File name: invest_ni___spotlight_on_australia_-_richard_ennis_&_chia-yi_cheng___introduction.mp4

Moderator questions in Bold, Respondents in Regular text.

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Richard Ennis: Good morning to all of you joining us from Northern Ireland, and good evening, and good afternoon from those of you in Australia, and from across the APAC region. It's great to see so many familiar names registered for today's webinar. For those of you that don't know me, my name is Richard Ennis, and I'm Invest Northern Ireland's Regional Director for Australia and New Zealand. I would like to officially welcome you all to today's webinar, Spotlight On Australia, MedTech and Digital Health, where we will be discussing the life, health, and science sector in Australia, and why you should consider Australia as an export destination. We will also explore how to export to Australia, the regulatory environment, and the trends and opportunities in the MedTech and digital health sub-sectors. I also want to extend a very warm welcome to our speakers today, Myrna Surrey-Hodvitch (ph 00.57), principle consultant at Fully (ph 00.59), Dr David Batka, senior consultant from Adjutor Healthcare, Gary Li, from the UK Department of Business and Trade, FTA utilisation team, and Jonathan Tierney of Seating Matters, an Invest NI export champion. Last but not least, our moderator for today's webinar, and the life, health, and science sector lead in Australia and New Zealand, Chia-Yi Cheng. Thanks again everyone. I hope you find the information in today's webinar useful, and I look forward to the opportunity of supporting you, and welcoming you in Australia soon. Without further ado, over to you Chia-Yi.

Chia-Yi Cheng: Thanks, Richard, for that kind introduction. Hello everyone. My name is Chia-Yi Cheng, and I'm the regional officer for trade and investment here in the ANZ region. I have been in the role for 17 months, and during that time, I have worked with and assisted over 50 Northern Irish companies entering or expanding into the ANZ market. In terms of supporting our client companies here, on the ground, as Richard mentioned, I have a focus on life and health science sector, and my role is assist Invest Northern Ireland client companies here in the market directly. We support you by providing market research, facilitate direct connections with locus encoders (ph 02.34). We also provide introductions, conduct business matching, and arrange meetings with potential customers, and potential distribution partners. In addition, we also support our client companies on inward visits to conferences, exhibitions, meet the buyer events, and individual or sector trade missions. Some of you might remember, and have participated, in our previous spotlight webinar in 2022, where Australian life and health science sector in general was covered. Since then, in the post-COVID era, a lot has changed across the world. Australia is no different. There was a rising demand for digital technologies, and an increased adoption for MedTech technologies.

In today's webinar, we will update you on what has changed in Australian MedTech and digital health in the last three years. The aim of today's webinar is really to help you understand, and get you prepared, for

entering the Australian market. I'd also just like to echo Richard's comments, and extend my gratitude, and welcome today's webinar speakers, from our local partners, and partners across government, to share their knowledge with you today. Picking up the speakers, Myrna Surrey-Hodvitch will be providing a market update and an in-depth overview on the Australian life and health science market. We will then gain insights into the Australian regulatory environment from Dr David Batka, senior consultant from Adjutor Healthcare, who will give us an overview of therapeutic fields administration, and things to bear in mind when filing a TGA conformity assessment application. Gary Li, from the FTA utilisation team, will provide insights into the benefits of the free trade agreement between Australia and the UK. Then we'll hear from Myrna again, who will elaborate on the trends and opportunities for Northern Irish companies in Australia. And, finally, you'll hear from one of our export champions, Seating Matters' Jonathan Tierney, commercial director, who will share his experiences and the challenges of building a successful business in Australia.

After the keynote sessions, I will share Invest Northern Ireland's planned activities for life and health science in Australia in 2025. Finally, we will have a Q&A session. So, if there's any questions that spring to mind during the webinar, please put them in the chat, and we will do our best to pick them up at the end of the session.

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Moderator questions in Bold, Respondents in Regular text.

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Mirna Sarihodzic: Thank you very much for the introduction. Good evening from Australia and good morning to everyone listening in Northern Ireland. My name is Mirna and I'm a trade and investment consultant with Foley based in Sydney and I will be talking today about Australia's healthcare sector and opportunities for Northern Irish companies. Starting with a brief introduction, just a few general comments about Australia. before we get into the main topic of healthcare. As many will be aware, Australia is large country with a relatively small population of 27 million, expected to reach 31 million in the next 10 years. Australia is a federation of six states and two territories, and we have three levels of government, federal, state and local, which will also have implications for the health sector we'll be talking about shortly. In terms of trade, Australia's an importer, with China being our largest two-way trading partner, both in terms of imports and exports of course, the UK, a major trading partner for Australia, our ninth largest source of imports in 2023. When it comes to economy, we like to say Australia's punching well above its weight. We were the thirteenth largest economy in 2023, and Australia's GDP growth has constantly outperformed most other Western economies. Obviously, during the COVID-19 pandemic, Australia experienced significant decline in GDP. However, the economy has since recovered and while the growth has slowed down a bit, it still remains positive.

And now, moving into the health space. Compared to other developed nations, Australia is among the leading countries for public health expenditure per capita. We can see here Australia ranking within the top five in 2023, just ahead of the UK at number six and Canada at number seven. In the 2024 world index of healthcare innovation, Australia was ranked nine overall and we performed particularly well in the category's quality and choice, and we were also well recognised for medical research, clinical trial capabilities and we have vibrant MedTech and biotechnology sector. So, you must be thinking, why should Northern Irish companies think of Australia as their next export market? And besides some obvious advantages of Australia, I'm just going to highlight a few points here. We have a healthcare system that faces significant challenges due to rapidly ageing population, increased burden of chronic diseases, which are all expected to increase our domestic demand for healthcare and medical technology and over the past few years, the Australian government and state governments have committed record funds towards new and upgraded health and hospital infrastructure facilities, both in Metropolitan areas but also, in regional locations. And our limited manufacturing capability also means that we are heavily reliant on imports for medical products. More than 85% of all medical products are coming from overseas and over half of all imports are coming from the US and Germany, which I guess speaks to the demand for high quality and advanced medical technologies. Australia also invests significant funding into health and medical research. We have a 22 billion cumulative long-term investment fund which supports health and medical innovation, and Australia's also considered to be a low-risk test bed to develop and test medical technology products with relatively streamlined regulatory environment and less stringent

requirements, particularly for lower risk medical devices. Which allows companies to trial their technologies and early stage innovations.

