

REMARKS

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PROGRESS AND EMERGING TRENDS IN ETHICAL BUSINESS PRACTICES

OBJECTIVE: SHOWCASE PROGRESS WITHIN AND BEYOND THE APEC REGION TO STRENGTHEN ETHICAL BUSINESS PRACTICES IN THE BIOPHARMACEUTICAL SECTOR, WITH FOCUS ON THE ASIA-PACIFIC AND THE AMERICAS. PROVIDE PERSPECTIVE ON KEY CHALLENGE AREAS AND EMERGING TRENDS IN ETHICAL BUSINESS PRACTICES FOR THE BIOPHARMACEUTICAL SECTOR.

2016 APEC BUSINESS ETHICS FOR SMES FORUM

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Good morning, ladies and gentlemen.

I want to begin by thanking APEC and its partners for supporting the Biopharmaceutical Ethics Initiative. If it wasn't for the partnerships established over the past 5 years the progress to date would not have been able to take place.

And congratulations and thank you to Peru for the strong delegation and tremendous advance work in preparing this initiative.

Felicidades y gracias, Peru, por tan excelente delegacion y el increible



trabajo de preparacion en anticipacion a esta iniciativa.

We have a huge responsibility in APEC, representing 2.6 billion people , 60% of world GDP and 47% of world trade. Ethics and integrity are essential ingredients if we are to continue to facilitate sustainable trade and economic growth. You are part of this movement and I sincerely hope that over the next few days, we will take the necessary next concrete steps together to reach our 2020 goal of full implementation of ethics Codes throughout the APEC economies.



APEC and meetings like this provide an invaluable opportunity to build relationships with international colleagues, learn from each other and have important discussions about issues that affect all healthcare stakeholders...and ultimately, billions of patients.

Meetings like this also allow us to take stock and celebrate the achievements that we have made individually and as a group and prepare for the challenges and opportunities that will face us in the future.



SLIDE (Complex environment)

Whether its relationships with generics, innovators governments, doctors, nurses pharmacists or patient groups...

The environment is complex and fraught with challenge...but I have always believed that with challenge comes opportunity.

Five years ago, an APEC Expert Working Group developed 'the Mexico City Principles', a set of principles to guide ethical standards for all industry stakeholders. Workshops, like this gathering in Lima and others, continue to advance collaboration and are driving the implementation of these principles



across the APEC region. There's no question, we are making important strides forward and this is evident in the just released Report on Code of Ethics Implementation by APEC Biopharmaceutical Industry Associations that you all have received

When this Initiative's capacity-building program was launched in 2012 to support implementation of the APEC Mexico City Principles, 25 of the monitored associations had a code of ethics. In 2016, 50 of these associations have a code of ethics or formalized commitment. Progress has been made since 2012, and some challenges remain, for the biopharmaceutical industry



associations in (A) code governance, (B) code alignment with the APEC Principles, and (C) member implementation of the code. We have made progress in that we now have 25 new codes or code commitments in 7 economies that did not exist in 2012. We are seeing an increase in leadership commitment to the Codes and a majority of the economies embrace all six fundamental principles

There some provisions of the APEC Mexico City Principles that have lower adherence and those include public sector relationships and procurement, clinical trials, and patient organizations.



We have also noticed is that there is opportunity for associations to expand regular code trainings, which may be currently limited due to finite resources and that the implementation of codes is always a challenge..

Even with commitment at the highest levels of leadership, pharmaceutical companies occasionally are at the centre of scandals involving unethical business practices – compromising the long-term reputation and integrity of our industry and everyone working within it.

In truth, many policy makers see our industry as a health and economic asset



but a political liability....a liability directly related to industry's reputation.

Regardless of where a scandal breaks, it impacts the entire industry's reputation in every market around the world...and as a result, the quality of our collaborations suffer with all stakeholders.

I have a suggestion and a comment for how we might build on our commitment to voluntary codes of conduct and take ethical practice to the next level.

First and foremost, by accepting that ethics is all of our responsibility, not just



one part of the system and to protect and advance ethics we need strong mutual understanding and collaboration. This is time consuming and pushes us out of our stereotypes and traditional thinking. It requires communication, commitment, and trust. It needs to be public and measurable.

Research shows that there is a strong business and societal case to be made for prioritizing ethical business practices above short-term financial gain. Organizations with strong positive reputations attract better talent and are perceived to provide more value. The economies were they function become stronger. They have higher market



values because investors believe that they will deliver sustained earnings and future growth. In the end if people are going to buy into building a positive reputation it must make good business sense.

Good ethics is also good government and health policy. The partnership which can be forged are substantially more beneficial to the population and all those concerned.

Building a strong positive reputation requires persistence. It begins with the recognition that reputation is a matter of perception...what others think matters.



