EPR (Extended Producer Responsibility) Regulations

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In collaboration with Joe Hage and the LinkedIn Medical Devices Group

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Joe Hage: Hi this is Joe Hage. I have the privilege of leading your Medical Devices Group which as of this recording has 305,000 members worldwide and one of the reasons we've grown so large is we have members like Emma and Graham on the line. They are members of the group and they are experts in EPR and it's something I knew absolutely nothing about until I spoke with Graham and I said, this is something important that members need to hear.

So Graham, are you on the line?

Graham Margetson: I am indeed. Hi Joe!

Joe Hage: This is your show. I will put myself on mute. Take it away and have a good webinar. Thank you.

Graham Margetson: Thank you. Thank you for the introduction Joe. It's a real pleasure talking to you all in whatever time zone you may be in. We've got hopefully some good information for you which you will find helpful and what you had hoped to hear. Just before we get, I'll pass over to Emma, I just like to give you just a very brief couple of words about our company, Lorax Compliance.

We are based in the UK and we are the developers of software. We're a technology company but as our technology specifically focused on assisting corporations to comply with Global Extended Producer Responsibility Regulations. Then of course we also have quite a large consulting operation to help and to guide people we're talking to who may not understand what they need to do, where they need to register, what their obligations might be and so forth.

So as well as a software business, we also have a very important consulting side as well of which Emma is a senior consultant.

So in short, we are a technology-led regulatory compliance business. I just like to give you just a brief overview of the topics which we're going to be addressing during the meeting.

Definitely clear I think in terms of the invitation that you saw that we'll be talking about packaging waste. Quite a strong focus on the EU and several of these directives because it is in the EU that many of these indeed most of these directives started and of course EU's got 28 countries so if you're trading there then there's going to be an impact. But we're using that as a model not the final statement. We will be looking at other countries as well.

We of course will be talking about WEEE which will no doubt impact many of you and of course batteries which is primarily what you'll find in the EU.

Also, in Europe, there's been increasing talk now about what's referred to as these circular economy. Now, this is a topic which has appeared over the years with various names and it's really good sound environmental common sense which Europe are putting some significant clout behind.

So Emma will make some references with this. We'll just give you a heads-up of the direction in which the environmental compliance in Europe in particular is going. And at the end of this, we'll give you a summary of what we've covered and then Emma will be ready to take your questions.

Obviously we'll take as many as we can in terms of the time aligned. And also though, if your questions are reasonably complex, then it may well be that the best methodology will be until after the meeting to send Emma an email with the detail of what you'd like some answers on and we can respond to that as well.

So with that, I'd like to pass you over to Emma. Emma Mundy is our Senior EPR Consultant and she'll be giving you this presentation and I hope you get real value out of it.

Thank you.

Emma Mundy: Thanks Graham. Afternoon everyone from the UK.

As mentioned in the agenda today, we're going to be looking at the Extended Producer Responsibility waste directives and legislation. This session is designed to be an introduction to those directives. So let's start by looking at the definition of EPR.

So Extended Producer Responsibility or EPR is the shifting of responsibility of products at the end of their life towards the producer and away from municipalities. So essentially, it's the

producer-based principle. Producers need to take into account environmental considerations when they are designing their products. They also need to take into account their lifespan and the recyclability or reuse of materials also needs to be considered.

And the EPR principle has evolved to successfully ensure that producers take responsibility for managing the waste generated by their product.

So what are the directives that fall under extended producer responsibility?

Well today, as Graham mentioned, we're going to talking about the packaging and packaging waste directive, the waste electrical or WEEE directive and the batteries directive.

Now these directives are the EU directives. We're going to be talking about those today because they are the most established and the ones that more likely to affect you as medical device companies.

However, I will be talking about other countries as well.

So in the EU, you've got the EU packaging waste directive as amended. You've got the EU waste electrical and electronic equipment directive.

Now the first WEEE directive came into force in 2002 and it has since been amended and we now have a new WEEE directive that came in in 2012.

We've also got the EU batteries directive from 2006 and that's also been amended several times. But of course you've also got worldwide implementation of EPR directives as well.