I mentioned previously, we have a three-tiered government system in Australia. Federal state, territory and local councils and they all share responsibility for running our health system. Our main federal government agency is Department of Health and Aged Care and there are also some other agencies in the health portfolio. Some of the key responsibilities on the federal government level are developing our health policies and strategies, funding the public healthcare and hospital services, subsidising age care sector, including residential and home care services and also regulating medicines and medical devices, which will be very important for our suppliers so our national regulatory body, TGA, is equivalent to US FDA. It's also part of the federal health portfolio. Federal government funds, as mentioned health and medical research, and also operated funds our Medicare, universal healthcare scheme, through which the government subsidies medical services, public hospitals and some medicines. And then, moving to the next level are the state and territory governments which each have their own state and territory health departments that run public health systems in their jurisdictions. So, state and territory health departments manage public hospitals and health facilities through a network of local hospital-, local health district or hospital networks. They're called different in different jurisdictions. And an example of that being southeastern Sydney local health district, one of the six districts in the city metropolitan area and one of the largest local health districts in New South Wales. And they deliver healthcare services to nearly one million residents and manage a total of nine hospitals. Likewise, there's similar district to our networks in other states and territories. And of course, we have the emergency medical services in Australia that are also provided by state ambulance agencies. I wanted to highlight a few trends when it comes to health expenditure in Australia. After the COVID-19 pandemic, our health's pending return to the pre-pandemic trends pretty much in 2022, 2023. An estimated total of 252 billion Australian dollars was spent on health goods and services in 2022, 2023. Which is approximately 10% of our national GDP. About 70% of this total funding was provided by the governments with the remaining 30% provided by non-government sources, including insurance, private health insurance, and out of pocket expenses, etc.

In terms of the major areas for health spending, the majority is spent on public and private hospitals, 43%. Then, we have primary healthcare 33% and the remaining funding spent on other services research, capital spending. And then, when we look at the right-hand side in terms of where the money's being spent, I guess, the most, New South Wales and Victoria account combined for more than 50% of all total health expenditure in Australia. Which makes sense as these states also represent more than half of the Australian population. A few comments I wanted to make on our federal health budget, released in May 2024 which allocated significant funds to our health sector estimated at 112 billion and expected-, projected to increase to 122, almost 123 billion in 2027, 2028. And again, you can see just a few, sort of, key components of the budget going towards state health support, funding state, public hospitals, Medicare, aged care and also again health and medical research. But one thing I wanted to briefly mention here is our medical science co-investment plan. In April last year, the federal government released a plan as part of their commitment to boost our domestic manufacturing capability, and the plan aims to support the development of manufacturing in Australia in the medical science sector. So, the money will predominantly focus on several priority areas, including digital health, medical devices and

complex therapeutics. An example here of a state health budget, we talked about federal state, every state and territory also publishes their health budgets. So, the state of Victoria made a record 13 billion dollar investment in their state's public health system and again, we talked about infrastructure. There's 1.7 billion dollars allocated towards improving health infrastructure across the state.

There's also other key elements, ambulance services, disability, mental health, and even funding towards cyber-, affecting health services from cyber attacks. So, as a MedTech manufacturer or supplier, it is important that you're aware of the hospital landscape when you think about who your end customers are and you want to think about the hospital distribution throughout Australia, funding they receive and perhaps, specialised clinics that may be relevant to a specific area of your MedTech. So, this-, all of this might enable you to prioritise introducing your technologies in those states with health facilities that have the funding and they also have the capacity to support these technologies. So, we have our public and private hospital sectors, public is managed-, is managed by our state government health agencies. An example-, you can see here on the screen examples of some of our large public hospitals. On the other hand, we have a similar number of private hospitals, whereas private hospital sector's quite fragmented, it consists either of hospital groups such as Ramsay and Healthscope which operate multiple hospitals under one company. And then, we have individual or unaffiliated hospitals which also can vary in size. Private hospitals are owned and operated by private organisations, either for profit or not-for-profit organisations like St. Vincent's health. And you probably will be aware that Ramsay and Healthscope are the biggest private hospital operators in Australia. So, I guess entering the Australian medical device or MedTech will require significant planning but also in-depth understanding of our healthcare system, procurement processes, also compliance with national local regulations, etc.

So, I guess TGA or regulatory approval process that we will talk about in a few minutes is maybe even the most critical part of this process but after obtaining your TGA approval, there are many different pathways for your medical technology to be procured by our public or private healthcare systems. I won't go into too much detail when it comes to this diagram on the screen but it basically outlines different pathways for MedTech entering the Australian market in various stages from regulatory approvals, reimbursement and finally reaching your end customers. I do want to make a few general comments about procurement, particularly public vs private sector. Public health procurement is, as mentioned again, managed at the state or territory level, there are certain differences in agency structures and practices but basically, MedTech companies or distribution companies supply to healthcare providers in public sector, either through direct engagement or negotiated purchasing contracts. And what's interesting about Australia is that some states such as Victoria and New South Wales have dedicated central procurement agencies for their public health sectors that basically act on behalf of hospitals for certain high volume or commonly used products. And examples here include HealthShare New South Wales, HealthShare Victoria. For the rest, for other products that don't fall under these procurement agencies, hospitals general manage their own procurement and market engagement activities are overall undertaken-, overall market engagement activities that are undertaken in the procurement process will depend on many things including the complexity of the procurement, budget timeline, etc. And if they do go out to the market, states and territories who will publish tenders and each state and territory will have its own tendering and procurement platform. Which is often a good starting point for suppliers to look for opportunities and of

course, it should be noted that some state and territory governments or their health agencies are open to unsolicited proposals as well. And of particular note I guess to, to note in our suppliers is that many procurement agencies and public hospitals will public their procurement activity plans on their website and that also provides an indication of possible sourcing activities for the next financial year or in some cases, several years head. And on the other hand, we have our private health sector organisations, hospitals, clinics, aged care providers, etc. And they typically use a combination of direct procurement and supply arrangements which is, I guess, the most typical path and then, also public approach to the market with tender however, one difference is that private sector tenders tend to be invitation only. And hospitals and health facilities in the private sector typically work with established network of suppliers and distributors but some of them also may decide to purchase products directly from manufacturers. So, Northern Irish MedTech suppliers or the local distribution partners can access private healthcare sector either through responding to contract tenders or approaching providers for procurement opportunities and that means typically direct engagement with hospitals, their procurement teams and clinical staff. And just a very, sort of, brief example again using the state of Victoria as an example, their department of health delivers health services through, I believe, 80 hospital and health services across the state. And that covers both metropolitan and rural and regional areas. And as mentioned before, HealthShare Victoria is a procurement organisation that manages standing offer contracts for a variety of products and outside of these product categories, health and hospital services in Victoria are free to make their own purchasing decisions.

So, MedTech suppliers or their distributors should review HealthShare Victoria's website and see if your offering aligns with any available standing offers, contracts or tenders. And if so, then you can register as a supplier on their website and you will be notified of any opportunities, any upcoming contracts or tenders. And you, again, may also want to keep up to date with their procurement activity plan and another option is if you're offering a product or technology does not align with those contracts, standing offer contracts then they-, another solution is to approach hospitals directly. So, I guess there's probably more that can be said about procurement and different pathways but I guess with this slide, I'd like to conclude the first part of my presentation. I believe we'll hear a bit more about the regulatory environment TGA and then, I'll continue with opportunities in Australia in digital health and medical technology.

Captions by Verbit Go.

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Moderator questions in Bold, Respondents in Regular text.

KEY: **Unable to decipher** = (inaudible + timecode), **Phonetic spelling** (ph) + timecode), **Missed word** = (mw + timecode), **Talking over each other** = (talking over each other + timecode).

