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IFPMA Weekly COVID-19 Update 6 April 2020

IFPMA Operating Status: IFPMA offices remain closed and all IFPMA staff are working from home until further notice. All IFPMA in-person meetings through end of May have been postponed or converted to virtual meetings. Please note that IFPMA staff will be "off-line" for Geneva Public Holidays: Good Friday (10 April) and Easter Monday (13 April).

Communications

On 19 March 2020, IFPMA organized a <u>virtual media briefing</u> highlighting industry's efforts and future commitments to address the current global coronavirus crisis. Media coverage was extensive both in terms of the quantity of articles, the quality of the media outlets, the range of positive messages included in the contents and the geographical reach. IFPMA continued to leverage the media briefing by publishing related blogs (<u>Global Health Matters</u>, <u>Pharma Boardroom</u>), video clippings with soundbites, and quote cards for social media use. IFPMA has also released a <u>series of videos</u> explaining the industry's commitments. IFPMA continues to identify and respond to media opportunities (Thomas Cueni gave interviews to BBC, Financial Times, Nikkei, NRC, NZZ, Pink Sheet, STAT News, etc.). As part of the proactive strategy to position the biopharmaceutical industry's collective efforts to bring solutions to COVID-19, IFPMA plans to hold a second virtual media briefing with member companies possibly timed for second half of April or in relation to a news announcement. In addition, IFPMA will sponsor a Financial Times Special Report "FT Health: Combating Coronavirus" (series of 6 articles). IFPMA continues to manage and where possible mitigate stories that are critical of industry's response to COVID-19. In this context, IFPMA has taken a stance on Costa Rica's request to the WHO to set up a patent pool for COVID-19.

IFPMA Resources:

- In addition to the IFPMA daily press review, we are circulating a daily COVID-19 update with in-depth coverage of discussions shaping COVID-19 R&D, clinical trials, IP, and health systems response.
- IFPMA Webpage: Novel Coronavirus (COVID-19)
- IFPMA Webpage: Novel coronavirus (COVID-19) Industry's R&D efforts
- IFPMA Webpage: Novel coronavirus (COVID-19) Industry's support on the ground
- Recording of the media briefing
- News Release: "Industry Commitments Global Biopharmaceutical Industry pulling out all the stops to address Coronavirus public health crisis"
- <u>Industry Commitment</u>: "<u>Global Biopharmaceutical Industry Commitment to Address Coronavirus Public Health Crisis</u>"
- Industry Commitment <u>videos</u>
- Backgrounder on COVID-19

Contact: Morgane De Pol (m.depol@ifpma.org)

WHO Engagement

COVID-19 will take centre stage in the upcoming World Health Assembly, which will be "virtual" rather than "in person" (18-21 May); details still forthcoming from WHO. In this context, IFPMA is working to ensure a coordinated set of policy responses in relation to this discussion point, and is exploring other innovative ways in which to disseminate key policy messages given the exceptional nature of this WHA. A "special session" of the Executive Board is also potentially likely to take place before WHA, and IFPMA will be conducting structured outreach to its networks to gain more information in this regard. We note that all WHO HQ staff are still working virtually until further notice, and efforts are ongoing to ensure close contact with key topic leads at WHO to keep abreast of policy developments and changes which could impact how decisions are made in relation to critical WHA agenda items. Over the last two months, WHO and IFPMA have had more consistent interaction with weekly updates between key members of senior leadership on both sides, to discuss various issues pertaining to the pandemic. IFPMA is also exploring other mechanisms by which to ensure our involvement in critical avenues of dialogue on the COVID-19 response, such as in discussions around vaccine development. (See below for additional updates on WHO engagement by subject area.)

Contact: Vanessa Peberdy

Geneva Mission Outreach

We have noted a very high level of interest from Missions on industry engagement related to Covid-19. The feedback received showed that while there is enormous amount of information scattered around different media (some less other more credible) they are not easy to collect and aggregate. With that in mind we have established a network of Geneva based Missions with which we keep regular contacts. On a daily basis we provide them with latest top information which emphasises industry's continued efforts in addressing current challenges (not only R &D) but also captures other relevant news and information. Additionally, we respond to their specific requests and provide a link between their capital-based experts and global pharmaceutical industry. This is an ongoing cooperation for which we have received great amount of positive feedback.