It is a perpetual work in progress. It demands constant attention from all parts and levels of an organization and a culture that values ethical decision-making first and foremost because it's the right thing to do!

As I've said, voluntary codes are an important part of establishing and maintaining this culture. The leadership of the global industry is dedicated to compliant and ethical promotion of medicines. And I see that growing in so many local economies. An ethics based self-regulatory approach has been established around the world to help



ensure that our relationships with healthcare professionals and other stakeholders are appropriate and ethical. These mechanisms are vital to improve trust and although there have been important achievements in recent years; we all know that there is room for progress in assuring full implementation.

EMERGING TRENDS

THE NEED TO COLLABORATE (Notion that everyone must be at the table)

The need to work together, to be seen working together, is very much a trend I see developing , possibly APEC through



our initiatives has helped to create this momentum. But it is clear to be , blaming on part of the system or criticizing from the margins is not effective or supported by many. The work we have be doing on multi stakeholder collaborations is a good example of steps in the right direction. Stakeholders can and should align on common ethical standards and build common platforms with which to collaborate and build trust around issues of ethical business practices, despite the different views they may have on other important issues.

Ethical collaborations among the medical device and biopharmaceutical industry, healthcare professionals,



patients' organizations and other stakeholders are essential to the delivery of high quality patient care, patient access to life-saving and health-enhancing medical technologies and therapies, and the development of new medicines that meet patient needs. No one group can achieve an ethical environment in these sectors alone. Ethical collaboration among stakeholders also strengthens the ability of small and medium enterprises (SMEs) to sustainably operate and engage in cross-border trade.



The work towards the development of multi-stakeholder relationships is imperative. The journey to build them is as valuable as the end result. I believe that through the universal elaboration of Consensus Frameworks across the APEC region by 2020, as endorsed by APEC Ministers under the Nanjing Declaration, we will begin to witness previously unimagined activities to strengthen ethical business practices in our economies. We may begin to see joint codes of ethics We may see joint ethics trainings between industry groups and health care professional organizations. We will begin to see those who act unethically cut out of the marketplace,



unable to engage in collaborations with others.

TRANCPARENCY

Looking ahead, we should anticipate and respond to a continued push for transparency. Transparency is important in many different areas of our industry – and again, this is an area where expectations are continually evolving. Today’s conversations about transparency generally focus on two areas of pharmaceutical business practices – first being clinical trials and



second being the area of marketing practices, in particular the notion of compensating doctors, nurses and pharmacists

The industry is also developing global processes to enhance data sharing with qualified researchers, share results with the patients who participate in clinical trials I believe these are important steps in the right direction to improve industry's transparency around Clinical Trials.



Transparency and disclosure of payments

While some like to cast a dark shadow over all interactions between the biopharmaceutical industry and health care professionals, the fact is that relationships between the people responsible to make and sell medicines and the people responsible to use them is in the best interest of patient care.

In fact, it would not make sense that those who make and sell medicines do not interrelate with those who prescribe,



dispense, and use the medicine. But the relationship must be professional and well defined.

There is significant benefit for the health care system and patients in particular to have these interactions between industry and health care professionals. We believe there is value in the communication and the transfer of core information.

Interaction with industry, conducted within a transparent and ethical framework, can ensure that healthcare



professionals have up to date and comprehensive information about medical developments. It also ensures that companies benefit from the expert knowledge of those on the front-lines of delivering care. Communication flows both ways.

In an effort to expand transparency around relationships with health care professionals, associations are considering transparency measures that are currently being implemented elsewhere and are currently evaluating the value that this information will deliver for consumers.



Also, , we must remain vigilant to ensuring that Continuing Health Education and sponsorships are appropriate, transparent and in the best interest of patients.

The healthcare challenges facing patients today and into the future are not going to be solved by anyone 'going it alone'. We must work together with health care professionals, patient groups, governments, employers - industry aims to be an active and trusted partner in developing solutions.



It's a challenge for some stakeholders to see our industry in this light...but as they say 'the proof is in the pudding'.

Industry's job is to continually demonstrate its character – and I believe that begins with an unwavering commitment to ethics and compliance.

In this context, we know that self-regulation is a privilege, not a right, and that honouring this responsibility is essential to maintaining the public's confidence.



Thank you and I look forward to advancing progress with you over the coming days.

Now, before I step down I would like for everyone to do a little homework.

We have an exercise this afternoon that we would like you to participate in.

We will be asking you to think about Self Regulation and will be asking each economy to identify on the matrix, that you all have in front of you, where it believes the Industry is relation to self regulation and the second question would be where the economy would like to be. ?



Please hand in your grid to Andrew once you have completed it and we will be discussing the results later on in the day.

Thank you