Speaker1: Hi everyone. My name is David Batka, and I work for Adjutor Healthcare, who's an Australian full-service consultancy company, and our name means helper in Latin. Let me give you today a high-level overview of the medical device registration process in Australia. So, this talk is divided into six sections, starting from the regulatory basics, then we will head to the registration process and timelines, the potential impact on your global strategy, and two case studies. So, first let's start with the Australia regulatory framework and environment. So, in Australia, the medical devices are regulated by the Federal Health Agency, which looks after all kinds of therapeutic goods. This is called the Therapeutic Goods Administration, or the TGA. The legal framework is the Therapeutic Goods Act 1989, and also the Medical Devices Regulation 2002. Additional legal requirements are often communicated by the TGA via the Therapeutic Goods Orders, Determinations and Instruments. These provide further clarifications on, for example, excluded or exempt medical devices.

Now, let's move on to some basic terms and definitions. So, the most-used terms and definitions are listed here, and also on the next slide. I'm not going to go into the details, because the aim of these two slides was just to provide you with a single source of reference, as the slide deck will be available online for, for later. In general, we always recommend however that reviewing the definitions of the medical device, software as medical device or kind of medical device combination product, and also the manufacturer, or in some countries legal manufacturer, in each target country, because country-specific differences may occur. And we can just move to a more specific information slide on softwares as medical device. Now, I understand that some of, of you in the audience may be interested in, in softwares, so let me show you this TGA roadmap, and you can see the source and additional information in the footnote. The aim of this roadmap is to clarify as to whether your software is classified as medical device in Australia, and if so can it be considered as an exempt or an excluded device? In general, excluded products are grouped into five categories. One is the consumer health products, or in other terms the wellness products. The other is enabling technology, like telehealth or remote diagnosis. Another is digitalisation of records, but others also include analytics and laboratory information management system.

And let's move on to the registration process and timelines. You will see probably a lot of information on this slide. Let me walk you through what you can see here. You will see the main steps of the registration process here. Just the same as you could do in Europe, it starts with the determination, if your product is classified as a device, and also the applicable device risk category. Why is this important? It's, it's exactly the same reasons why it's important in Europe, because the device risk category is directly proportional to the level of evidence that is required, and it also impacts the clinical and registration strategy. As you

would assume, the device risk category may differ among countries, and may also change over time. In the next step, you establish your supply chain model and identify the legal manufacturer who will be responsible for the product, and also start working on the QMS system to comply with the International Standard ISO 13485. At this stage, you also start generating technical evidence to demonstrate that the product is safe and it performs as intended. Next, a conformity assessment application is submitted. This can be either to a notified body, similar to Europe, or a regulator like the TGA. After you receive approval for the conformity assessment, the remainder steps are usually administrative processes.

In terms of timelines, the time frame for a device registration in Australia, you could see on this slide, can vary greatly. It depends on the type of overseas evidence and the device risk category, among others. Regarding the conformity assessment application, the TGA target time frames is actually one year, but they used to use 255 working days. This step is not applicable if the product has a CE mark or the lowest risk Class 1 device. The next step is the manufacturer's evidence. This is a minor administrative process, usually completed within a couple of weeks, and similar to the previous one, it is not required for Class 1 devices. And last is the device registration step. After this process, you will be able to start marketing or launching the product. This step usually takes around one month, and is administrative in nature, unless the product is selected for a TGA application audit. Now, some devices must undergo a mandatory TGA audit, for example, the highest risk Class 3 devices, or Class 4 IVDs, but also IVDs for self-testing. Any other medical device can be selected, however, at the TGA's discretion. If selected, the TGA reviews the technical documentation and also any conformity assessment evidence. They do have target processing time frames, which can be between 30 and 60 days, depending on the level of the review. 60 days, of course, stands for the more in-depth audit. Unfortunately, though, due to TGA backlogs, the actual process may take much longer, and in our experience, this step can take up to one year, which is, of course, worst-case scenario.

Now, what if your product has overseas approval? So, as mentioned in the previous slides, all devices require conformity assessment evidence, except the lowest-risk, Class 1. The good news is that you do-, you can leverage the CE mark, or CE certificate, you may have in lieu of a TGA conformity assessment. This can save you a significant amount of time and money. Some common examples are listed on this slide. Most importantly, you can still use the current EC certificate issued under the previous EU MDD with extended validity, but if you have the more recent or the current European MDR certificate, then the process may be even quicker and less, less expensive. A comprehensive list of acceptable overseas evidence is provided in the TGA document in the footnote. Definitely worth having a look, because you can leverage Singapore, US, Canada, Japan and other overseas evidences.

Now, if we move on, how does an Australian registration impact on your global strategy? So, we know that there is no generic regulatory strategy that fits all device categories and markets. We wish there would be one. There are so many aspects to consider, like competitor landscape, supply chain model, or in specific which entity will be considered as a legal manufacturer? What QMS or conformity assessment evidence do they have? And requirements, the regulatory requirements, or the target markets? And the list

goes on.

So, any device, other than Class 4-, Class 1, as mentioned, does need evidence. Now, although there is not, not a single type of evidence that is accepted globally, but there are really good invaluable reliance programmes that actually you can use to your advantage. Historically companies used to leverage the CE mark, but now the reliance on the US FDA approval or the MDSAP pathways are getting more and more attractive. A growing number of companies with no CE marks are nowadays considering MDSAP. MDSAP stands for the Medical Device Single Audit Program, that is an acceptable in US, Canada, Japan, Brazil and Australia, and the observer countries are all over the world, and their numbers are growing. Now, this is a fast and cost-effective alternative to CE mark outside Europe. Certificate can be issued actually via the notified bodies, the same notified bodies who you would usually issue CE certification, but they can also be issued by health agencies.

Alright, so let's move on to the case studies. Let me walk you through two studies. The first one will be an overseas manufacturer who wanted to register their device in Australia, leveraging their CE certificate under the old or the previous EU MDD with extended validity. Firstly, determine the Australian device risk category, and also confirm that their overseas CE certificate was indeed acceptable in Australia. We worked with the local Australian entity, which is known as the sponsor, who is responsible for the product registration. We established the necessary procedures to comply with the TGA requirement, and as part of that we facilitated the execution of the quality agreements between the sponsor and the manufacturer. Afterwards we created Australian-specific labelling and promotional materials, and prepared and submitted the applications to the TGA. The approval was granted within a month. The other case study is about an Australian manufacturer who had a Class 2b device under development. We worked with the manufacturer to develop global registration strategy to cover several Tier 1 markets. The MDSAP certificate, or pathway, was selected as the main conformity assessment evidence in all these countries, which is, again, recognised by Australia, US, Canada and Japan. The CE certification was a second priority back at that time, due to the long wait list and uncertainties with interpretation of the EU MDR requirements. We also worked on the clinical development strategy with this client. The main study was conducted in Australia, which was an excellent destination for running clinical trials. The data is acceptable in all Tier 1 countries, and the government offers R&D tax incentives for local companies.