Contact: Grega Kumer

G20 Engagement

On Thursday, 26 March, <u>G20 Leaders</u> held a virtual meeting and released an <u>Official Statement</u> on the global response to the Covid-19 public health, economic, and social crisis. Building on statements made by WHO DG Dr Tedros, G20 Leaders "committed to presenting a united front against this common threat" in the "spirit of solidarity". IFPMA contributed to a <u>statement</u> issued by the Global Business Coalition on behalf of the health industry calling on G20 to support for measures to prevent the spread of COVID 19 and mitigate its effects on people & markets. In addition, <u>G20 Trade and Investment Ministers</u> met on 30 March and released a <u>Statement</u> reiterating the need of a coordinated global response during *and* after the crisis, based on the principle of international solidarity. Soon after, the <u>G20 Finance Ministers and Central Bank Governors</u> met on 31 March in order to concretely define a joint action plan to respond to the COVID-19 pandemic. The discussions, wrapped up in a press <u>release</u>, aimed at translating the priorities predefined by the Leaders the week before into a series of concrete measures.

Finally, a joint <u>G20 Health & Finance Ministers</u> Virtual Meeting is currently planned - possibly on 18 April (TBC). In keeping with the approach adopted by the Trade and Investments Ministers' roadmap, the discussions will seek to elaborate on priorities defined by G20 Leaders. IFPMA, as a member of the G20 Health and Development Partnership, will take part in an April 6 meeting the Partnership has organized with WHO DG Dr Tedros, aiming to discuss policy proposals toward establishing and strengthening a framework for global health security.

Contact: Sara Amini

OECD Engagement

In line with initiatives emerging from other multi-lateral organizations, the OECD has undertaken policy discussions on how to tackle the cross-sectoral COVID-19 crisis through a three-staged strategic approach – 1) immediate policy measures; 2) sector-specific stimulus package; 3) economywide recovery plan. <u>Business at OECD (BIAC)</u> is engaging with the OECD to convey the industry perspective. IFPMA DG Thomas Cueni in his capacity of **Chair of the BIAC Health Committee**, will take part in the strategic planning for BIAC's contribution to these discussions.

The IFPMA Digital Health Task Force, with strong internal portfolio coordination, responded through BIAC to the OECD request for business input on the development of OECD digital policy guidance in light of the global COVID 19 health crisis. The submission addressed key aspects of different types of health-relevant data and its importance in addressing this public health emergency, while preserving a healthy innovation ecosystem. Furthermore, the OCED Trade Committee Meeting will take place on "virtually" on April 7-9. BIAC's meeting will take place on April 06, 2020. IFPMA submitted comments to the initial policy recommendations.

Contacts: Sara Amini, Luka Srot (Digital), and Komal Kalha (Trade)

UNGA Resolution

The UN General Assembly has approved <u>a resolution</u> on "Gobal Solidarity on COVID-19". The text is not controversial and mostly encourage countries to collaborate in the fight against the pandemic, highlighting the importance of multilateral institutions. Another resolution, sponsored by the Russian Federation, is still under negotiation. IFPMA is following the negotiations closely.

Contact: Guilherme Cintra

Africa Engagement

On March 16, in the last Africa Engagement Committee (AEC) call, the committee discussed the current situation in Africa and actions taken by some governments to prevent the spread of COVID-19. It is expected that the number of cases will worsen in the coming weeks and that countries are lacking capacities to combat COVID-19. The question was therefore to identify how our industry could support countries in their endeavour. IFPMA asked the AEC members to share information about their activities dedicated to supporting combating COVID-19 and IFPMA shared with members IFPMA available resources.

IFPMA will also seek to share information about industry continued efforts in combating COVID-19 and in addressing the diverse current challenges with the African missions in Geneva.

Finally, IFPMA is following closely what some stakeholders are doing on the ground, such as WHO Afro, the Africa CDC, and AMREF. If you are not yet part of the AEC, and would like to join the committee, please send your interest to Cyntia Genolet.

