Melissa Barnes & Thomas Cueni on the IFPMAâ??s New Code of Practice

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Eli Lilly and Companyâ??s Melissa Barnes, who chairs the Ethics and Business Integrity Committee (eBIC) at the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), and Thomas Cueni, the organisationâ??s director general, outline the key features of the IFPMAâ??s ambitious new Code of Practice and discuss the state of ethics and business integrity within the global pharmaceutical industry today.

Melissa, could you begin by introducing yourself and your roles at Eli Lilly and Company and at the IFPMA?

Melissa Barnes (MB): I am a lawyer by training and have held several legal roles within Lilly during my 25 years at the company. Lilly has been very good at moving me around and not letting me get bored in any one role!

My current position is senior vice president for enterprise and risk management and chief ethics and compliance officer. This position does not involve practising law but is a â??people roleâ?? â?? trying to understand and motivate people to make decisions with integrity every day.

This role, along with my other position as chair of the Ethics and Business Integrity Committee (eBIC) at IFPMA, are what I refer to as â??change jobsâ?? â?? getting an organisation like Eli Lilly and Company, and an industry through the IFPMA, to move with the rapid pace of change in societal and regulatory expectations.

In your view, why have ethics and compliance within the pharmaceutical industry taken such a key role?

MB: We, as the pharmaceutical industry, make medicines that are prescribed by physicians for patients at the most vulnerable points of their lives. This requires an extreme level of trust; trust in what we say about our medicines, how we make them, and how they are distributed. Trust â?? among all stakeholders in the healthcare system â?? is incredibly important. In order for us to establish that, we need to make every decision with integrity and with the patient at the centre. If we do that, then we will gain the trust that allows us to fulfil the noble mission of delivering medicines to sick patients who are waiting for them.

> I am a firm believer that if you aim for compliance, you may get it, but you will not necessarily also get ethics and integrity. However, if you shoot for integrity, you will very naturally get compliance â?? Melissa Barnes

The new IFPMA Code of Practice is effective from January 2019. Some of your peers have described it as a very bold document. Could you outline the â??spiritâ?• of this new Code?

MB: To give you some context, two years ago, the group within the IFPMA that worked on this Code was called the Code Compliance Network. Upon taking the role, I felt the strong need for a name change as I could not envision myself leading a group focused on compliance. I am a firm believer that if you aim for compliance, you may get it, but you will not necessarily also get ethics and integrity. However, if you shoot for integrity, you will very naturally get compliance. Therefore, changing the focus of the group from compliance to integrity and the name to the Ethics and Business Integrity Committee (eBIC) creates a much more engaging and motivating message â?? we must remember that we are dealing with human beings that we need to engage, motivate and influence. Rules are important â?? indeed, we are rightly one of the most heavily regulated industries in the world â?? however, if we *only* follow the rules, we cannot be said to be fully meeting societal expectations.

This shift in mindset set the stage for the new Code and for our Ethos which is intended to provide a context for how the Code is interpreted.

With a changing business environment, regulations, laws and expectations, there are only a few things that are black and white. There is no way that we would be able to codify every potential scenario or question. If we did, we would end up with a huge tome. The idea is to provide a shared understanding and a shared set of values that can be used to interpret the Code and to which we can hold ourselves accountable. When we are making a decision, we are doing it within the context of our Ethos.

That is what sets this Code apart from the work we have done in the past.

> The biggest change in the Code itself is a global ban on gifts and promotional aids for prescription medicines â?? Melissa Barnes

What are some of the most important changes to the IFPMA Code of Practice?

MB: The biggest change in the Code itself is a global ban on gifts and promotional aids for prescription medicines. That is a recognition of societyâ??s changed expectations as well as the evolution of the industry and its relationship with healthcare professionals. The US and Europe have been leading the way on this issue for a number of years, but this Code aims to bring the rest of the world into alignment.

In the past, there were still some exceptions or waivers to this provision related to customary gifts such as mooncakes (traditional pastries given as gifts during the Mid-Autumn Festival in China) and condolence gifts in parts of Asia. The industry is now at the point where we do not want anything to even potentially suggest that we are trying to get between the healthcare professional and the

patient at the time of the prescription decision.