And let's just recap what the main messages are. So, the take-home message is that Australia is indeed an attractive market for meta (ph 13.30) companies due to its population size and wealth. The TGA, the local regulator, is fully committed to provide timely access to the latest innovations without any compromise on patient safety, and with specific requirements for labelling, advertising and post-market reporting. And this concludes my presentation, so hopefully you found it useful, and thank you for listening.

Captions by Verbit Go

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Moderator questions in Bold, Respondents in Regular text.

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Speaker 1: Hello everyone. Welcome to this session on how to utilise the UK-Australia free trade agreement. My name is Gary Li. I'm from the FTA utilisation team at the Department for Business and Trade. So, just to kick off, a very quick, what is the free trade agreement? So, free trade agreement 101, as it were. So, a free trade agreement is an agreement between two or more countries, setting out the rules that cover the trade in goods and services. It reduces restrictions on imports and exports, and secures market access, which can make trading easier and cheaper. And I'll go into more information and detail on this in the next few slides. So, you can see on screen that the UK currently has quite a few trade agreements with various countries. These include rollover agreements, continuity agreements, as well as from scratch free trade agreements, and the UK-Australia FTA, as you can see, signed-, or came into force in 2023 is one of these brand new from scratch free trade agreements. As I mentioned earlier, these free trade agreements are designed to remove tariffs, as well as regulatory restrictions for businesses when they're trading. Now, it's worth noting that some of the provisions in the free trade agreements occur automatically, meaning that you don't really have to do anything to benefit from it. So, these are largely related to those in the services sector, so free travel for business people, access to markets, non-discriminatory measures, that sort of thing. So, these things just happen in the background, and, if you are in these particular sectors, then you don't really have to do anything to enjoy its benefits. Having said that, for those who are looking to export goods to specific markets, in this case Australia, you do have to do a bit of homework before you can benefit from one of the biggest improvements provided for-, for FTAs, which is 0% tariffs, what we call preferential tariffs.

So, just to go over some of the very, very broad-, the, kind of, key provisions that FTAs bring to the table. So, the first part is for those that provide or sell services into specific markets-, and, of course, there are many other provisions in the background as well, but these four are worth flagging, if you're not familiar to what an FTA does. And the first one, as I-, I hinted at earlier, temporary entry. So, that basically means, if you are a business person looking to conduct business in a specific country that we have agreements with, it should be easier for you to gain access to that-, to that country. So, this does not replace visa regimes of specific countries, because visa regimes can change all the time, but FTAs stay relatively static, after it's been signed, but it does offer more legal guarantee in-, legal surety (ph 03.07) in gaining access to that market and that country for business purposes, should you need it. So, it should be a smoother process if you try to apply for a business visa, for whatever purposes. Data flow. So, this is quite important as well. So, the UK-Australia FTA in particular has a special digital chapter, which allows the free flow of data, and that-, this makes providing services, and obviously the-, in the sectors such as MedTech, this should be quite advantageous. Specifically, there are no unjustified data localisation requirements, meaning you don't have to have a localised data centre in order to conduct business there. So, you can send your information from Australia back to the UK for analysis, and then

back to Australia, if it's required. Having said that, it is, you know, noted that there are always going to be legal caveats on a lot of these issues, as well. So, do talk to the-, the importer, and do consult local regulations, as well, on the legality of-, of storing certain types of data, and what other, kind of, special requirements that they might have in those specific markets.

So, equal treatment. Bit of a blanket one. Equal treatment basically means that, if you are going to be operating in Australia, you will be treated the same way as an Australian company, or a competitor from any other country, and you will not be discriminated against just because you are a UK company. And then, finally, access. Fairly similar. For investment, there should be open market access for a UK company in Australia, as well as the same kinds of protections and movement of capital. So, now we'll move on to the, kind of, selling goods side of things, and, as I mentioned, you might have to do a bit of homework if you're selling a particular product that's been manufactured in the UK. You can enjoy 0% tariffs, but you need to prove that your goods are what is called originating, which basically means it counts as a UK-produced good. And there are different ways of meeting this requirement, and, within the FTA, these are referred to as product-specific rules, or PSRs. And this is based on your HS code, and, depending on the nature of your product, the rules might be slightly different, the requirement might be slightly different, but they're all designed in a way to make it fairly easy for you to prove whether something is made in the UK or not.

So, there's two very quick examples on screen. One is called change of chapter rule, which basically means if your final product, in this case biscuits, is made from products from two other completely different chapters-, so, if you notice, biscuits is in chapter 19. Wheat and milk are in different chapters. So, that counts as sufficiently manufactured, and meets rules of origin requirements from the FTA. And another type is called regional value content, which usually stipulates the percentage of a cost of your good is from the UK. Or, that 40% of the material used is originated from-, from, from the UK, and that-, that counts as well. And there's just a note that there are additional guidance links on this slide deck, which will be distributed after the presentation, so you can, sort of, look at additional guidance on this. So, once you've identified your commodity code, and you determine whether it meets the rules of origins, you need to fill in a declaration form, which you can find online, as well, and then, after that, you need to have that accompanying your good, and-, and give that to your importer, so they can declare, on their end, that this is a British product, and they don't have to pay additional tariffs on it. Now, there's a very powerful tool online, offered by the government website, .Gov.UK, and this is called the Check How to Export Goods tool, commonly known as the CHEG tool.

It's a very, very useful tool. As long as you have your HS code for your good, you can basically identify what the product-specific rules are going to be like on that product. So, I have a very, very quick screenshot of an example on the right-hand side. I think, in this case, it's for hearing aids, of the code 902140. As you can see, it is-, it's set so that it's being exported to Australia, and, at the top of the example, you can still see there are three tariff amounts listed. Luckily, in this case, hearing-, hearing aids don't actually have a-, a most favourite nation duty amount of more than 0%. Usually, the majority of

goods being exported to Australia under the FTA have to pay MFN duty of 5%. So, sometimes that might come up for your-, for your particular good. In this case, it's 0%. So, so, if it is in the case of 5%, then you can, sort of, see that there are two more duties on top of that, the preferential duty, under the UK-Australia FTA, which is 0%, as well as a preferential duty under the newly-enforced CPTPP agreement, which is also 0%. This is an interesting-, interesting case here. So, after signing CPTPP, if you're exporting to Australia, or any of the other countries that we have a bilateral agreement, as well as the CPTPP agreement, you can choose which rule you use, which rule you want to meet, in order to meet the rules of origin requirements.

So, if you look at the rules on the bottom of that screenshot, you've got one set of rules-, you've got a regional value content rule, for example, saying not less than 40%, a change-, or a change of subheading that aren't covered under the UK-Australia FTA. Now, under that, you've got another set of rules, basic rules, under the CPTPP agreement, which offers you a selection of-, of different types of methods of-, of, of meeting the requirement. So, basically, based on which rule to you makes the most sense, or easier to meet, then-, then pick the one that you want, and declare under that particular-, particular method. So, they will have different templates that you can use for-, for declaration. So, just make sure that you are picking the-, the, the right-, the right one, but the end result is the same. Both, both sets of rules should reduce 0% tariffs-, allow you to enjoy 0% tariffs, if you meet those rules. So, it's worth flagging that we also have considerable amounts of online guidance for the UK-Australia FTA. These can be found on the Australia country market page, on Great.Gov.UK. We have screenshots on the screen now. And they contain both thematic guidance on some of the key provisions, such as rules of origin, or procurement, and so on, as well as very handy setter (ph 10.02) guides, of which life sciences is-, is one of them. So, highly recommend everyone to take a look at the online guidance that we have available. I'll just round off-, I just want to remind everyone that DBT offers a comprehensive export support ecosystem.