So we'll be touching on this in each section. However, a lot of the legislation elsewhere is newer and it's still developing. So it might not always affect medical device companies just yet. But of course that's not to say that you shouldn't be keeping an eye on this legislation because it is ever evolving just like the EU directives.

So where did EPR start and how is it evolved? Well the EU legislation was introduced in 1980's but it wasn't really until the 90's that things started to gain pace. The directives were introduced to reduce the environmental impact of products at their design stage and also to make the products and packaging out of the materials that are easy to recycle and reuse.

Non-EU European countries also have similar regulations and other countries elsewhere in the world have also implemented legislation.

So really, it's an area that is constantly developing. It's important to note though that the scope and structure of EPR directives can vary significantly. Each county imposes their own ideals on the best way to deal with waste.

So let's now look at the packaging and packaging waste directive in a bit more detail. What I'll do is I'll give you some background on the regulations. We'll go through the essential requirements and then we could look at what is packaging, who is obligated with regards to the EU directive and then we'll look into what's happening elsewhere.

So firstly, let me take you through some details of the EU directive. The first piece of EU packaging legislation was introduced in the 1980's. At this point, some member states started to introduce their own measures and this meant diverging national legislation appeared.

So harmonization was needed in EU level and this harmonization was introduced in the form of the EU packaging waste directive in 1994.

The directive is split into two parts. You've got the essential requirements and packaging waste. The packaging directive was last amended in 2015 and the amended aims to reduce the consumption of lightweight carrier bags.

So firstly, let's look at the essential requirements. So what exactly are the essential requirements for packaging? The essential requirement addresses the concerns about potentially excessive packaging of consumer products. Packaging needs to be minimized at their design stage but it still needs to maintain the necessary levels of safety, hygiene and acceptance for the consumer. Packaging also needs to be designed to permit recovery and or reuse and heavy metals in packaging need to be restricted.

Hazardous substances in packaging must also be minimized from things like emissions and ash from incineration or landfill. Doing this not only lessens the environmental impact but it could also save you as a producer some money in the long run.

Here in the UK, it's Trading Standards who make sure that companies are complying with the essential requirements for their packaging.

So what is packaging? Well, packaging includes primary, secondary and transport packaging. Primary is of course the first level of product packaging such as things like the bottle or the jar or the tube. Secondary packaging not only protects the product but also the primary packaging. Things like cardboard boxes and retail displays. And transport packaging is used to group secondary packaging but also to aid handling and transportation and to prevent damage during transit.

Packaging does include items that filled at the point of sale. But if it doesn't include items that are integral to a product and are intended to be used to consumed and disposed off together.

If you do have any doubt at whether something is packaging or not, it's always best to check rules and specific guidance of the country that you are selling into.

We have had a few unusual queries regarding medical device packaging in the past and often schemes have had to go away and check the answers themselves.

Just to give you some examples of obligated packaging, things like glass bottles for injections, dilutions, sterile barrier systems and devices for measuring dosage are all clusters packaging.

All consumer, commercial and industrial packaging waste marketed in the European Union is covered by the directive and all EU EPR directives have targets on what needs to be collected for recycling and reuse.

Member states need to document and prove that they have met these targets otherwise they'll be fined by the EU.

So by 2001, member states have to achieve 50-65% recovery of packaging wastes. By 2004, they have to achieve an overall packaging waste recovery target of 60% and by no later than 2008, between 55% and 80% by weight of packaging waste have to recycled.

A packaging producer must register in each obligated country in order to achieve recovery and recycling targets. Dependent on the company's obligation, they may need to join a compliance scheme or set up of their own collection infrastructure.

Producers will also have to pay fees based on their individual obligation and EU member states compliance processes and fees can differ significantly.

So you do need to be clear on the rules and processes for each country you sell into.

Unfortunately, I don't have time today to go into specific countries and their reporting requirements but this is something that we will cover in other webinars throughout the year.

There is a current review of waste policy and its proposals under the EU Circular Economy package which I'll talk about towards the end of the presentation. So just be aware that the packaging waste directive is set to change again.

At this point, if you don't already know, you might be wondering if you do actually have any obligations into the packaging waste directive. The responsible person is obliged to ensure that all packaging covered by the regulations complies with the essential requirements and heavy metal limits in addition to the other provisions of the regulation.

