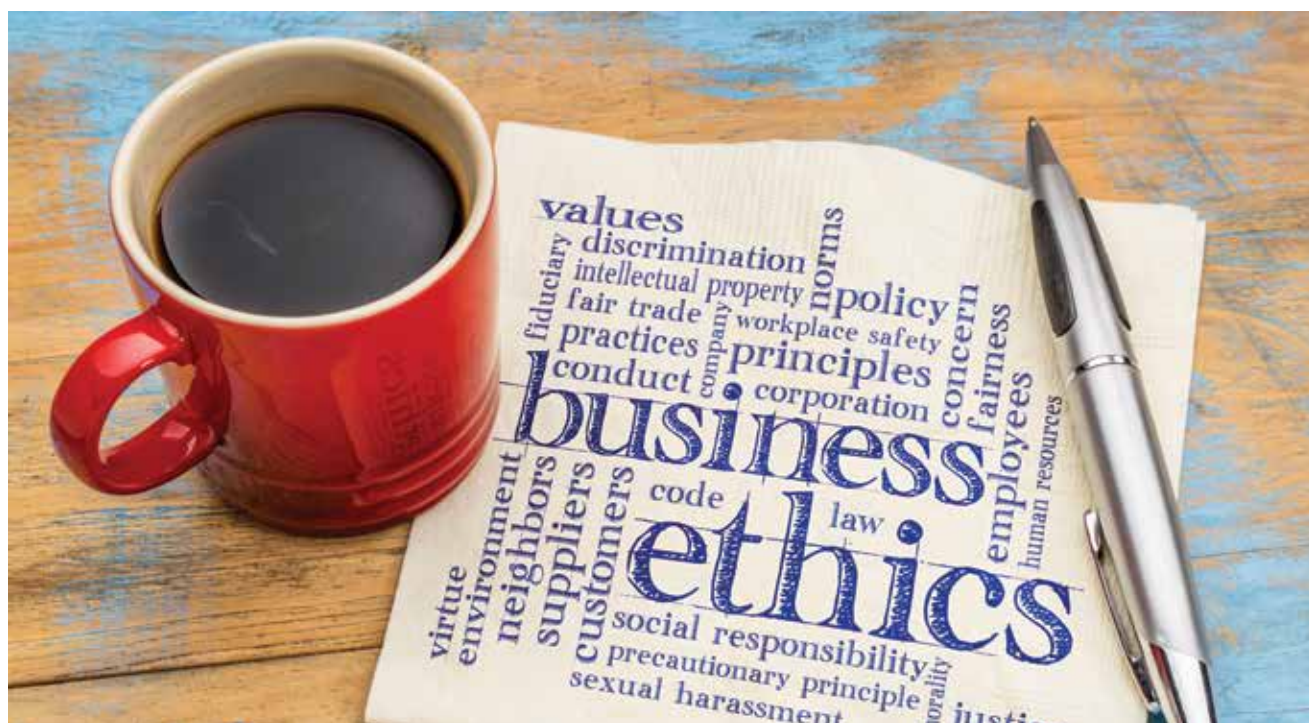


A Decade of Reinforcing Business Integrity

Making Asia-Pacific better prepared for COVID-19



Over the last decade the Asia-Pacific has seen an unprecedented shift in the adoption and implementation of high-standard ethical business conduct across its healthcare enterprises, including in the biopharmaceutical sector. This positive uptake of integrity had positioned the region to better prepare for, and now to hope to recover from, the current pandemic.

