emergency preparedness, and outlines six steps to describing the risks to a country.

While this results in a country risk profile which includes a risk matrix and risk summary, the process uses a participatory approach whereby the expertise and knowledge of key stakeholders are embedded. Following risk assessment, the majority of included countries also reported that it was difficult to decide what products to stockpile. While expert advice was again used to facilitate product identification, research suggests that a combination of drug prescribing and utilisation data, expert and stakeholder advice, and company registration data (for the companies supplying products of interest) may protect against medical supply vulnerability.[26]

Another possible option to determine what is stockpiled is the use of health technology assessment (HTA) methodology. HTA is defined as 'a *multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.'* [27] HTA may provide an opportunity to overcome the difficulties identified with decision making for emergency preparedness.[27] HTA has the potential to offer a standardised, robust and independent approach for emergency preparedness. Experts from the European Public Health Association (EUPHA) have developed a conceptual framework for building a preparedness plan using a HTA approach.[27] This could help to counter the concerns highlighted by some of the experts in our study in relation to limited budgets and public concerns about costs and associated waste. One example where a HTA approach was employed was a 2023 paper by Watson et al.[28] where they used evidence synthesis and decision tree modelling to determine whether or not neuraminidase inhibitors should be stockpiled for pandemic influenza use.

None of the countries interviewed reported that they formally assessed the costs and benefits of their stockpiling approaches, although all five countries acknowledged the challenges of implementing stockpiles with limited budgets, as well as managing or minimising waste. Assessing and comparing the costs and effectiveness of various stockpiling approaches that include an array of MCMs for various purposes is complex, as noted by four of the included countries. However, narrowing the scope to focus on specific MCMs for specific public health emergencies presents a more feasible question to consider. A number of studies have modelled the costs and or cost-effectiveness of using antivirals in influenza pandemic scenarios, including the costs of replacing stockpiled antivirals that expire between pandemics.[29-31] These studies provide examples of how having antivirals readily available to provide treatment may be cost-effective from a societal perspective, particularly in high severity pandemics. However, these studies did not include all potential costs associated with stockpiling that may be relevant for policy makers to consider. For

example, costs associated with storage of physical stockpiles, potential costs of compensating wholesalers if stockpiles are held by industry, or costs associated with stockpile management and distribution. Such costs are relevant, highlighted by the number of the countries included in this report that commented on them during interview. However, these costs are also not necessarily unique to each MCM and may be dispersed as part of a national stockpiling approach that includes many MCMs for a variety of public health emergencies.

Waste of stockpiled products, and therefore public finances, was highlighted as a challenge by all five countries interviewed. Equally, all countries acknowledged that waste could not be entirely avoided, but should be managed and minimised. Rotating products out of stockpiles as they approached their expiry dates was identified as a practical way to minimise waste, and has also been advised as best practice based on a previous literature review.[33] Countries interviewed reported that they rotated stock by selling, auctioning or donating products, mainly to national health and civil protection services. However, certain barriers to achieving this were noted by a number of countries, as well as issues with trading or donating to other countries, due to EU trade policy and contractual arrangements with manufacturers and wholesalers of MCMs. Once systems for rotation are in place, some countries noted that it is also important to ensure that replacement stocks are ordered a sufficient period of time in advance of rotation or destruction, so that adequate supplies are available in the event of an emergency. This requires an active approach to stockpile management, since manufacturing, procurement and delivery times may vary considerably for different products.[33]

In regards to governance, all five countries reported that national governments were ultimately responsible for their stockpiles. This was supported by the HERA AMR report which identified that governance of stockpiles within individual EU countries is generally managed at a national level, and responsibility for the stockpiles usually sits with national health authorities and or medicines agencies.[18] Active management has also been cited as key to ensuring a stable supply of medications during pandemic times,[34] and was also suggested within the current report to ensure stockpile waste remained low. One country also noted that, in relation to operational delivery, once requested, a stockpile must be deployed within 4 hours. This is similar to the US Strategic National Stockpile (SNS) which deploys a broad range of pharmaceutical and medical supplies, to an unknown threat, within 12-hours of a federal decision in a “12-hour Push Package”.[35] The SNS can also deploy a large quantity of products to a known threat within 24-36 hours of a federal decision.