So, what that basically means is that we have resources and online help for every step of your export journeys. So, whether you are planning to look to-, to export to Australia-, so, I just mentioned that country market pages. So, that's a great place to start. Or you want to talk to someone about your particular business plan, in which case you can reach out to our international markets service, or maybe see if you're eligible for international trade advisor who can offer tailored one-to-one support, should you be eligible for that support. And then you can use the CHEG tool to do some internal compliance work, and make sure that your product can enjoy 0% tariffs, for example, if you're exporting goods. Finally, you can also reach out to our export support service, any time, if you're stuck during your exporting journey. There remains just for me to say thank you for attending this session on what is the FTA, and how to utilise the-, the FTA to Australia, and this presentation deck actually contains a lot more resources for you to look at, handy links, and other-, other examples, and case studies, for example, of other companies that have exported to Australia. So, please take a look at it, once you receive it. And, like I said, please contact the DBT's export support service if you have any other follow-up questions for your particular export journey. Thank you everyone.

File name: invest_ni___spotlight_on_australia_-_mirna_(pt.2)_(trends_and_opportunities) (240p).mp4

Moderator questions in Bold, Respondents in Regular text.

KEY: **Unable to decipher** = (inaudible + timecode), **Phonetic spelling** (ph) + timecode), **Missed word** = (mw + timecode), **Talking over each other** = (talking over each other + timecode).

Mirna Sarihodzic: Hello again. I'm going to talk a little bit more about the opportunities in the Australian market and discuss some of the market entry considerations as well. Starting with just looking at the broader life sciences landscape in Australia, there's well over 2,600 organisations across the entire ecosystem, and the Australian life sciences industry segment, in particular, is dominated by the medical technologies and digital health companies. And that figure was around 600 in 2022. I guess, these numbers change constantly, but it just gives you an idea of the size of the industry. And apart from some major players like Cochleer, Alcidion, Telstra Health, that you may have heard of, Australia's local MedTech industry predominantly consists of small and medium-sized companies. A lot of them pre-revenue, in the process of translating medical research into commercial product. I guess, the scaling of innovation and commercialisation is often very challenging in Australia, and it's sometimes taken offshore. I've also mentioned earlier that our domestic manufacturing capability is quite limited, and the market has been dominated by large US and European multinational companies that have a long-established presence in the region. We are a mature market for medical equipment, and due to limited domestic capacity and capability, we're dependent on imports and basically, positioned at the end of a long and complex supply chain for most of the medical supplies, and a large share of medical products is imported from the United States and Europe.

And again, looking at the broader life sciences ecosystem in Australia, east coast is where most of the industry activity is based, and also, the majority of the Australian population. Victoria and New South Wales are critical hubs of the life sciences industry, with more than 70% of the entire industry based in these 2 states, and mainly concentrated in the state capital cities, Sydney and Melbourne. We have a few major life sciences pre-syncs or hubs, and those include the Melbourne Biomedical Precinct and the Westmead Health Precinct in Western Sydney. And there are, of course, other emerging life sciences hubs developing in other regions and cities, including Brisbane, and Gold Coast, and Queensland, and Adelaide in South Australia. And now, diving a little bit deeper into opportunities and areas of demand. Australia represents a growing market for MedTech companies that are seeking to address significant national healthcare challenges and also capitalise on emerging trends. And as an example, Northern Irish companies offering solutions that can address the needs of an ageing population, increasing burden of chronic diseases, challenges of remote and rural healthcare, will find significant potential in the market. There is a growing demand for a wide range of health and medical equipment and solutions. So, for example, we're talking about demand for home monitoring in chronic disease management, tele-health and mobile health solutions. We have also seen huge investment in new and upgraded hospital infrastructure, which is supporting demand for smart hospital technologies, improved patient management, hospital efficiency solutions, but also, solutions that address healthcare workforce shortages, as an example.

So, we have automation and AI-driven solutions, as an example. And when we were preparing-, completing research and preparing for this webinar, our office spoke with a number of stakeholders and key players about the MedTech digital health solutions of interest in the market. And as an example, a major distributor of MedTech has identified technologies that identify remote monitoring and home care as something that they are very interested in, as well as solutions in precision medicine and personalised care. And interestingly, in addition to clinical solutions, a procurement manager at a major age care facility has also noted that they have huge interest when it comes to the operational or administrative side. So, as an example, they highlighted software that would help track hours of care, provided by clinical nurses, as something that would be very useful for their organisation. And similarly, systems that could help optimise or automate procurement would also be in demand, as that is typically a manual process that is managed by a nurse. A recent industry report has also highlighted 3 key areas of tele-health, remote patient monitoring, and virtual care, as the most promising areas for transforming the Australian health system. And additionally, we have health analytics, AI, clinical decisions supporting solutions that also have significant potential for data-driven healthcare solutions. And I also wanted to highlight a few recent trials in Australia that could also help, sort of, paint a picture of what's been-, what technologies and solutions are being introduced in the Australian healthcare system. And I'll focus here on the first example on the screen.

So, following a successful trial or a series of trials, an advanced cardiac care technology by a German medical device company was rolled out in Sydney in April last year, and this technology includes a cardiac monitor defibrillator and transmission platform, which allows paramedics, hospitals and emergency departments to access real-time patient data. Now, some of the new capabilities on this communication platform include, as an example, in-app audio calling, messaging, and also, image sharing. And all of this helps streamline patient information, handover, and also facilitates information sharing between paramedics, emergency workers, and doctors at the hospital. And this particular technology is hoping to improve communications for approximately 17 ambulance stations and around 12 hospitals across metropolitan Sydney. And the programme is being delivered by eHealth New South Wales, which is New South Wales' government's health agency, in partnership with New South Wales Ambulance, local health districts, and Device Technologies, which is the local partner for this German company. And I believe also, that they are going to start implementing this particular platform in rural and remote areas in New South Wales. So, now, moving a little bit more into the digital health space, I thought it would be interesting to highlight an example of Medibank, which is Australia's largest private health insurance company, with over 4 million customers nationwide. And last year, Medibank announced partnerships with 2 US digital health platform companies, to provide personalised healthcare experiences for their customers, and also, trying to integrate those virtual solutions with Medibank's health insurance membership.