Contact: Cyntia Genolet

WHO R&D Blueprint & Regulatory

IFPMA reiterated its message to WHO in several fora recently about the need for closer coordination and engagement between the two organizations. Work under the <u>A COORDINATED GLOBAL</u>

<u>RESEARCH ROADMAP: 2019 NOVEL CORONAVIRUS</u> is ongoing and Working Groups have been established, however the IFPMA Secretariat has not been included to-date to receive updates.

WHO's responded positively and will ensure invitations are shared with IFPMA moving forward.

IFPMA's Regulatory Science Committee (RSC) will be hosting a call with WHO to understand better the organization's outreach to national regulatory authorities (NRAs) in low- and middle-income countries (LMIC) and to highlight some of the critical regulatory challenges industry is facing in light of Covid-19. The RSC will also use this engagement as an opportunity to share activities from NRAs in other markets that could be seen as best practices for WHO to take forward with its LMIC outreach.

Similarly, IFPMA, ABPI, EFPIA, JPMA & PhRMA met to review the outreach being taken at the national levels with NRAs for sustaining R&D and supply of medicines and vaccines. While the specific regulatory needs for individual markets may differ, the majority of the challenges identified were in alignment. The Associations agreed it would be important to facilitate coordination and communication between the more mature NRAs.

In response to an inquiry from the World Bank via the ICC about constructive policy decisions, IFPMA highlighted its appreciation for NRAs' rapid response to the COVID-19 pandemic by releasing in a timely manner highly relevant new and updated regulatory guidance to support continued R&D and facilitate regulatory procedures & approvals. Ultimately facilitating access to COVID-19-related and essential medicines and vaccines for patients. IFPMA hopes the guidance being issued by the various NRAs can serve as a basis for regulatory reliance and convergence with other countries during this global health emergency and ask for increased coordination among and between regional regulatory networks.

Contact: <u>Janis Bernat</u>

API/Supply

Concerns around the availability of API in China are easing as many production facilities are back up and running. Logistics and transportation do however remain a bottleneck in some instances. Now WHO is shifting its attention and closely following the supply situation in India. Recent conversations between WHO and Indian Generics Manufacturers point at 2-3 months availability of finished pharmaceutical product and 2 months of API. However, the effect of the recent lockdown measures on the pharmaceutical manufacturing industry has yet to be seen. Estimates are that 20-60% of the workforce and logistics may be affected. Even though WHO sees no immediate risk, the organization is starting to be concerned about the availability of narcotics, anesthetics, and paracetamol in general and the potential impact to existing HIV and Malaria programs.

Contact: Janis Bernat

Vaccines

We are hearing that social distancing and travel restrictions will impact routine immunization, introductions of new vaccines and vaccination campaigns will be delayed – we will see a surge of vaccine-preventable diseases (VPDs) outbreaks. Recent modelling of measles deaths if immunization programs fail estimate >1.5 million death annually. WHO continues its works to protect critical immunization services during the COVID-19 pandemic and released on March 26 new guiding principles and convened the Strategic Advisory Group of Experts (SAGE) on Immunization this week. WHO continue to plays a central role on the coordination of vaccine candidates research and development. WHO is now working on modelling the impact of COVID-19 on immunization and potential VPDs related deaths and will release a FAQs on the planning of immunization services. COVID-19 opportunities have also been identified, including the acceleration of novel vaccine delivery strategies for campaigns and life-course immunization and most importantly the establishment of a comprehensive VPDs surveillance system. In advance of the IFPMA Vaccine CEO Steering Committee virtual meeting on May 6, the Vaccines Committee will convene a COVID-19 Task force to proceed with a strategic assessment of the impact of COVID-19 situation on vaccines manufacturers' operations and vaccines access policies. This will inform future Vaccines Committee's 2020 priorities and our strategic engagement with WHO Director General - a meeting being foreseen early May.

The **Gavi Alliance** convened a COVID-19 Board call on March 21 and issued a <u>public announcement</u>, which summarizes a series of measures to support Gavi eligible-countries. Countries that qualify for Gavi support will be able to quickly reallocate up to 10% of grants extended to them under Gavi's health system and immunization strengthening program. This should allow to address vital short-term gaps linked to national preparedness plan and preventing to some extent the diversion of domestic immunization program resources to respond to the threat posed by COVID-19. Board members also expressed support for the use of Gavi's innovative financing instruments, such as its International Finance Facility for Immunisation (IFFIm) and Gavi's Advance Market Commitment to accelerate vaccine development and access where needed. Board members proposed adopting a country-led approach to start preparing now for deployment of a vaccine once one becomes available. Seth Berkley raised at SAGE whether we should use the Alliance mechanisms for procurement and distribution of an eventual COVID-19 vaccine beyond Gavi countries.