Packaging producers can include supplies of packaging materials, packaging manufacturers and converters, fillers and users, importers, distributors and distant sellers.

So even if you're not based in a particular country, if you sell into it, you may still have obligations.

Who is obligated will also vary depending on the country you are selling into.

So the UK works on a shared producer responsibility system where all producers in the chain pay a percentage for their packaging compliance that many other EU countries work on the principle of the first producer to place onto the market is the obligated producer.

Also, be careful if you're sell via B2B and B2C routes as compliance rules will vary again by country. But also remember that if you sell to a business, it doesn't always mean that you're selling B2B if that product could end up with a consumer.

So you need to look at the type of goods and who they're intended for and which way stream they are likely to arise in.

Next, I'm going to talk about the Green Dot and this can be an important part of packaging compliance. The Green Dot is a widely recognized symbol in many European countries. It signifies that for each piece of consumer packaging, a financial contribution has been paid to a national packaging recovery organization.

It's a mandatory trademark in some countries which means that the first person to place the packaging onto the market must pay a license fee to use the Green Dot in that country and ensure that the Green Dot is printed on their packaging.

As you can see from the picture on the slide, the Green Dot is the circle with the two arrows wrapped around each other.

The Green Dot doesn't actually have any meaning in the UK and it's not a recycling symbol in the UK. If you are the brand owner of goods sold in the UK which have Green Dot symbol displayed on the packaging, you will be required to pay a UK license fee.

Some countries require a separate license fee and in some countries, the compliance fee is called the Green Dot fee. So again, you just need to make sure that you're complying correctly and paying the right fees.

There are currently 33 European countries where the Green Dot can be used and it is mandatory in certain countries such as Portugal, France and Greece. The Green Dot is also licensed in the United States and Canada through Green Dot North America. And if you sell the Green Dot printed on packaging to other countries, you will need to pay a worldwide license.

Also, just to note, as you can see, the Green Dot is not always green. But there are guidelines as to how it should be printed and sizes, et cetera.

So before you print the Green Dot on your packaging, you need to make sure that you are complying with the rules and regulations on the Green Dot.

Now let's have a look at what's going on outside the EU. While it is clear that other countries also have packaging waste on their agenda, although packaging waste compliance might not yet be fully established in some countries, again, it's worth keeping an eye on because things are changing rapidly.

So just to give you a snapshot, Mexico has a comprehensive waste law which includes deposit and return systems. Uruguay has implemented a packaging waste law and Chile and Uruguay have agreed to packaging waste covenants. Jamaica and St. Lucia have also adopted eco-taxes on packaging.

Australia has something called packaging covenant and this is a voluntary component of a co-regulatory arrangement based on the principle of shared responsibility throughout the chain. And this is between packaging producers and the government.

The covenant is designed to reduce the environmental impact of packaging waste, encourage recycling and reuse and encourage better design.

So in a lot of ways, it's very similar to the EU directive.

Canada also has provinces with packaging waste regulations and stewardship obligations. And there are currently packaging recovery schemes in Ontario, Manitoba, British Columbia and Quebec.

So that brings me to the end of the packaging section. Just to conclude really, I think it's important for medical device companies to know that packaging obligations will vary depending on the route to market and the country that they sell into.

So if you sell a mixture of consumer and business products, the compliance process is likely to vary.

The next directive I'm going to look at is the Waste Electrical and Electronic Equipment directive or WEEE directive and again, we're going to cover the background of the EU directive. We'll look at the details of it and cover what's changed since the new WEEE directive came into force and we'll also look at the impact of those changes.

And again, I'll detail some of the countries outside of the EU which also have legislation.

So to start with, let's look at a bit of background on the EU legislation. So the first WEEE directive entered into force in February 2003 and again the aim was to increase recycling and reuse as with all the other EPR directives.

And then a new WEEE directive entered into force in August 2012 and became effective on the 14th of February 2014.

Not all EU countries met this deadline. So for example Germany only transposed the directive in October last year.

So why was the WEEE directive introduced?