And as an example, Amplar Health, which is part of the Medibank group, has partnered with US company, Amwell, to support the delivery of their new lifestyle management virtual app, designed to promote wellness, and also help prevent chronic disease amongst the patients. So, Amwell is, basically,

and their automated care platform will provide Amplar Health customers with access to a digital companion that will help guide the patients through their healthcare journey. And Amplar Health at the same time will also be a reseller of Amwell's automated care platform, and also, SilverCloud digital mental health platform by the same company. And I wanted to also say a few things about AI digital tools. When it comes to AI, many Australian healthcare organisations are still in the early stages of understanding AI and how advanced analytics can benefit their operations, but we are seeing a significant proportion of providers that are in either planning or proof of concept stages when it comes to AI, and some have already implemented live use cases as well. It is important to mention, however, that the scale of adoption is still relatively small, compared to other developed markets, particularly the US and the UK, and there are certain challenges around the use of AI. I have added 2 examples here, and maybe just focus briefly on the second one. An American company, Net Health, based in Pennsylvania. Their tissue analytics app was used in a trial with the Sydney Local Health District, which was trialling the app for use in hospital and remote settings, working with a local distributor, a company called Virtual Care, to help to integrate this app into Sydney Local Health District's electronic medical record platform.

So, based on the positive study and trial findings, the researchers recommended that this wound care app is rolled out across the entire health network. And similarly, Amplar Home Health, the company I mentioned previously with Medibank, has also introduced a tissue analytics platform to help improve and streamline their wound management for patients in their homes. Here, we have a few examples of the UK health tech successfully introduced in Australia, and I'm sure the list is much longer, but I'd particularly like to highlight a Northern Irish company called Adoreboard. They offer an AI tool for employee and customer experience management, and Adoreboard has successfully partnered with Australia's second largest private healthcare operator called HealthScope. I think they operate around 38 hospitals across Australia. And Adoreboard's solution, basically, enables HealthScope to analyse patient surveys using AI, and that allows hospital executives to better understand and prioritise their patient emotions and experiences, so quite an interesting collaboration. So, just to briefly recap that this is what you'll be thinking when you start thinking about the Australian market, this whole ecosystem of players and stakeholders. And as mentioned, we have out state and territory health departments, federal agencies, we have healthcare providers, hospitals, aged care in private and public setting, industry associations, NGOs, such as Cancer Council of Australia. And of course, MedTech companies like device technologies. So, companies who may be a potential partner or may already be working with a company out of Northern Ireland.

And, of course, we have also a number of so-called peripheral players, growth centres, accelerators, health and medical research institutes, and as we have seen as well, private health insurance companies that also maybe encouraging the uptake of innovative solutions. So, the opportunities are definitely there, and the key thing for the Northern Irish company at this point will be to start thinking about your market entry strategy, and at a high level, your successful market journey will always start with understanding the Australian market, the ecosystem, understanding who your key customers and end users are. And, I guess, also thinking about where your product or technology fits in. And then, looking at the regulatory side of things as well. So, you may decide to engage with a regulatory consultant, to advise you on the TGA requirements and what the relevant application procedure is for your particular product or

technology. And when you think about the big picture, appointing a local partner in the Australian market will be absolutely critical. Distribution is generally an ideal market entry model, particularly valuable in the MedTech and digital health space, given the importance of local knowledge and local networks. And you should be aware that generally, distributors will be looking to partner with suppliers that can demonstrate successful track records. So, case studies or testimonials from other key markets, but there's also others that will support nation, I guess, novel technologies that can-, and they can certainly assist with introducing these to the healthcare community in Australia.

In addition to partnering with local integrators or technology companies, you can also consider aligning yourselves with some of the other key stakeholders that we mentioned, such as (mw 14.12) research centres, organisations like Diabetes Australia, and there's certainly opportunities for collaboration trials and pilots, which may be a good entry point into the market as well. Things you need to be aware of, of course, there is strong competition for attention and for funding, and also, sometimes hospitals and clinics can be reluctant to change suppliers. But again, if you can demonstrate, if you have a good track record in your market and if you have case studies that will increase your chances of success. So, to summarise, understand the market, be aware of potential challenges. I guess, the final thing we always like to highlight is to get your feet on the ground. So, Northern Irish companies should consider visiting Australia as soon as you've made enough connections. You can do it with the aim to connect with potential partners and customers, or to attend trade shows, industry events, conferences, and it will ideally be a combination of all of these things, and this is where Invest Northern Ireland and Foley can help you as well. So, spending some time in the market will help you better understand the Australian context, help you build relationships, and relative business opportunities. So, I guess, that the final thing maybe is to have a look at some of the major events we have in Australia, and obviously, we're not Germany, so we don't have Medica or events of that scale, but we do have a few key events that will be of interest to Northern Irish companies, such as the Australian Healthcare Week, our AusMedTech Conference, or Digital Health Festival as an example. Australian Healthcare Week is our largest and most comprehensive health event. It does include several different streams. I think for 2025 events, they have introduced something called Healthcare 20/40 and that explores also the role of AI across diagnostics, predictive analytics, and also looks at surgical innovations, robotics, and some other areas. So, with this slide, I'd like to conclude my presentation. I know there is a lot of information for you to digest. I wanted to thank you very much for the opportunity and I'm looking forward to any questions after the webinar.

Caption by Verbit Go

File name: invest_ni___spotlight_on_australia_-_jonathan_tierney_-_seating_matters_(case_study)(240p).mp4

Moderator questions in Bold, Respondents in Regular text.

KEY: **Unable to decipher** = (inaudible + timecode), **Phonetic spelling** (ph) + timecode), **Missed word** = (mw + timecode), **Talking over each other** = (talking over each other + timecode).

Jonathan Tierney: Hello, I'm Jonathan Tierney, commercial director of Seating Matters, and we're a company based in Limavady, Northern Ireland, that manufactures specialist seating and medical devices for the healthcare market. From Limavady, we export our products around the world, mostly UK, Europe, Canada, America, and Australia and New Zealand. And I'm really excited to speak at the Exporter Case Study regarding Australia, because Australia is actually our-, probably our best case scenario of how we export. Australia has been a partner of Seating Matters for about 10 years, and so much so that even the chair on the left of the screen here is called the Sydney chair. It was developed along with the University of Sydney, with our partner in Australia. So, they've been influential in our growth, and has-, have been a really good partner, and it's a really good country for Seating Matters to do business in. So, the-, the picture on the left here shows the team in Australia, along with Martina Tierney, my mother, who, last year, at the global-, our global summit, they won distributor of the year. So, again, that's why I'm happy to share our experience, because I feel we've had really good success exporting to Australia. We've been working with the team there for over 10 years, and they are exclusively selling the Seating Matters products.

So, the-, it started off that they're a clinical team that contacted us because of our research on pressure injury prevention. It started off they were a pharmaceutical company, owned pharmacies, and have-, since, they've taken on Seating Matters chairs, they have divested the other products, and the other part of their business, sold out of the pharmacy, and have become exclusive to Seating Matters. And in the last couple of years, we have actually invested in the company and are now part owners. So, it's went full journey, from manufacturer to supplier to becoming our master distributor and now bringing it in-house to the Seating Matters group of companies. From our main office in Sydney, where we have 18 people, we have set up sub-distributors for some of the further areas, like the Northern Territories for Perth/ And we have our own sales team in the east coast, so mostly Sydney and Melbourne, and now moving up into the Gold Coast as well, and we're using the base that we have there as a launch pad. So, we've now expanded into New Zealand, and we're looking to go into other geographical areas from there as well, which I'll-, I'll discuss.

