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Moderator questions in Bold, Respondents in Regular text.

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Adrian Bootes: Hello everyone, my name's Adrian Bootes and I'm pleased to be speaking to you today from Australia, and I welcome this opportunity to talk to our friends from Northern Ireland, and talk about the opportunities for medicines and medical devices. Australia you may not know too much about, so I'm going to enlighten you. And first of all I'd just like to point out that we are actually a net importer of medications, you can see here we import approximately A$14 billion per year of products, and this doesn't include medical devices which would be additional to that. In-, the counterpoint to that, of course, is that we don't export very much, about A$3.6 billion of pharmaceutical products and A$1.7 billion of medical instruments. So, there's certainly a lot of opportunities for people who wish to import into the Australian, Australian market. When you look at how much people do bring into Australia, and I think this is an indicative slide, that if you look at medicines, new active substances, we're seeing about 27 new active substances per year, whereas the European Union is seeing, seeing 35 and the US 50. So not every company brings their products to the market, which means there's opportunities and not as much competition in what is a first world country. The nice thing about working for the TGA is it's been our raison d'etre for a long time to have a consistent and predictable approval pathway. And you can see on the right hand side of the slide here that the timelines for TGA have been dropping over, over the years, particularly in 2020 when we brought in new priority pathways, sometimes they're happening very quickly. But the, the bars have been quite narrow compared to the variation you might see in the FDA or Swissmedic there, for instance, so a predictable timeline. That's for medicines, medical devices not quite so-, quite so good, but, but, but again it-, we're certainly trying to improve the matters there. Within Australia there are actually many, many stakeholders that are interested in products. The TGA is one you would have heard of, the equivalent to the MHRA, but we also have the States, who have control over the poisons and medicines, medicines scheduling.

The Pharmaceutical Benefits Scheme, which pays for a lot of our medicinal products, the Medical Benefits Scheme, or Medicare, which pays for a lot of services, and then if it's a gene regulated product, the Office of Gene Technology. But then of course there are other stakeholders as well, but the main one I'm going to talk about today, and the main one that you will deal with, is the-, is the TGA. So, the TGA deals with therapeutic goods, and a therapeutic good is when it's got a therapeutic use, it's an ingredient for something that could be a therapeutic good, it could be a container for that. Or it could be represented as being a therapeutic good, so if it looks and smells like a therapeutic good, even if it doesn't really have a significant therapeutic active effect, it will be regulated as a therapeutic good. So, if you-, if, if a product that you have purports to make you lose weight, even if there's no particular strong active ingredients there, it will be regulated as a therapeutic good. Within our acts (ph 03.44), there are four types of therapeutic goods, medicines,

medical devices, biologicals, and, and biologicals, the definition varies between various countries but in the Australian case a biological is something which might be made from human cells or human tissue, or live animal cells. It's not an antibody or a vaccine, they're considered biological medicines and they're regulated as medicines, so that's a separate-, that's, that's a separate distinction that we have. And then there are other therapeutic goods, such as products that might sterilise or disinfect, including things that might sterilise or disinfect a medical device. So, when you're supplying in Australia, generally you have to have-, be regulated or have an exemption, so you need to be registered on the ARTG or provisionally regulated, such as the COVID vaccines, listed or listed-, authorised, and they're generally the OTC medicines. Also, registered and listed are the-, are the medical devices.