Well, there are major environmental and health problems is WEEE is not handled correctly and if it's landfilled. Also the production of EEE requires the use of valuable resources and these resources can be gained from recycled and reused waste electrical equipment.

In order to achieve this, the WEEE directive set about improving collection, treatment and recycling of EEE at the end of its life. And the two directives to address this are the directive on waste electrical and electronic equipment and the directive on the restriction of the use of hazardous substances in EEE.

As with the packaging directive, the WEEE directive also sets targets for recycling and recovery. And the directive puts responsibility on producers to finance a collection system and also the responsibility on distributors to take back used EEE.

Electrical equipment must be marked with the crossed out wheeled bin symbol as you can see on the slide to show that WEEE must not be landfilled.

Producers also need to collate and submit data on EEE that they have placed onto the market.

Certain exemptions do still remain such as large scale fixed installations and infected medical devices and also equipment designed specifically and solely for research and development purposes.

A list of the exemptions can be found in the regulations.

There have been quite a few changes since the new WEEE directive was introduced. So let's just have a look at the new directive in a bit more detail.

So the new directive gives EU member states the tools to fight illegal export of waste more effectively and it will also force exporters to test and document the nature of their shipments when their shipments run the risk of being waste.

The new directive also aims to improve harmonization of national registration and reporting requirements and member states registers for producers of EEE will now have to be integrated more closely.

The commission adopted a harmonized format to be used for the supply of information so administrative burdens are consequently expected to decrease significantly but harmonized enforcement is expected to increase significantly.

So they're hoping to get rid of any free riders in the market.

So how might these changes affect you?

Well, obligated parties have expanded. So now there is going to be an open scope and also all countries must obligate distant sellers. Previously, some didn't as it wasn't possible to register with certain schemes with no local office.

Distant sellers now in member states will now have to appoint an authorized representative if they're not established in that state to fulfill their obligations.

Retailers with the sales floor space of more than 400 meters squared offer free take back for small weight and photovoltaic panels are now in scope from the 14th of February 2014.

Member states are allowed to introduce a de minimis threshold for small producers and from 2018, there will be an open scope which means no more Category 8 for medical devices.

I'll go into the new categories in a bit more detail in a moment.

Medical devices are also now subject to recovery and recycling targets. So from entry into force, medical devices will subject to recovery target of 70% and a recycling target of 50%.

These targets were increase on the 15th of August to 75% and 55% and after the introduction of the new equipment categories on the 15th of August 2018, the recovery and recycling targets for medical devices will become 85% and 80% for large equipment and remain at 75% and 55% for small equipment.

So on this slide, you can see the current categories and the new equipment categories which will be introduced in 2018.

Medical devices will then be scoped into other large and other small categories.

Small equipment is equipment with no external dimension of more than 50 cm and large equipment will have any external dimension of more than 50 cm.

And just to note on B2B and B2C products, where there's any ambiguity as to whether an item should be scoped as business or consumer, the default position is usually B2C.

So B2C products can be sold to both businesses and consumers but they will be similar to household waste.

So again, you just need to be careful on how you're scoping your products.

So let's have a look at who's obligated into the WEEE directive.

Producer under the WEEE directive means any natural or legal person who manufactures EEE, resells EEE, or places EEE on the market on a professional basis and also sells EEE by means of distance communication or sells under their own name or trademark in a member state.

Distributor means any natural or legal person in the supply chain who makes EEE available on the market. A distributor can also be a producer.

If you are the first company to place that product onto the market in a member state then it's very likely that you will have the obligation.

So what does the WEEE directive mean specifically for medical device companies?

Well it's important to note that not all medical equipment is excluded from the directive. Exclusions only apply to end of life equipment that could be infective and active implanted medical devices.

Monitors attached to single use items that become infected are still obligated. So for example, electrodes used to attach to a baby's had in order to monitor their health during birth, the electrodes are disposed of as infective hospital waste and the monitor which had no patient contact would not be excluded. So you would have to comply for that.

So check your obligations by country as sometimes it can be a bit of a grey area as to certain exclusions because items such as electric toothbrushes and thermometers which do come into contact with the body are not excluded from the regulations.

