Transcript FOOTNOTES EPISODE, Season 1, 2023, MA-MM-05934

Guest: Dr. Alan McDougall, Senior Vice President of Medical Affairs in Europe and Canada

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Hello and welcome to The Science of the Matter. This is a podcast that digs into data where you will meet the scientists that did the research and where we meet guests that in different ways are involved in making the lives better for patients. My name is Helena Jones, and I will be your primary host for a series of episodes of The Science of the Matter.

I work at the Department of Medical Affairs, and I will repeatedly say that "this podcast is brought to you by Medical Affairs". One can wonder what that actually means? What does the Department of Medical Affairs at a pharma company actually do? So I thought it would be a good idea to introduce us in this footnotes episode. I have invited the Medical Affairs Senior Vice President, Dr. Alan McDougall, that heads up this department for Europe and Canada, so that we can find out.

In this episode, Dr. McDougall shares with us what he wishes every physician knew about the pharma industry. What we do here and what he thinks the future holds for us. I'm so glad to have you here. Please enjoy this episode!

- So, Hi Alan, and welcome to the podcast!
- Hi Helena. It's good to be here.
- What does it mean to be the head of medical affairs in Europe and Canada?
- It's quite an honour to be heading up 300 professionals working in medical affairs, working in very diverse countries, and very diverse situations, but all with one common aim, which is the patient and how can we make patients' lives better. I have to say, I wake up every morning and I look forward to going to work and I get inspired by the people that I work with because they come from lots of different backgrounds. We have medical professionals who are qualified doctors, we have pharmacists, we have Ph.Ds. and the diversity that they bring to their work is simply quite astounding. And the breadth of knowledge that exists within the Medical Affairs organization is really remarkable.
- What is it that we do at the Department of Medical Affairs?
- So Medical Affairs has three main functions. The first important function is understanding the external environment. So how people might use our future medicines or are using our current medicines. Are there any problems or issues? Are there any data gaps? You know, are the questions, scientific questions, that remain unanswered? The second function is around data generation. So one of the most important things we do is to generate data on our medicines, and those data would be to meet genuine data gaps. When we have scientific questions we don't know the answer to. That's when we put studies in place to try and answer those questions. And the third thing we do is data communication. That's not just about study results, but it's also education. And that education is both internal to people working in commercial functions and to other medical professionals within the company, but also external. So being

able to educate clinicians and other health care professionals around the data on our products, because we should always know the data on our products better than anybody else.

- Is medical affairs just a department or is a bigger than a department? How would you describe it?
- Yeah, that's a great question. It's often described as the bridge between the development organization, the people who do the earlier stage research to get the medicine licensed, and the commercial functions. But I think we're more than that. And I think in the last 10-15 years, people have realized that Medical Affairs has a very strategic role to play in the company. And we are customer facing as commercial, but we have a different role. Our role is not to sell anything, but it's, as I said earlier, it's to understand what's going on and also to educate where necessary and then to feed back into the company. What we're hearing, you know, if people are saying things that aren't quite consistent with our understanding of our medicine. Then we've got to look into that, and we've got to decide, do we have a genuine data gap here? Is there something we need to look into more? Because at the end of the day, a clinical trial or a clinical trial program, will have several thousand patients in it. But when a medicine is available for use for prescribing, tens and hundreds of thousands of patients will used it. And that's sometimes only when you realize if there's an unusual side effect or an unusual benefit. That's when you see it coming through. And you have to listen to the health care professionals that are using our medicines because they will teach us what is really going on in the real world.
- Tell us a little bit about your story. How do you end up as the leader of medical affairs in Europe and Canada?
- I'm a physician. I spent 14 years in the UK at National Health Service, and during that time I developed an interest in diabetes and I used to work in a local diabetes clinic at a local teaching hospital in Glasgow. And through that experience I had more and more contact with pharmaceutical companies, including a great Danish company, Novo Nordisk. I never met anyone from their medical function, but I liked the commercial people that I met. They seemed very smart, very bright, very switched on and a job offer came up and I thought, why not? Let's go for it. So I did it. I moved through a few other companies like AstraZeneca and Pfizer, and then I joined Astellas. I feel very lucky, very fortunate to be given these opportunities. How I actually got here, I'm not sure so much. I think it's a combination of maybe just being in the right place at the right time, and that goes for a lot of senior jobs. So, yeah, but I feel very, very lucky and very honoured to be leading this great team.
- What do you wish physicians knew about the pharma industry? You said that you worked yourself as a physician and then you joined the pharma industry. What was that like and what do you wish people knew?
- Well, I had to retrain. The first thing I had to do was retrain. There's a two-year training course in the UK, the Diploma Pharmaceutical medicine. And I did that course. And that's when you realize that in medical school, you're taught nothing much about drug development. You're taught nothing about regulations, nothing about drug safety, nothing much about statistics. And these are massive gaps that have to be filled if you want to have a career in pharmaceutical medicine. I think the biggest thing that I would like physicians, practicing physicians to know is the high degree of regulation that we work under because people are still suspicious about pharmaceutical and the pharmaceutical industry. They still think that we do things that are underhand and dishonest, and they (pharmaceutical companies) are so frequently inspected by the regulators. And these inspections are absolutely deep and clinical. If there's anything that's going wrong, it will be found. We also do lots of audits ourselves, so we don't wait to be inspected. We have whole quality assurance mechanisms so that we pick up anything that's going wrong before it's discovered by an external inspector. But occasionally it does happen. So I

think if there's one thing I'd like people to know, it's that they can trust when we publish data, when we put something on a website, when there's something in, you know, a sales representative, promotional brochures, it's all been vetted and checked and there will not be mistakes in there. There won't be ridiculous claims that cannot be substantiated with data. And I do think a lot of doctors don't appreciate the amount of rigor that goes into the work that we do.

- It is a lot of work that goes into every single thing that we produce. Yeah, you're right. Are there any particular unmet needs, medical needs that are close to your heart that you wish we would really dig into?
- Yeah, I think there are two massive unmet needs. One is dementia. My father passed away several years ago from Alzheimer's disease, and it's very frustrating as a physician to know that there's nothing that I could do to help. And watching this stress that my mother went through, through that period, which was pretty bad. The other is obesity. And we're making steps in the treatment of obesity. I think we've made some good progress, but it's still on a global scale, it's still a huge problem. And the irony of obesity is that many countries in the world are facing severe food shortages. And other countries have got excess of food.
- If you could choose, I guess, to come on to the Science of the Matter, who would you choose and what would you want to learn about?
- I think the future is in gene therapy, and I would invite somebody who is an expert in gene therapy to tell us exactly how you go about producing a gene therapy. To tell us how you insert genes into the human being, how you monitor their effects, how you think about long term safety off target effects. I think that would be absolutely fascinating. So, I don't have a particular person in mind. It's like science fiction, but it's here today. It's real. We can do this. And there are more and more gene therapies that are in development and across the pharmaceutical industry. And I think that would be a really fascinating episode.
- I think you have given our listeners a quite nice and broad insight into what we do at Medical Affairs. I think it's important to remind our listeners what it is that we do. Thank you so much for coming on The Science of the Matter, Alan. It was great having you here.
- Thank you for the invitation, Helena