The European Commission has stated that its role is to complement member states’ stockpiling in order to mitigate any gaps that might occur and to act as a safety

net.[36] This role was acknowledged by the countries interviewed, with most clearly stating that they prioritised national stockpiling over EU initiatives. Nevertheless, all countries were involved in EU stockpiling and emergency preparedness, and expressed positive opinions on initiatives such as the EU Civil Protection Mechanism, rescEU stockpiling and HERA, with some indicating that these helped to inform their national approaches. In addition to the roles outlined by the European Commission,[36] some countries identified opportunities for further alignment at EU-level in future, such as coordination to promote sharing of national stockpiles for specific public health threats. While some informal cooperation with neighbouring countries was reported by those interviewed, a more coordinated approach may be beneficial, particularly for smaller countries with a relatively lower demand for certain MCMs than larger EU member states.

A further example of EU alignment reported to be largely beneficial by the countries interviewed was the European joint procurement agreement. This agreement was introduced in 2014 with the aim of providing fair and cost-effective access to medicines and vaccines, after the 2009 influenza A (H1N1) pandemic highlighted the inefficiency of member states competing against each other for the same scare supplies.[37] The countries included in the current report noted that they participated in joint procurement during the COVID-19 pandemic, as it was the only way to get access to certain MCMs at that time. While the potential for cost savings through joint procurement were acknowledged, its efficiency was questioned by some countries due to the delays they experienced in accessing MCMs early in the pandemic. Despite this, since its introduction up to 2020, the number of countries participating in the joint procurement agreement increased from 6 to 37, demonstrating a growing acceptance and recognition of the role of joint procurement.[37] The potential for expansion of the joint procurement agreement has also been suggested as a means of building on the cross-border cooperation seen during the COVID-19 pandemic and to potentially enable purchasing of advanced health technologies.[38]

Lastly, a number of other future approaches were outlined by the key representatives. These included the use of a national independent expert group or national security board to assess risks, the use of an active stockpile management group, and decentralised stockpiles. These opportunities, combined with reflection and analysis of the difficulties encountered to access and distribute MCMs during the COVID-19 pandemic,[39] may provide guidance on future national approaches to MCM stockpiling.

4.1 Limitations

While this report presents an overview of national approaches to stockpiling of MCMs for public health emergencies in five countries, there are notable limitations.

Firstly, the information presented within this report is based on six semi-structured interviews with key representatives from five countries, and therefore may be subject to bias (such as selection bias and interviewer bias).[40] Steps were included within the study design to limit bias, including the development of an interview guide. However, given the limited number of participants and lack of data saturation, bias cannot be excluded.

Additionally, thematic analysis in itself is not without its limitations, as there is subjective input from the researcher when identifying and developing themes and codes from the provided text.[41] To limit this subjective bias, each interview summary was initially coded independently by three researchers. Following this, a draft codebook was developed and this was refined iteratively using a flexible approach, where researchers discussed their understanding and interpretation of the codes. Themes were also developed and refined through researcher discussion.

Lastly, the countries selected for inclusion are unlikely to represent the full scope of national approaches to stockpiling of medical countermeasures. While five countries were included with varying levels of experience with MCM stockpiling, high-income countries with prominent strategic MCM stockpiles such as the United States, Australia, Canada and the United Kingdom,[14] were not included. However, given that Ireland is located in Europe and a member of the EU, the inclusion of EEA and EU countries were deemed more applicable to the current report.