Previously, medical equipment didn't need to meet recovery and recycling targets and this has now changed since WEEE too was introduced. What this could mean for you is it could mean higher cost due to more medical equipment needing to be recovered and recycled.

A lot of medical devices are also shipped between countries that are in need of repair or testing. This could be an issue as the new WEEE regulations play stricter enforcement on the shipping of WEEE and used EEE could be mistaken as WEEE if the correct processes are not followed.

Again, I focused on the EU as medical devices are obligated throughout the EU. Although many countries in the world have electronic regulations not all of them currently obligate medical devices.

So in Canada, of the Canadian provinces that do have EEE waste legislation in place, the scope of products that have an obligation to recycle does vary significantly. British Columbia is currently the only province in Canada that obligates medical devices.

Australia also have a take back scheme for certain products but it doesn't currently include medical devices.

And in the United States, some states do have producer responsibility laws but most states tend to obligate items such as TV's, monitors and laptops.

So far, 25 states passed EEE recycling laws.

Brazil has various jurisdictions that implemented take back laws for electronics and expired medicines and China has recently published a new WEEE law which expands the list of WEEE that must comply with the Chinese WEEE regulations.

The new list includes 14 categories which will enter into force in March this year. Medical devices are not specifically listed in the 14 categories but things like monitors and computers are.

Again, hopefully that's given you a good introduction to the WEEE directive and now let's move on to the batteries directive.

So this is the last directive I'm going to talk about today. And again, I'll do it in the same format. So I'll go through the background of the EU directive or look at the detail in the latest amendment, who's obligated and then I'll detail back to requirements elsewhere in the world.

So the first batteries directive was introduced in 2006 and it has been amended three times since.

Again, as with the other directives, the aims are to increase recycling and reuse of batteries. Portable, industrial and automotive batteries and accumulators are all within scope and this also includes batteries within equipment.

Portable batteries are batteries that are sealed, can be hand-carried and are neither industrial nor automotive batteries. They can be rechargeable and non-rechargeable.

Industrial batteries are batteries that are designed exclusively for industrial or professional uses or used in any type of electric vehicles.

The UK recently updated their regulations so the portable battery definition included a weight threshold of 4 kg rather than the word hand-carried as that can often can be quite ambiguous.

The directive establishes an overall collection target for all spent portable batteries of 25% which was to be achieved by 2012 and 45% by 2016.

There is currently no collection target for industrial and automotive batteries because producers or third parties acting on their behalf are obliged to take back waste batteries from the end-users and it's thought that this obligation combined with the ban on landfilling and incineration should be enough to ensure that these batteries are collected.

The directive details restrictions on the use of mercury in all batteries and restrictions on the use cadmium and portable batteries with certain exemptions such as batteries intended for use in emergency alarm systems including emergency lighting and medical devices.

The directive states collection requirements for all batteries as well as collection targets for portable batteries. It also requires that all batteries and accumulators collected must undergo sound treatment and recycling.

Article 21 of the batteries directive requires that all batteries are to be labeled with their chemical symbols across their written symbol and the capacity label.

The batteries directive has recently been amended. The transposition of the 2013 directive happened on the 1st of July last year. The new directive prohibits the placing on the market of batteries and accumulators that contain more than 2% of cadmium by weight. It also prohibits the placing on the market of all batteries or accumulators whether or not incorporated into appliances that contain more than 5% of mercury by weight.

So who could be deemed a battery producer?

Article 3 of the directive states that battery producer is the person in any EEE member state who supplies or makes available to a third party batteries or accumulators including those incorporated into appliances or vehicles within the territory of that member state for the first time on a professional basis.

Just to give you some examples of who could be a battery producer, we'll just have a look at these examples on the slide.

So Example 1, a retailer sells batteries in a particular EU member state but he bought those batteries in a different country.

Well in this case, as the retailer is placing these batteries onto the market for the first time, the retailer would be classed as the producer.

In Example 2, we have a battery manufacturer in a particular EU member state who sells batteries to a private label owner in that member state. These batteries are then sold in the same member state under the label of the private owner and not under the label of the battery manufacturer.

Well in this case, the private label owner will be the producer because he places the batteries with his own label on the market in that country for the first time.