Thomas Cueni, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Director General and Co-Chair of the APEC Biopharmaceutical Working Group on Ethics

The Asia-Pacific (APAC) region is no stranger to confronting and defeating disease outbreaks. From SARS and Avian influenza to MERS and H1N1, the region's economies have demonstrated remarkable resilience and with each new occurrence found themselves better prepared to confront the challenge. The global health emergency and ensuing economic crisis brought about from COVID-19 represents a far greater trial and one that will have ramifications to regional growth and development for years to

come. I am proud to say that today, perhaps more than any moment over the past century, the patient-focused mission of the global biopharmaceutical industry is resolute in a common cause: leaning into science to safely treat and vaccinate against COVID-19. Never before in my lifetime have I seen such collective action, including with and between Asia-Pacific nations, and it gives me tremendous hope that we will defeat the virus. It is also once in a lifetime opportunity to showcase how integrity and trust are central to these endeavours. Luckily, we are not starting from scratch – both on the innovation needed to fight this coronavirus and the need for ethics to ensure that we are trusted in our endeavours.

What many may not realise is that over the last decade, APAC has seen an unprecedented shift in the adoption and implementation of high-standard ethical business conduct across its healthcare enterprises, including in the biopharmaceutical sector. This positive uptake of integrity had positioned the region to better prepare for, and now to I hope to recover from, the current pandemic. Substantial investments have been made across the APAC to bolster best practices from the moment a new medicine is imagined through to when it is received by those who need it. As the premier forum for facilitating economic growth, cooperation, trade and investment in the region, the APEC (Asia-Pacific Economic Cooperation) forum has shown great leadership in setting up the world's largest public-private partnership to strengthen ethical business practices.

A decade of work

From 2012-2019, as a result of the Business Ethics for APEC SMEs Initiative, industry associations of both innovative and generic medicine manufacturers and distributors have extended through the increased number of codes of ethics high standard ethical business practices to over 10,000 enterprises of



every size across the Asia-Pacific, including in seven Asian economies where they previously did not exist. The APEC ethical principles for the biopharmaceutical sector detail strong practices, including measures for enterprises to preserve integrity and legitimate intent while upholding independence and accountability.

As my colleague Sabrina Chan, Senior Executive Director of the Hong Kong Association of the Pharmaceutical Industry (HKAPI), who has been actively involved in the APEC Business Ethics for SME Forum over the past decade, it is no mean feat to get everybody onboard. She has told that “it is a tough mentoring work, but one that yields a lot of satisfaction when approached by new organisations on how to review their code of ethics to align with ever-evolving societal expectations in terms of doing what is right”.

Such efforts pay off. In the last two years alone, Australia, China, Japan, the Philippines, and Vietnam have pioneered ground-breaking consensus agreements for ethical collaboration to align ethical standards across nearly 200 peak public and private healthcare bodies representing thousands of companies and healthcare providers as well as millions of patients. There is no doubt that these collective successes strengthen the region's resilience and agility to confront the current crisis.

As an industry, we applaud our member associations and experts who have played an integral part in achieving these results. And let there be no doubt – this goal post moves constantly, especially for an industry like the biopharmaceutical industry that has a huge and vast impact on people's lives.

In Australia, my colleagues at Medicines Australia have made pioneering strides in bringing others along for the benefit of patients. Medicines Australia has been a foundation collaborator in the development of the Australian Consensus Framework for Ethical Collaboration¹. This has been jointly signed by over 50 peak health-related bodies in Australia and has become the most wide-ranging consensus framework in the region. Elizabeth de Somer, the Medicines Australia CEO, who has shown outstanding leadership in this field, says “it's wonderful to see so many organisations co-operate to clearly articulate how the work they do together will always put the best interests of patients first and foremost”.

Standing the test – COVID-19 is creating a heightening risk of unethical behaviour

Nearly all of these agreements have been activated to reinforce integrity during

¹ <https://medicinesaustralia.com.au/media-release/ma-welcomes-the-australian-consensus-framework/>



the pandemic and many companies and associations are working together to prepare for the aftermath in ways that would have been impossible just a few years ago.

According to the APEC forum, economic activity in APAC has been at a near standstill as economies implemented stringent measures to contain the pandemic, including travel bans, quarantines, lockdowns, and social distancing measures to curb the spread of COVID-19. Healthcare systems are under enormous pressure and are grappling with acute shortages of medical supplies and equipment as well as inadequate numbers of hospital beds and isolation units². At the same time, there is an outbreak of disinformation and misinformation about COVID-19, ranging from fake cures, false claims and harmful health advice. Likewise, there are heightened concerns that organised networks and bad-acting opportunists are waiting to exploit this period of uncertainty and trade illegitimate or non-compliant products.