Now, if you don't have that then you have to look at an exemption, whether a clinical trial, phase I, II, III, or IV, Special Access Scheme product for when there's a, a single patient need. Authorised prescriber, that might be prescribing to a group of people. Export listing, that's going in and out of the-, of the country very quickly or it's going out of the country only. A Section 19 exemption when there's a shortage, or a person's able to import a product for themselves or their immediate family members. If you're bringing in a product just for lab testing or just testing out manufacturing or planning, it's not a therapeutic good, and so the TGA does not regulate that sort of supply for those purposes. So, talking a little bit more in detail about medicines. There are now seven pathways for prescription medicines, and I implemented six of these when I was at TGA. So, the first plan is the standard pathway we've had for about 30 years, a priority pathway, a provisional pathway for things such as COVID vaccines or cancer drugs which you have immediate need. A collaboration we now have with other countries called ACCESS, Canada, Singapore, Switzerland, and now the UK as well as ourselves, jointly evaluate products that enter that pathway. Project Orbis, which we have set up with the FDA in Canada, but now extended to other countries including the MHRA, for oncology medicines only. Comparable Overseas Regulator Pathways A and B, where we use an evaluation report for a product that's already been approved in, in another country, and commonly we've used an evaluation report from Europe, but there are six countries where we can use those evaluation reports. So, when-, for the first few of those pathways, of those seven pathways, we have a pre-submission meeting, it goes through and then it proceeds as either a priority provisional or a standard pathway. And you can actually have an orphan system as well, which is similar to the European orphan, that means that your submission is for free.

Moving on, and just briefly on medical devices. So, we have our own act, and regulations and guidelines on medical devices, they are separate to the EU and FDA. It is-, it is, however, somewhat similar in that we will take into account if it has a C-, CE mark, if, if it's subject to an MD sat approval (ph 07.36), if it's subject to an FDA approval. And we look at the general matters that other regulators wouldn't look at. Is it demonstrated fit for it's intended purpose, the benefits are greater than risks, and you can prove all the claims that you wish to make. And a quality management system based on ISO 13485, which you'd be familiar with. Also, we have evolving guidelines on software as a medical device. And for instance sometimes we've taken a different path, if you look at the Apple Watch, for a while there we didn't approve the ECG, ECG, ECG

function on the Apple Watch, it was a-, there was a concern that it might have a therapeutic use, so until that was proven to be okay that software wasn't allowed on, on the Apple Watch, but it now is. So, we have a similar process and system to the Europeans, we-, for general medical devices, I, IIa, IIb, III, and active implantable medical devices, with increased requirements with the increased risk and the increased importance of those medical devices. As I mentioned, we have a QMS based on 13485, and you need to maintain that and surveil its use in Australia, and let us know if something happens overseas that might impact upon the approval here.

Lastly, I just want to touch on clinical trials. This might be an opportunity for you that you're not aware of, but many companies have come to Australia because we have a very fast start mechanism for clinical trials. A clinical trial notification scheme involves an approval by an ethics committee and local governance, but in fact when it comes to the TGA, because it's notified, we mark it in our database but we don't do more than that unless there's a particular problem with that particular product. And so, often Australian clinical sites can be the first site in the world to start, and that's, that's a real benefit. Also, we have got a burgeoning phase I and first in human sector as well, that allows a quick decision as to whether that product (TC 00:10:00) can continue development or not, by nature of the fast approval process. Biologicals are a little bit more complex, but for most small molecules, devices and antibodies it's a very quick way of doing clinical trials. So, just on that point, when do you talk to us about clinical trials? The Europeans and the FDA in particular, wish to talk to you about your development programme, but Australia doesn't have the same level of engagement or the same resources. We suggest that if you're wanting to enter the EMA or the FDA you might want to talk to them about what their requirements are for clinical trials and bring those to Australia, and usually those requirements will be fine for starting a study in Australia.

If you have a biosimilar coming along, or a generic medicine, I'd suggest very much just to check that the comparator that you're using is appropriate to make sure that it's-, it-, that what you're doing in a clinical trial will pass the regulatory test when you come to have it approved. So, the key points in, in, in this brief presentation is we follow a European approach and dossier. We adhere largely to ICH, the PIC/S GMP guidelines, the standard pharmacopoeias, but we do have Australian additions to those. We have increased use of international collaboration and reliance pathways for new products and generics, very much so in medicines and increasingly so in devices. And our timelines are reliable and shortening, there's improvements for OTCs and devices coming, but they're still being implemented. They are (sic) quite as quick, but certainly the TGA's moving to make the pathway as painless as possible. So, if you wish to know more details, I-, I'm-, work, have worked at a senior level in the TGA and also know the industry very well, and I'm contactable through the biomedical department consultancy that is based in Australia and the UK. So, thank you very much for your attention and look forward to answering any questions that you might have.