Again let's have a look at some non-EU countries that have regulations in place. In the United States, they have many states which have battery recycling regulations in place. 1996, the US Congress passed the Mercury-containing and Rechargeable Battery Act.

Canada also has some provinces with battery regulations in place. In British Columbia, as of July 2010, primary batteries and rechargeable batteries are characterized as household hazardous waste. In Manitoba, as of April 2011, companies selling household primary and rechargeable batteries must operate or subscribe to an approved stewardship program.

As of 2010, Ontario has a primary battery product stewardship program and as of July 2012, Quebec implemented a mandatory collection of recycling program for all batteries sold as products.

And as of July 2013, the same regulations apply for products that contain easily removable batteries.

In Australia, they have something called the Australian Battery Recycling Initiative. This is currently a voluntary initiative but the Minister for Environmental has approved two priority products this year under the product stewardship act. These are batteries weighing less than 5 kg and waste architectural and decorative paint.

Now the current status of the EEE directives is due to change because in December, the European Commission adopted an ambitious new Circular Economy package to help European businesses and consumers make the transition to a stronger and more circular economy where resources are used in a more sustainable way.

Now the proposed actions will contribute to closing the loop of product life cycles through great recycling and reuse and it will benefit both the environment and the economy.

Therefore, the European Commission adopted a legislative proposal to review recycling and other ways related targets in the EU waste framework directive, the landfill directive and the packaging and packaging waste directive as well as the WEEE and batteries directives.

The main elements of the proposal include a ban on landfilling of separately collected waste and promotion to discourage landfilling.

Measures to reduce food waste and promoting best practice across member states.

They also want to improve traceability of hazardous waste and there will also be economic incentives for producers to put greener products onto the market and support recovery and recycling schemes.

So EPR and waste legislation is constantly being assessed but not just in the EU. More countries than ever are introducing this legislation and putting on producers to be responsible for products that they sell when they become waste.

The Circular Economy Initiative highlights that progress is still to be made even in the EU. Bearing in mind that legislation here has been ongoing for over 20 years. It does also show that it will become increasingly harder to be non-compliant with these regulations.

So just to summarize everything I've spoken about today, although the directive started in the EU, it's not just the EU that has EPR legislation in place.

We didn't have time to cover other countries in great detail today but this will be addressed in other webinars throughout the year.

Hopefully now you will have a better understanding of the waste directives that are in place and how they affect you but of course it's important to note that compliance, registration and cost can vary considerably from country to country.

Lorax Compliance will be holding more detailed individual webinars on packaging waste, WEEE and waste batteries throughout the year and these will include more details on compliance processes and data submission examples.

Please follow us on Twitter for the webinar dates and the latest updates on EPR directives. You can also tweet us your questions if you want to. If anybody has any questions that they'd like to ask confidentially, then please feel free to email me.

Joe Hage: You won't have to wait that long Emma because we have a couple of questions for you here.

Emma Mundy: Yeah that's it for me. So I just want to say thank you to everyone and yeah, ready for questions now.

Joe Hage: The first question is mine. Almost everything you said on this presentation was news to me. I'm curious and folks, you have a chat box there if you would just type in was this brand new news for you or was this degrees of detail that you didn't know?

I'm curious just for an overall view from the group.

In the meanwhile, the first question comes from Beth and she says, “If I only ship a small amount of product, do I still have to report? Is there a minimum?”

Emma Mundy: Wow. It depends which regulation you’re talking about because again, with the packaging, WEEE and batteries directives, they vary. With the packaging directives, there are more thresholds that these vary by country.

So for example in the UK, you’re only obligated if you place 50 tons or more onto the market and have a turnover of 2 million plus whereas in some countries, from the first piece of packaging you place onto the market, you’re obligated.

And again, with WEEE, it tends to be no thresholds and batteries, no thresholds but with the WEEE recast, there was the introduction of a de minimis threshold which countries were allowed to introduce. The only place I’ve seen it so far though I think is the UK. The rest seems to be again from the first product that you place onto the market, you become obligated.

Joe Hage: Interestingly, while you were answering, we have an even 50-50 split among folks who this was brand new for and degrees of information they already knew.