5 Conclusion

National MCM stockpiles are a key resource that may be deployed as part of a response to public health emergencies and disasters. However, different approaches to MCM stockpiling are observed internationally, and may be linked to factors including an individual nation's threat identification, geographical location and healthcare system. The current report identified themes around:

- past stockpiling approaches
- scope and current stockpiling approaches
- threat identification, risk assessment and product identification
- cost considerations and efficiency
- management and governance
- national, EU and international coordination and collaboration
- suggested future approaches.

These themes, along with their associated sub-themes, represent potential key areas for consideration for the development of a national MCM stockpiling strategy in Ireland.

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Appendix 1 Interview topic guide

Questions:

a) Opening the interview

Thank you for agreeing to participate in this interview. This interview will focus on your country's national approach to stockpiling of medical countermeasures for public health emergencies.

b) Questions around national stockpiling of medical countermeasures

Past and current national approaches:

1. What is your country's current national approach to stockpiling of medical countermeasures?
2. How and when was this national approach developed?
3. Prior to the development of your national stockpiling approach or policy, how did your country ensure the availability of medical countermeasures nationally?

Scope, threat identification and risk assessment:

4. Is your national stockpiling approach focused on specific threats such as Serious Cross-Border Health Threats, or does your strategy address more general medicine shortages?
5. How does your country decide on what risks to stockpile for?
6. How is your country's assessment of national stockpiling needs linked to other national or international risk assessment measures?
7. Once threats are identified as requiring a stockpiling approach, how does your country assess what medical countermeasures are included and what quantities are required?

Interaction with other strategies:

8. How does the country's national stockpiling approach interact with preparedness plans for specific health threats? For example, do pandemic preparedness plans also address stockpiling requirements?

Efficiency:

9. For individual threats, how does your country examine if stockpiling is the most efficient way to ensure the availability of medical countermeasures?

10. How does your country evaluate the role of stockpiling versus other ways of accessing medical countermeasures? For example, national stockpiling versus joint procurement or direct procurement or access to EU stockpiles.

Management and governance:

11. What Ministries, agencies or structures are leading on the operational delivery of MCM stockpiling in your country?
12. Where there are shared responsibilities for stockpiling across various sectors, how do the relevant Ministries, agencies and or other bodies work together?
13. What governance structures are in place to provide oversight of stockpiling?

Cost considerations:

14. What disadvantages to stockpiling approaches have been identified at a national level (such as waste, for example)?
15. How does your country assess the costs and benefits of stockpiling approaches?

EU coordination:

16. How does your country ensure that stockpiling at a national level complements EU initiatives in this area?

c) Closing the interview

Thank you for participating in this interview. The research team will now summarise the notes collected during this interview. You will be provided with a copy of the summary notes for your information, and will have the opportunity to clarify anything you feel necessary. We will be in further contact with you in the coming days.

Appendix 2 Participant information leaflet

Information leaflet

An overview of national approaches to stockpiling of medical countermeasures for public health emergencies

Evaluation Team:

Dr Máirín Ryan, Director of Health Technology Assessment, Health Information and Quality Authority

Dr Eimear Burke, RCPI Aspire Fellow, Health Technology Assessment, Health Information and Quality Authority

Dr Michelle Norris, Senior Health Technology Assessment Analyst, Health Technology Assessment, Health Information and Quality Authority

Dr Valerie Power, Health Services Researcher, Health Technology Assessment, Health Information and Quality Authority

Dr Susan Spillane, Deputy Director of Health Technology Assessment, Health Information and Quality Authority

Ms Michelle O' Neill, Deputy Director of Health Technology Assessment, Health Information and Quality Authority

Funder: HIQA

Data controller: Dr Máirín Ryan

Data protection officer: Dr Lydia Buckley

Introduction

You are being invited to take part in a project that aims to explore national approaches to stockpiling of medical countermeasures for public health emergencies. Before you decide whether or not you wish to take part, you should read the information provided below carefully. Take time to ask questions – do not feel rushed or under pressure to make a quick decision. You should clearly understand the risks and benefits of taking part in this project so that you can make an informed decision. You do not have to take part. A decision not to take part will not affect your relationship with any of the evaluation team. If you agree to take part, you are free to withdraw at any time. You are not required to give a reason for your withdrawal.