The other part of the ban is on promotional aids â?? items such as pens, notebooks and post-it notes that are company or product branded. Those kinds of materials do not further or facilitate the education and the important exchange of expertise that should happen between medical representatives from our industry and healthcare professionals. While these promotional aids are of minimal value, from a reputation and perception standpoint, stopping the exchange of these items was important as it was being seen to trivialise the intended interaction between the medical rep and healthcare professional.

We can, however, draw a distinction between promotional aids such as post-it-notes or pens and â??items of medical utilityâ??, which, in certain parts of the world, are important to continue to provide. This includes items such as small medical devices, textbooks, journal subscriptions and USB sticks with medical information on them.

What is the Code of Practiceâ??s approach to education? The pharmaceutical industry has traditionally had input by providing travel to symposiums and conferences â?? especially in countries where practitioners cannot afford participation by their own expenses?

Thomas Cueni (TC): The nature of conferences has changed dramatically over the last 20 years. Historically, conferences were equal parts scientific and social events. That has now changed throughout the world.

For the past few years, IFPMA has been in the driving seat in terms of building consensus among all stakeholders and ensuring ethical conduct in the running of conferences. Banning the giving of gifts is the first step, but this has expanded to include a wide range of other incentives or promotions. Those organising conferences are now aware of the reputational damage that they may incur if they overstep the boundaries.

Outside of the US and Europe, we are very involved with the APEC work stream on Business Ethics and have seen significant progress in a number of countries, with new national consensus frameworks presented and adopted. As a representative of the pharma industry, when you overstep the mark you are held to a higher standard because we sell life-saving medicines. Moving forward, the shift from a traffic-light or policing approach to a principle-led approach is important and will allow us to carry our partners with us.

> We are dealing with fallible human beings who can make mistakes â?? therefore it is important to have a comprehensive programme that involves a code of regulations but also involves communication and training â?? Melissa Barnes

What do you see as fundamentals in order to change mindsets within the industry around ethical issues?

TC: Within the industry, you need strong top-down leadership from people such as Melissa, who reports directly to the new IFPMA president, David Ricks, President, Chairman and Chief Executive Officer of Eli Lilly and Company. Another important element is that within companies, ethical

missteps are seen as serious, not just in terms of moral or ethical behaviour but also in terms of company valuation. Ethical compliance risks are now being taken into account in the market capitalisation of companies. Therefore, companies are deeply conscious of the fact that ethical issues *do* have a financial and commercial impact, either in terms of fines or of market capitalisation. This awareness simply was not there 10 or 15 years ago.

How do you envision the ideal ethical compliance reporting process within individual companies in order to ensure people feel not only accountable but also free to speak out â?? especially from within country affiliates?

MB: Drawing on my own experience, at Lilly I report directly to our CEO, I sit on our executive committee and I also have a dotted line to our board of directors, with whom I meet every time they convene. That presence is important.

I also think it is very important that companies have a programme for these issues. We are dealing with fallible human beings who can make mistakes â?? therefore it is important to have a comprehensive programme that involves a code of regulations but also involves communication and training. It is vital that these programmes are taken seriously, that people are held to account and that there are consequences if the rules are broken, at all levels.

At Lilly, our programme is built on two pillars. The first is independence â?? people working at our country affiliates have a line directly to me, rather than to their GMs. The second pillar is what we refer to as â??meaningful presenceâ?? â?? the ethics personnel are present at the leadership table within these affiliates and able to influence the discussion and decision-making process. This is not to suggest that the other people at the table are not ethical, but more to train, communicate and implement an ethical programme at the local level. Ultimately a companyâ??s global ethics programme is only as strong as that of its weakest affiliate.

How do you respond to some industry stakeholdersâ?? complaints that this Code of Practice is too strict and can leave certain companies at a disadvantage, especially in countries where some companies are not IFPMA members?

TC: There is a deep sense that, actually, some standards have to be set and we are very optimistic that these standards will become the rule. When one looks at patient expectations and rule-setting from government, companies that misstep will, sooner or later, be called to order. The research-based pharmaceutical industry is expected to lead.

Companies are increasingly choosing longer-term restructuring of their ethical practices over short-term increases in top-line sales due to a heightened recognition of the potential costs, both reputationally and financially, if caught. It is important that the message is clear and uncompromising: this is the way to go.

Download IFPMAâ??s new Code of Practice.

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