² <https://www.apec.org/Publications/2020/04/APEC-in-the-Epicentre-of-COVID-19>

The pandemic is putting everyone to the test. Actors across healthcare systems are confronted with an unprecedented demand in products or resource reallocation, trying to respond to a set of new challenges while trying to preserve and maintain patient trust. COVID-19 is creating a heightened risk of unethical behaviour, which organisations must resist.

In times of uncertainty, integrity becomes a differentiator. Frontrunners in integrity will distinguish themselves as never before, and those who remain behind are likely to be held accountable after the crisis has passed for breaking trust or failing to act according to societal expectations.

Ethical collaboration in the biopharmaceutical industry on a global stage

The biopharmaceutical industry is unlike any other, as it researches, develops, and distributes products that prolong and save lives. Trust is the sector's life-blood.

There is great hope placed in science and in the biopharmaceutical's industry

efforts to find a solution that allows the world to “return to normal”. As the biopharmaceutical industry is at the heart of developing tests, treatments and vaccines and getting them to billions of people around the world, integrity and trust has taken a global stage. I am proud to say that from the first days of the COVID-19 pandemic, the industry has been united in its response, acting with urgency and integrity. As a critical participant in the global healthcare ecosystem, we are bringing the full force of our scientific and medical expertise to address the coronavirus pandemic around the world. Society needs to know it can count on the biopharmaceutical industry. We have a responsibility to work tirelessly and rapidly to tap into the industry's innovation capabilities to bring solutions. Today, hundreds of treatments and vaccines candidates are being tested in record time, inching the world closer to the much-awaited return. Not all will succeed, but with multiple shots on goal, I am confident that science will prevail.

Industry leaders have been clear that we must demonstrate to the world that

it can count on our innovation, our commitment, our courage, our resilience and above all, our integrity to win this fight. We at IFPMA have found that our recently launched Ethos has been indispensable in helping provide the necessary framework to anchor ethical decision-making, where no specific rules could have previously been anticipated. As we continue what looks to be a long ride, the need for shaping our actions around the concept of Ethos has never been clearer. As Rady Johnson, chair of the IFPMA Ethics and Business Integrity Committee has conveyed at the beginning of the pandemic, “with the core values of trust, care, fairness, respect and honesty, our Ethos provides the framework to ensure that even in times of crisis, we act with integrity. With our Ethos front-and-centre, the integrity of the decisions and actions we make while navigating this crisis is assured”. The Ethos is a principles-

driven approach that will continue to guide IFPMA members’ conduct as they adapt to the evolving COVID-19 operating environment. We hope it can serve as a guide for other industries and for APAC economies to consult during these uncertain times, as it very much has done in the past. The IFPMA Code of Practice has been a building block for the APEC ethical principles for the biopharmaceutical sector.

Collaboration and coordination, embedded by strong ethical values, have been the foundation of the biopharmaceutical industry’s response throughout this crisis. It has become apparent that efforts to keep borders and trade open need to be coordinated, as well as to ensure integrity in the supply chain and distribution of legitimate, high-quality medical products. Biopharmaceutical leaders have been working with governments and relevant authorities to ensure continuity of manufactur-


ing and availability of product supply. Global pharmaceutical supply chains are incredibly complex, with multiple manufacturing, testing and distribution sites – and an issue at any one of them can lead to delays in supplying essential treatments. The list of disruptions can become extremely long, and much less predictable than for the supply chains of other commercial goods. But there are safeguards in place and good practices, with compliance officers and experts doing their due diligence. The global supply chain has stood the test.