Why is this project being conducted?

The COVID-19 pandemic highlighted the need for countries to improve preparedness for emerging health threats. The European Union (EU) Health Emergency Preparedness and Response Authority (HERA) was therefore established to prevent, detect, and rapidly respond to health emergencies at European level. The top three key threats to health security as described by HERA include: pathogens with high pandemic potential; chemical, biological, radiological and nuclear threats; and threats resulting from antimicrobial resistance. Actions to improve preparedness to respond to such threats include increasing medical, or medical countermeasures, stockpiling capacity. Medical countermeasures include items such as vaccines, medicines, medical equipment and diagnostics. At a national level, the World Health Organization and HERA have also recommended that individual countries develop national strategies for stockpiling of medical countermeasures.

We are conducting this project to inform the development of a national strategy for stockpiling of medical countermeasures in Ireland, through supporting the work of the Health Security Unit in the Department of Health. The Health and Information Quality Authority (HIQA) Health Technology Assessment (HTA) team will perform reviews of organisation websites, published and grey literature in order to identify any documents of relevance. As publicly available information relating to stockpiling of medical countermeasures is limited, semi-structured interviews will be conducted with key representatives in selected countries.

Why am I being asked to take part?

You have been asked to take part because you are a key representative within your country's public health system with expertise in relation to stockpiling. The evaluation team would like you to share information about your country's national

approach to stockpiling of medical countermeasures for public health emergencies. This will inform the report we will prepare for the Department of Health in Ireland.

What will happen if I agree to take part?

If you decide you are happy to take part, we will provide you with the project protocol and the interview questions so that you can review these prior to scheduling an interview. Then, we will invite you (via email) to take part in a semi-structured interview. The interview will be with three members of the evaluation team and you will be asked to share your thoughts on the specific questions we have in relation to stockpiling. No sensitive or personal data will be collected during the interview.

The interview will be via Zoom or Microsoft Teams and should take approximately 60 minutes. With your permission, we will take notes during the interview so that we can we can analyse the information. Interview note summaries will be pseudonymised and any information that may make you, or your country, identifiable to others will be removed. The notes will be stored on a secure server in HIQA and will only be accessible to members of the HTA directorate. You will have the opportunity to review the notes of the interview to correct any inaccuracies and ensure that the notes accurately reflect what you wished to say.

We will summarise the findings in a HIQA report which we will make available to the Department of Health and publish on the HIQA website. No personal data will be included in this publication.

What are the benefits of taking part?

The findings will help the team complete a report on an overview of national approaches to stockpiling of medical countermeasures for public health emergencies. This will help to inform the development of a national stockpiling strategy in Ireland.

What are the risks of taking part?

One potential risk is a breach of confidentiality. As the evaluation team will not collect sensitive/highly personal information as part of this project, and have put in place several steps to protect participants' confidentiality (including pseudonymisation of interview summaries), the risk is deemed very low.

Is the study confidential?

The evaluation team have put in place several steps to make sure the project is confidential. Only members of the evaluation team will know your identity or be able to match your name with the information you provided. Any information that might

make you identifiable to others will be removed before the data is shared with the rest of the evaluation team for analysis.

The data collected (interview notes) will not be stored with your name on it. We will assign a pseudonym to you, e.g. 'Participant 1', and this will be used to name any data files relating to your interview.

All your information will be encrypted and stored in secure restricted folders used specifically for this project. Access will be managed by the evaluation team to ensure that your identity and data are protected. Any reports or presentations arising from this project will not identify you in any way.