So, some of the reasons and advantages of doing business in Australia is I feel that imports are normal. So, unlike other countries, you know, that we work in, we're often going up against local competitors, and naturally, a lot of customers like to buy from their own country, manufactured in their country. But in Australia, we find that all our competitors are-, are also being imported, and it's such a normal thing for

them that it's not a question, it's not a barrier to-, to tenders, and it's not a barrier in the customer's mind. They also-, because they're importing-, they're importing from many different countries, but they really appreciate the products, and I think we're seen in a higher light, coming from Northern Ireland, being a European product, and our-, in the-, our industry, or at least with our products, our approvals, our CE mark and our medical device registrations-, all the standards that we meet for our home market translated right over. We didn't have to make any product adaptations, or any changes to our product. It was very much a paperwork exercise to get all the accreditation that we needed. They took our standard product. So, unlike other countries, where we would often have to adapt the product to meet their standards, or suit the market, we didn't have to do that for Australia. I find that, culturally, it's very similar.

We actually have people from Northern Ireland working in our team there, and a lot of our customers are from the UK or from Ireland. When we go to hospitals, the nurses, the doctors, are from there. So, we find that being from here is a natural fit. They're so used to people from other countries working there, and, culturally, they're very, very aligned. For a country that's so far away, doing business with them is often very, very similar to doing business in the UK, or doing business in Ireland. And it's a very financially strong country, a robust economy, and, especially in our industry, they have really good reimbursement schemes for healthcare products. They have really good healthcare insurance payment systems. That has really helped our business grow there. And, although it is a massive geographical area, we find that most of the business is naturally done in the large cities. So, Sydney and Melbourne are the two cities that we focused on for the first eight or nine years, and have grown our business massively. So, although it's a big territory, and often you look at it as a really hard country, because of the size of it, we were actually able to focus on the population centres, and grow our business massively there. So, obviously it doesn't come without its challenges, and the distance being a really obvious one.

The logistics of getting product to the other side of the world-, it often delays a lot of our product launches. It's a lot more difficult to service if things go wrong. It's far away to travel to, and we do find that that does cause some operational challenges, as well as the communication, and-, because of the time zones. So, for example, when our office hours are open here, it's night time there, and the opposite way around. So, we often have our team here having to work outside of hours in order to hold meetings there, and, vice versa, we often have the team in Australia having to work outside of hours just to communicate with our office, or get information that they need. And we-, I also talk here about technology and systems being an operational challenge, and the-, but it's also been an answer to some of the problems, so the logistics and the time zones, because we have built all our systems-, that we can share our information between the two countries. So, we very much have-, a lot of our technology and systems are shared. So, they're using our same software, our same-, they're logging into our same CRM, finance packages, so they can help to answer their own questions. But we've also found that, you know, our website and email addresses all had to be .com, .au.

We have a totally different website for the Australian market, that talks about their funding systems. We've got, you know, that kind of talks in their language. So, that's something I would recommend for

people, that as you establish yourself, in any country, but I've found especially in Australia, that we needed to have our own marketing team there, we needed to have our own customer service team there, because they weren't able to access the answers from our office here in Northern Ireland. So, you know, we haven't had that same issue with our European or-, or even our US-, they're-, they can easily call us in their morning, and still talk to the people in the-, our office here. That is-, just doesn't work for the Australian market. And with the Invest NI, I would highly recommend using the support that they can offer you. Invest NI have an office in Sydney and know the market really well. We actually worked in Australia for many years without using the support from Invest NI. And I think that's something that has probably, probably held us back from accessing some of the funding around the insurance funding that's there, and our journey could have been accelerated or speeded up if we had have tapped into the Invest NI support at an earlier stage. And we are doing that now, when we go to other countries. So, Canada, for example, when we-, when we went there, we were able to tap into some of the things a lot quicker than we did in Australia. So, I would highly recommend, for anyone thinking about going there, to use that support from the-, from the start.

The other thing that we see as a massive advantage for using Invest NI is we're using Australia as a launch pad for us into other countries. So, we've already expanded from there into New Zealand, where we're supporting our New Zealand customers through our Sydney office, and we're looking to do that into Asia as well. So, we're looking at Japan and Singapore, and Invest NI will be able to help us to move into them regions, and I think that's another major advantage of having a presence in Australia, is you're much more aligned with the Asian market, as far as time zones. It's a much easier commute for our Australia team to get to Singapore or-, or Japan than it is for us, and, again, using that as the launch pad for them countries. So, what I would recommend, for anyone looking to go into Australia-, first of all, I would be happy for Invest NI to put me in touch with anyone who is exploring that. If you wanted to talk to me at Seating Matters, I'd be happy to share our journey in-, in more detail.

I would use the-, the help that Invest NI can-, can give you. As I said, they have people on the ground. They're running trade missions there. So, they really know the market. If you haven't explored that already, that help is all available. And even just to help with market research, making sure that your product is a fit there, and making sure that the funding is available. And something that, you know, took us a few years to get to, but having your own brand identity and-, in Australia is really, really-, we find, is one of our competitive advantages. So, we're now branded Seating Matters Australia. They use our logo. They use our name. Everything looks the same as-, as we do here, and that has really helped to grow our brand, and build confidence, even in our customers here, seeing that we have, you know, export offices. That has been something that has really, really worked, but, back to the operational challenges, unless you have a-, a presence there, it is a difficult market to-, to service. And what we have also found, you know, when I compare what we're doing, compared to competitors, is they're trying to supply multiple companies from the UK, and it's-, it's difficult to manage.

For us, having one major importer, as a strong distribution centre, and now that we have-, especially now

that we have some ownership of that company, we find that's a really good platform, and then we sub-distribute from there. So, if I was to say what does success look like, that's probably one of the big drivers for Seating Matters in Australia. So, I'd like to thank Invest NI for giving me the opportunity to present on Australia. As I say, for us, it's one of our success stories, and I'd be happy to talk to anyone that wanted to discuss that further. Thank you.

Captions by Verbit Go

File name: invest_ni___spotlight_on_australia_-_chia-yi_(a_look_forward) (240p).mp4

Moderator questions in Bold, Respondents in Regular text.

KEY: **Unable to decipher** = (inaudible + timecode), **Phonetic spelling** (ph) + timecode), **Missed word** = (mw + timecode), **Talking over each other** = (talking over each other + timecode).

Speaker1: In this session I will provide an in-depth overview of how Invest Northern Ireland supports our clients in the market. I will also share our plans for the year head in Australia, including the key events I'll be attending and how I can bring value at those events. Our in-market team plays a crucial role in helping Northern Irish businesses enter and succeed in Australia. We provide business development support. We actively participate in key industry events and exhibitions representing Northern Irish companies, generating lead, facilitating B2B meetings and identifying future sales opportunities. We also have access to key networks and influencers. We leverage our extensive network to connect you with industry associations and key decision makers at the highest levels. Our services are further enhanced by nationwide multi-channel marketing and communication support across various sectors. Furthermore, we provide cutting-edge market insights, including regulatory advice, for example on what you just heard about TGA and free trade agreement, and update on policy changes that may impact your business. We also conduct company-focused research, which enables you to make informed decisions and tailor your offerings for the Australian market. This includes market intelligence, distributor and client research.