My friend Maren writes that she was aware of the material directives and the battery directives but packaging was new and that’s the kind of theme that went for the folks who knew a little bit.

Emma Mundy: Okay.

Joe Hage: But not everything.

Emma Mundy: That’s quite interesting because actually the packaging regulation is the oldest out of all of them but we do tend to find that in some ways that doesn’t get picked up because there’s a lot of other countries that now have introduced legislation, EPR legislation. They tend to start with WEEE and batteries regulations and packaging is always sort of … is often in last whereas in the EU, it was the first piece of legislations come in back in 1994.

Joe Hage: The other webinars that you’ll host later in the year will be good for folks who have a specific geography in mind.

Emma Mundy: Yes.

Joe Hage: Michael asks, “Are there any case studies of enforcement for medical device producer in violation of these waste directives? It’s not uncommon to see in the consumer electronics markets but how about the medical device industry?”

Emma Mundy: That's a good question actually. I haven't personally seen one for medical devices specifically but that's not to say that enforcement doesn't exist for particular producers because enforcement is stated in all the regulations.

So there's no sort of bias on the type of producer that could be fined with these regulations. It's just essentially if you're not complying and you get caught, then you will be fined.

But I don't have a specific example of a medical device company. I can try and find one.

Joe Hage: That's okay.

Well Sue asks, "Can you give us a sense of the magnitude of the fines for example if we were to ignore this responsibility and not pay the fine for a period of time and go for five years without being caught? Would it be offset by how painful the fine would be?"

Emma Mundy: Again, that's going to vary by country. The longer you go, obviously if you get caught then you're going to have to pay back the payments. If you haven't been caught and you decide that actually you want to start complying, the compliance scheme usually has a retrospective data submission that you have to submit.

So if you have not been complying for the last five years, they'll make you submit data for the past five years and pay for it.

If you do decide that you want to start complying. But again, fines vary per country.

So for example in the UK, I think the biggest fine was for packaging compliance. Red Bull were fined about quarter of a millions pounds in the UK. In Germany, they do it on … it's usually about 50,000 euros per infraction in Germany. But this is just my knowledge from working with companies in the past and working with compliance schemes in other countries because not every country will publish their fines and a lot of countries in the EU will not make public like the UK does when a producer has been fined.

So in a lot of EU countries, it's not in the press. It's not in the media. But these fines do take place.

Joe Hage: They're real and substantial? Eric has a straightforward and what appears to be easy question.

Should I have the Green Dot on all my packaging?

Emma Mundy: It relates to the consumer packaging, so you don't need to put it on a secondary transport packaging and that is an interesting question because it depends on the country you are selling into as to whether you need to print it or not. But a lot of people tend to do the

same print run on their packaging so if there is a country that you're selling into where the Green Dot is mandatory, often you'll print it on a lot of your packaging that goes to other countries and then you'll need to look at whether you need to pay a license fee.

But in the EU, the Green Dot often denotes compliance with the packaging waste regulations apart from the UK it doesn't.

So if you are printing out on your packaging and you're not complying, then you need to be.

Joe Hage: Tom has a few more detailed questions. So we'll give this a try. His system falls into Annex 1 Category 8 of the EEE part of the directive. Within the category, there's a minimum WEEE recovery of 75% and a minimum 55% for reuse or recycle.

Here's his question. Of the 55% for the reuse and recyclable, is the denominator of the calculation the weight of the whole system or only the total weight of the parts that are considered recyclable and reusable?

Emma Mundy: This is probably something I may need to check as it's quite a detailed question. However, the WEEE regulations do apply to finished products.

So I would say it would be the weight of the WEEE as a whole because when you're reporting the equipment to the compliance scheme, you would report the equipment as a whole in your data form and not at component level but I will go away and double check that.

Joe Hage: I have Tom's email. So we'll be sure to get that to you.

How about this one? Again from Tom, his device also has components that are included in Annex 7 and he wants to know if the 55% … pardon me. I'll ask as it's written. Are the components excluded from the 55% needed to be reused?

He's concerned that he'll not be able to meet the 55% for reuse and recyclable requirements if that is the case.