The period for which the data will be retained will not exceed 7 years. Once the retention period is complete, all data relating to the project will be deleted from the secure folders by a member of the evaluation team.

Who is organising and funding this study?

This study is being organised by researchers from HIQA as requested by the Department of Health. No external funding has been obtained to conduct this project.

Data Protection

1. We will be using the information you provide in our research to complete a report on national approaches to stockpiling of medical countermeasures for public health emergencies. This will help to inform the development of a national stockpiling strategy in Ireland.

2. We will be processing your data for scientific research purposes under Article 6 and 9 of the General Data Protection Regulation (GDPR) 2016.

3. Only the evaluation team will have access to information with your name on it. The wider HTA directorate will only have access to the information which has any identifiers removed.

4. The data you provide will be encrypted and stored in stored in dedicated secure restricted HIQA institutional folders. The data will be retained for 7 years after which it will be deleted.

5. The data collected will be managed carefully as described in line with Data Protection and GDPR requirements. As the data will not contain any personal details, impact of any breach is not expected to cause you any harm.

6. You are entitled to change your mind about taking part in this research. If you wish to withdraw consent you can contact a member of the evaluation team.

7. As a participant in this study, you have a right to lodge a complaint with the Data Protection Commissioner in Ireland if you are not happy with how your data is managed. Contact details are available upon request.

8. You can request access to your information and for a copy of it to be provided to you if you wish. This will be possible until the identifiable data has been removed.

9. You can request that your data is not processed for analysis until the point that the identifiable data has been removed.

10. You will be given the opportunity to view the notes of your interview in order to correct any inaccuracies and ensure that the notes accurately reflect what you wished to say. You have the right to request that your information be deleted if you wish. This is possible until the point that the identifiable data has been removed.

11. You have a right to data portability, which means you can move the information held about you to another data controller. This is possible until the point that the identifiable data has been removed.

12. There will be no automated processing of data as part of this research.

13. Your personal data will not be used for any purpose other than in the completion of this research.

14. In order to complete this research, the notes which have any identifiable data removed will be shared securely with researchers in HIQA. It will be shared as encrypted files in a restricted folder on HIQA's secure server. Access to the study folder will be granted to named evaluation team members. Logging in to their account requires an individual password and dual-factor authentication.

15. Data will remain with the project team at HIQA.

Where can I get further information?

If you need any further information about the project, now or at any time in the future, please contact:

Name: Dr Eimear Burke

Address: HIQA, George's Court, George's Lane, Dublin, D07 E98Y

Appendix 3 Participant consent form

Consent form

An overview of national approaches to stockpiling of medical countermeasures for public health emergencies

Please tick as appropriate:

I have read and understood the **Information Leaflet** about this project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	**Yes** ☐	**No** ☐
I understand that I don't have to take part and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect me in any way.	**Yes** ☐	**No** ☐
I am aware of the potential risks, benefits and alternatives of this project.	**Yes** ☐	**No** ☐
I have been assured that information about me will be kept private and confidential.	**Yes** ☐	**No** ☐
I have been given a copy of the Information Leaflet and this completed consent form for my records.	**Yes** ☐	**No** ☐
I consent to take part in this project having been fully informed of the risks, benefits and alternatives.	**Yes** ☐	**No** ☐
I understand that any data collected for this project will be stored securely in a dedicated encrypted and password-protected folder for no longer than 7 years.	**Yes** ☐	**No** ☐
I consent to be contacted by researchers as part of this project.	**Yes** ☐	**No** ☐
FUTURE CONTACT		
I consent to be re-contacted by researchers about future research *related to* the current project for which I may be eligible.	**Yes** ☐	**No** ☐

Participant Name (Block Capitals): _____

Participant Signature: _____

Date: _____

I the undersigned, have taken the time to fully explain to the above participant the nature and purpose of this project. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the project.

Name (Block Capitals): _____

Signature: _____

Date: _____

Published by the Health Information and Quality Authority (HIQA).

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