This year I will be attending two major events in Australia, focused on medical devices and digital health. AusMedtech is Australia's leading for the medical technology sector. It brings together experts, entrepreneurs and researchers to discuss the latest industry trends and opportunities. I will be on-site to support any Northern Irish company exhibiting or attending. For example, last year I visited Randox's stand at (mw 02.34) AusMedtech to offer an on-site support. You can see me talking to Randox colleagues in the first photo. At the expo I will be also be networking, generating business leads and conducting business development activities. After the event I will compile key insights into a report, which will be then shared via our Invest Northern Ireland newsletter and LinkedIn. The other event I will be attending is the Digital Health Festival in Melbourne. This is Australia's leading health technology event, covering key topics such as digital health, AI, cybersecurity, digital pharmacy, medical devices and wellness tech. Although the event only just launched three years ago it has quickly become one of the most influential events in its field. This year over 8,000 attendees are expected, with 40% of them being the decision makers. As with AusMedtech, I will be on site to support any Northern Irish companies that are exhibiting or attending. I will also be networking and facilitating business development connections. After the event we will publish a post-event report, so I encourage you to subscribe to our newsletter and follow our LinkedIn for insights.

If you are interested in either of the expos I encourage you to explore the programme. If there are specific attendees or delegates you would like to connect with please let me know. I'd be happy to facilitate

introductions and represent your interests on-site. Invest Northern Ireland is here to help you enter, navigate and succeed in the Australian market. Whether through business development, industry connections or high-level research, we are committed to supporting your growth. We will also update you on further relevant events or opportunities, so make sure to watch this space. I look forward to working with you all. Thank you.

Captions by Verbit Go.

File name: invest_ni___spotlight_on_australia_-_q&a (240p).mp4

Moderator questions in Bold, Respondents in Regular text.

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Moderator: Now I'd like to hand over to Sergio De la Puente, the International Trade Advisor for INI Life and Health Science sector, to chair this session for us. Please, Sergio.

Moderator: Thank you very much, Chia-Yi, for the webinar, and thank you to all the panellists today for contributing to this webinar. I thought we got really valuable information, and I hope everyone in the audience got some takeaway lessons today. So, considerate of the time, I'm just gonna go quickly to the questions we've got from the audience. I'm gonna put the first one to Jonathon-, sorry, to Marina (ph 00.45), that we just started here. So, the first question to her is how do you recommend proceeding in order to become a recognised or approved supplier for both the public or the private sector tender invitation process?

F: Hi Sergio, hello everyone. I guess when you think about-, we, we heard a lot about the regulatory approvals. There's also some quality certifications that the companies need to think about, but when we, I guess, focus only on, on how to become a supplier to a hospital, private or public hospital group, for public hospitals I guess it's probably just a question of registering for different tender sites. There's the federal government's Aus standard website where they publish all the federal health contracts, and also as mentioned previously every state health agency has their own public procurement portals for, for their healthcare sector. So, I think in this case a lot of the-, a lot of the suppliers work with local partners, Australian companies, who can register and basically respond to any opportunities that way. For the private health sectors it's slightly different because, as mentioned, the private hospitals manage their own procurements-, procurement, so suppliers can approach hospital groups, such as Ramsay or Healthscope, directly and engage with their procurement teams, and there is also procedure which may be slightly different for different hospital groups, but basically you can register on their website as an approved-, to become an approved supplier for that particular hospital group. And again, a lot of the Australian hospitals prefer to work with local distributors, so they would have a network of established partners through which they source different types of equipment. I think it's sort of slightly different for software solutions, but yes, it's-, yes, I could talk about that really for a long time, so-, but that, that's it in a nutshell, I guess.

Moderator: No, that's, that's great. Well, thank you very much Marina, really appreciate it. And the next question is for David, with, with regards to the TGA. So, what are the TGA requirements for sponsors, and what options does Northern Ireland companies have that does not yet have a, a presence in Australia?

M: Hi everyone. Yes, so that's, that's a good question. Let's just, just make sure that there is no echo in here. So, the Australian sponsor is basically it must be a local Australian entity who will be the first point of contact during the product registration. Now, often overseas companies mix together sponsor and distributor. There is no such requirement that these two entities must be the same. So, you can actually, if you are from Northern Ireland, you can engage with a local company only for the sponsorship for the registration aspect of your product, and engage with a separate entity for the distribution. That means that with that model you can really keep a good handle and control on the registration aspect of your device, and just deal with the supply or the distribution with another party. Now, the local sponsor is, as mentioned, the first point of call during the registration. They also must have some basic requirements for access to information, technical information, regarding the product. Also, they have to track the stock within Australia. So, if there is any recall or any adverse event then they will have to be able to notify the TGA as well as the distributors and the patients and hospitals. And they also are required to do the device vigilance, pretty much the same as they would use or they would do in Europe. That means collecting any post-market reporting data, submitting reports, if necessary, and the list goes on, but I would only just highlight these things.

Moderator: Okay. Well, that's, that's very helpful, thank you very much, David. And the last question we've got so far is for Jonathon. It's with regards to distribution centres. So, (inaudible 05.25) is considered (ph 05.26) distribution in Australia to serve Australia, New Zealand or any other nearby markets?

M: Yes. So we currently have a distribution centre in Sydney, and we've an office there that looks after that, and that's the master distributor. So, we send everything there, and then they'll supply, you know, the smaller distributors from there. So, we can send over full containers and we'll allow the customer to, you know, just get one chair at time if, if that's what they need. So, yeah, that's how-, that's how we work currently.

Moderator: Okay. Jonathon, just following up on that, is, is that the strategy you will advise one you have a more-, a, a wider presence in the region? Did, did it work well for you?

M: Yeah. I think that works well for us. It's, as I said at the start of the, the conversation, Australia is probably one of our better set up export countries, and is, kind of, a model that we would want to replicate when we go to other countries. We feel that Australia is the one that we've, we've, kind of, mastered, we've got it right as far as being able to be self-sufficient in the market, and, you know, being able to supply through multiple routes. You know, in other countries maybe we're working with partners where we're just in one area or we're just in one hospital or one sector of the healthcare market, whereas Australia we've hit every sector, we're in every state, and we're starting now to, you know, bounce from there out to New Zealand and hopefully other countries.

Moderator: That's great, thank you very much. We haven't received any more questions so far.

Conscious of the time, I'd like to advise anyone in the audience or anyone seeing this at the later stage that feel free to reach out to Chia, myself, to another other Invest NI channels to explore the Australian market and what opportunities might be there for you. It is a-, it will be-, glad to help you out on that region. We will have staff on the ground, we'll have staff in Belfast, and can help you out. Hopefully we can-, we can develop that market together for you. And, with no other questions that I can see I will conclude this session. I'll thank you, the panellists, again for the time, considering the times-, the time differences across the world, and thank you everyone in the audience for participating. Have a good day everyone.

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