Keeping patients and healthcare workers safe


During the COVID-19 pandemic, biopharmaceutical companies proactively interrupted face-to-face interactions between their representatives and physicians, in order to protect patients, healthcare professionals, and their own employees, and have replaced in-office



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visits and face-to-face congresses with online platforms, virtual meetings and other forms of meetings, such as webinars. Maintaining dialogue and scientific exchange with the medical community is critical to inform physicians about new possible treatments, alternative treatment protocols, product supply or safety and efficacy data. This meaningful engagement is even more critical during the pandemic, as physicians contend with the many medical questions of how the virus could affect their patients' existing treatments and at the same time need to remain informed about general scientific information and treatment options.

On 28 May, in close collaboration with 15 member associations across the APAC region, the IFPMA issued new guidance on ethical considerations for resuming in-person interactions with healthcare professionals after COVID-19. Keeping our HCPs safe and considering adequate protocols is important, like Francisco Tranquilino, member of the Pharmaceutical and Healthcare Association of the Philippines (PHAP) and a medical doctor himself attested.

New industry practices are also being assessed as I write this text that would uphold ethical business conduct and our patient-focused mission in an increasingly digitized world.

Not only does the sector owe these efforts to the patients and healthcare professionals who rely on our medicines, but ethical business conduct is crucial to the biopharmaceutical industry's ability to innovate.

Without trust and business integrity, collaboration ceases. Without collaboration, there is no innovation and no end in sight for COVID-19. As we engage to support businesses and the healthcare ecosystem to uphold integrity and ethical standards, we must also be active in communicating what we are doing and letting others help us do things right. As one of the principles of our Ethos, "accountability" is the key to building trust. It is important that

patients and healthcare professionals trust that we are doing things in the right way and that we will live up to that, whatever the political pressures are. Indeed, we need to go as fast as we can but as safe as we must. We are working at record speed to condense the time from lab to bed side, but never at the expense of patient safety. We are doing so by working smarter and more collaboratively across the healthcare ecosystem and with regulators as to do things differently would mean risking to undermine trust in vaccines and treatments for COVID-19.

In sum, this industry is motivated by integrity at the core of its mission and the Asia-Pacific region serves a central role in this global cause. As an example, I would like to mention the APEC SME Leaders in Ethics and Integrity Program (LEIP) to help biopharmaceutical industry associations equip leaders of their SME members with resources and a valued network to reinforce a culture of integrity within their enterprise. Using a "tone-at-the-top" approach, the mission is to integrate ethics principles into daily business practices of every SME that develops, manufactures, markets, or distributes any pharmaceutical and/or biologic product. This year the Initiative is launching pilots of the LEIP in the United States and China.



AUTHOR BIO

Building back better, on strengthened ethics guidance

The pandemic is drawing significant attention to several of the world's largest Collective Action initiatives that are reinforcing ethical business conduct in healthcare, such as the *Business Ethics for APEC SMEs Initiative*.

While these successes over the past decade are worth touting and have better prepared the APAC region amidst the current pandemic, the gains made through the APEC initiative cannot be taken for granted. Far more is needed to build upon the ethical advances that have been realised, especially as APEC economies turn to a sustainable and inclusive recovery from COVID-19. Health systems will face new challenges and ethical dilemmas, expected and unexpected, born through emerging technologies, supply chain evolution, and even higher expectations from society. Constantly evolving and incomplete evidence on new and repurposed therapies poses ethical challenges somewhat unique to this time in history as healthcare providers struggle to keep up with daily developments and manufacturers and biopharmaceutical representatives try and figure out how and when to scale production and increase promotion. Will most economies and businesses return to the pre-crisis status quo or will best practices emerge and be universally adopted? While it may be difficult to predict, we must set the course already and raise the bar even higher. This requires building back better than before, pursuing ambitious, forward-looking goals with strengthened ethics guidance. Long after the crisis has ended, society will see and applaud this integrity. ■

Thomas Cueni is Director General of International Federation of Pharmaceutical Manufacturers (IFPMA), the global association of research-based pharmaceutical companies and associations. IFPMA has official relations with the United Nations contributing industry expertise towards great global health progress. Mr. Cueni serves as Industry Co-Chair of the APEC Biopharmaceutical Working Group on Ethics.