The influenza vaccine manufacturers have assessed the potential impact on seasonal influenza vaccine production and distribution arising from the ongoing COVID-19 situation. Overall, for the **upcoming northern hemisphere influenza season** (October 2020) there is no impact so far, although manufacturers are concerned about potential shortage of supplies and personnel shall the pandemic persist over the next few months; there are also concerns about air traffic disruptions once the vaccines are to be distributed, as well as border closures. Nevertheless, there have been several delays with candidate virus shipments from WHO laboratories (needed for manufacturing) have already been experienced due to the pandemic. For the **ongoing southern hemisphere influenza season**, air traffic disruption adding challenges to vaccine distribution and logistics. An increase in seasonal influenza vaccine demand has been observed, as some governments aim to protect those at risk for influenza disease (which are the same groups at risk of COVID-19) and decrease burden of disease and hospital attendance. Those results have been shared with WHO upon their request.

IFPMA is drafting an answer to the three WHO reports on <u>Implementation of Decision WHA72(12)</u>, which will help inform decision making at WHA73. Beyond influenza, those reports have **linkages to the ongoing discussions of the Nagoya Protocol** on Access and Benefit Sharing, particularly on the topic of genetic sequence data.

Contact: Laetitia Bigger and Paula Barbosa

Costa Rica Patent Pool Proposal

Costa Rica has proposed that a Voluntary IP Pool be created for all COVID-19-related treatments. It extends beyond patents and includes know how, clinical trial data and designs. Many NGOs and stakeholders have endorsed the proposal. The responsibility for its implementation will likely be given to the Medicines Patent Pool (MPP), and UNITAID, its sole funder, has already indicated its support. Please see attached for the IFPMA statement.

Contact: Komal Kalha

Value and Access

In the global response to the COVID-19 pandemic, calls from governments, stakeholders and activists are mounting for equitable access to and affordability of eventual COVID-19 treatments and vaccine. Industry's policy responses relating to COVID-19 must consider on the one hand, current sensitivities and urgency to address the pandemic, but also potential longer-term impact such measures could have on the industry market and business model. In light of this shift in dynamics, the Value & Access Committee will reassess and adapt it planned projects and engagement on transparency, pooled procurement and bolstering the industry narrative on supporting access and preserving the innovation ecosystem. Meanwhile, WHO Secretariat has indicated that plans to comprise and convene technical working groups to prepare policy positions for the 2021 Fair Pricing Forum remain underway. The application period for these working groups closed on 20 March 2020.

Contact: Sara Amini

Code of Practice and the Ethos

The IFPMA Ethics & Business Integrity Committee (eBIC) is currently preparing a video message by its new Chair, Rady Johnson, Executive VP and Chief Compliance, Quality & Risk Officer at Pfizer. In the current pandemic, the Chair would underline the value of our industry's Ethos as guidance for the numerous questions IFPMA is receiving from members. Everyone is looking for answers in the Code of Practice, but for many of today's dilemmas there are no provisions, so people need to be encouraged to use the Ethos with its values and principles as a guiding star to prevent that they start cutting corners. The goal is to provide a general message that industry is united and continuing to do the right thing no matter how testing the circumstances.

Contact: Sofie Melis

Upcoming External Meetings and Events (6-17 April)

- 6 April H20 Dialogue Series with Dr Tedros Adhanom Ghebreyesus
- 9 April Weekly IFPMA DG & WHO ADG Call
- 17 April Weekly IFPMA DG & WHO ADG Call

Upcoming IFPMA Meetings and Events (6-17 April)

- 6 April: Cross Association Coordination w/ EFPIA, JPMA, PhRMA & RDPAC
- 7 April: Weekly Covid-19 Heads of Associations
- 8 April: Weekly Covid-19 Update for Committees
- 14 April: Weekly Covid-19 Heads of Associations
- 15 April: Weekly Covid-19 Update for Committees