Emma Mundy: Well this is done on sort of EU level or recycling targets or a country level. So as long as he is reporting what he places on the market and he is complying through a compliance scheme for that, then essentially it's down to the compliance scheme and the environment agents. Your government in that particular country to make sure that they are meeting the recycling target for each category respectively.

So I think really all you need to be concerned with is that you are reporting everything that you placed onto the market correctly.

Joe Hage: That's a question for me then. What is the most efficient way to make sure that you're doing it properly?

Emma Mundy: Again, this can vary depending on the type of products you're selling. Usually for consumer products, the easiest and most straightforward thing to do is to join a compliance scheme but this is something you would have to do in every country that you sell into.

That tends to be the most straightforward way because they would deal with everything on your behalf and you essentially would just send your data into them and pay a compliance fee.

But for business to business products, again, depending on the country that you sell into the compliance process it could be easier to join a compliance scheme or it could actually be easier and cheaper to contract a waste carrier to pick up the products at the end of life for you and then you just send in your data submission to the local environment agency or government … the correct ministry that you need to submit your data to.

So again, that's a variable question as to where you're selling to as to what the easiest option would be.

Joe Hage: So I have a question and so does Christophe and they're related. When you said that you have to go each individual country, that just sounds like an awful lot. Is there a way to engage someone to take care of all geographies and Christophe specifically asks if Lorax supports organizations with EPR consultancy.

Emma Mundy: Yeah. That's exactly what we do and that's actually something I've been doing since 2010 now. I used to work for a compliance scheme in the UK and we used to have a lot of queries from UK producers who sold elsewhere in the world as to how they could handle their submissions elsewhere and that's exactly what Lorax Compliance can help with anything EPR related.

If you need any help in any country with any of your submissions, that's something that we can guide and advise you on or we can take over for you and essentially do everything on your behalf.

Joe Hage: So you're a one-stop shop? That sounds easier.

Emma Mundy: Yeah.

Joe Hage: Questions now from Dana and Elaine. Dana asks, if you sell single used devices to hospitals with directions to dispose according to local regulations, is the manufacturer covered?

Emma Mundy: Not necessarily because if you're the first person to place that product onto the market, then you would have the responsibility to ensure that again, your data submission has

been turned to the correct authority and sometimes you can pass on the recycling obligation through your terms and conditions but not all countries will allow this but it doesn't mean you can pass on the data reporting obligation.

So either way, you're going to have some sort of obligation if you are deemed as the producer because essentially, the hospital is going to be classed as the end-user so the regulations don't obligate the end-user. They obligate the producer.

Joe Hage: Okay. And then Elaine asks, what are the requirements for shipping returned WEEE between countries within the EU?

Emma Mundy: Well essentially, you need to make sure it's packaged correctly. It has the right documentation. It's all stacked correctly because you don't want it to be mistaken for WEEE.

So as long as you have the correct documentation and it's packaged as it should be, then you shouldn't have any issues.

Joe Hage: Okay. And then the last question I have now unless someone else has something to offer is what are the implications of not meeting recovery targets? You mentioned fees.

Is it scaling? So for example if you do your best and you run in, come in a little short?

Emma Mundy: Again, the EU … I'm sorry. The recovery targets are set on EU level, so it would be the requirement of the compliance schemes in each particular country to make sure that they're doing their job properly and that the recovery and recycling targets have been met.

So essentially if a country doesn't meet their recovery and recycling targets, then they will be fined on EU level and they can be fined on a daily basis until they meet those particular targets.

As a producer, the effect this is going to have on you is probably going to be a cost effect because essentially if not enough is being recovered and recycled, then more in that country needs to be recovered and recycled so more money needs to go into the recycling loop and that may have an effect on your compliance fees they make up.

Joe Hage: While you were speaking just a few comments came in. One is good job. Another one is very helpful. A third says, I didn't know this. This will help me do my job better.

So the crowd have spoken and I have spoken. Emma this was very helpful. I'm going to wrap it up. Get the video online and have the slides out to everyone later today.

So thank you very much on behalf of the Medical Devices Group and all the folks who tuned in today.

Thank you.

Emma Mundy: Perfect. Thank you.