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IFPMA Weekly COVID-19 Update
1 May 2020

Communications

The IFPMA COVID-19 online hub is live on www.ifpma.org/covid19. This hub is designed to convey our industry's commitment to address the crisis (7 commitments) and shows how IFPMA member companies are making progress and delivering against each of these commitments. The hub also features related resources (Statements, News Releases, Videos, etc.). More resources are available here. Additionally, IFPMA prepared a 1-pager with some global key facts and figures, that are also featured on the new hub. The IFPMA Communications team will update the information on the website on a daily basis. Should you want to share your company/association updates, please don't hesitate to contact Morgane (m.depol@ifpma.org).

The second IFPMA media briefing took place on 30th April and focused on COVID-19 therapies. We had a great line-up of 8 leaders from our industry (MSD, AstraZeneca, Merck, Takeda, Sandoz, Pfizer and CSL), who shared their science, medical and technical insights on current efforts to research and test potential treatments, and on unique partnerships that are being forged to ensure that our expertise is shared across the scientific community. It was also an opportunity to underscore companies' tireless efforts to increase manufacturing capacities, and to keep supplying essential medicines for patients with other life-threatening conditions. It was a truly international media briefing with over 70 journalists from around the world dialling in. The recording of the media briefing is available here, and the News Release here.

The second wave of articles of the Financial Times special report – FT Health Combating Coronavirus, supported by IFPMA, have been published on 28th April (Drugmakers race to scale up vaccine capacity and The coronavirus pandemic is moment of truth for anti-vaccine movement).

On Monday, 4 May (3pm CET) European Union will co-host an online "Coronavirus Global Response International Pledging Conference" that will kick-off a global pledging effort with an initial goal of raising reach €7.5 billion. The pledging event will raise funds to support last Friday's Call to Action to make new vaccines, diagnostics and treatments for the coronavirus globally available, appropriate, and affordable. David Ricks, as President of IFPMA, has been invited to speak on behalf of the industry at the pledging event. Event will be live-streamed on EbS.

Contact: Morgane De Pol

Access to COVID-19 tools (ACT) Accelerator

IFPMA participated in a number of meetings this week to further progress the "Access to COVID-19 tools (ACT) Accelerator" that was launched on April 24. Although still a work in progress, the draft concept for the "Global Response Framework" for this initiative includes three distinct, autonomous partnerships on vaccines, therapeutics and diagnostics with a light-touch oversight through a "global stewardship council" and a transversal "connector" workstream on health systems and other cross-cutting issues. The governance and key workstreams of the various components of the ACT Accelerator are still being worked out, with the vaccines discussions being the most advanced. IFPMA

DG's intervention during a "principals" call hosted by Bill and Melinda Gates Foundation (BMGF) focused on support for the concept of "subsidiarity" and light touch oversight, importance of the private sector as equal partners within the operational pillars, and agreement on the need to manage conflicts of interest (including all partners who receive funding). He also noted our commitment to facilitating innovation through knowledge and data sharing, but cautioned against rigid "one-size fits all" set of conditions at the "global" level.

Vaccines. IFPMA actively engaged in BMGF-hosted kick-off call of the ACT Accelerator Vaccines Partnership. The aim was to rapidly nail down the basic structural elements and responsibilities of the workstream within the partnership, starting from a 4-leg end-to-end approach (i.e., Financing, Development & Manufacturing, Allocation, and Delivery-at-scale). Discussions are moving at fast pace and alignment aimed to be reached shortly on the workstreams' scope and lead organizations. Next steps will be to discuss the overall coordination of the Vaccines partnership. IFPMA coordinated IFPMA Vaccine CEOs' position and engagement with the Foundation in complement to IFPMA Director General's bilateral engagement with key partners to mitigate risks with the proposed overall construct.

Therapeutics. IFPMA also engaged in the Wellcome Trust hosted kick-off call of the Therapeutics Partnership under the ACT Accelerator. The discussions are at a very nascent stage and the scope of the partnership and the key work streams remain unclear. The existing Therapeutics Accelerator has been put forward as the "lead actor" to in this partnership, however, UNITAID has also positioned itself as a potential "co-lead". There appears to be consensus amongst the participants that therapeutics and vaccines have different needs and that this partnership should not necessarily "mirror" the vaccines partnership and that the focus of this partnership may be best placed on "downstream" issues. IFPMA DG's intervention focused on the need to avoid duplication of efforts, need to recognize the work already being done through International Coalition of Medicines Regulatory Authorities (ICMRA) on regulatory front, recommendation to focus on the needs of the least developed countries, and a note of caution on the implementation of "open science" and "open data".

IFPMA will continue to be actively engaged in these discussions as this initiative and underlying partnerships take shape.

Contact: Fumie Griego, Laetitia Bigger (Vaccines)

Preparations for the World Health Assembly

The Executive Board this week decided that the 73th Session of World Health Assembly (WHA73) will be a virtual "de minimis" Assembly opening on May 18th, to ensure continuity of governance, as well as to give due attention to the COVID-19 pandemic preparedness and response work that has been undertaken thus far. Technical items will be considered later in the year, including through resumed sessions of the WHO governing bodies. The informal consultations among Member States on the EU Resolution have started this week and will continue up to the Assembly. IFPMA has submitted coordinated comments providing positive feedback supporting the resolution, while expressing concerns around voluntary IP pooling language. According to our sources, the United States has asked to add an immediate evaluation of response actions into the Resolution as well as positive language around innovation. However, during the consultations, additional "access" language as well as reference to TRIPS flexibilities (including Compulsory Licensing) was included in brackets. We are closely monitoring the developments around the resolution, and are preparing policy messages in relation to this, as well as a number of other mechanisms through which to provide our advocacy response (see below in particular).

On Tuesday 5th of May, IFPMA will host a webinar providing an opportunity for Missions in Geneva (also open for capital experts) to ask questions and have an open conversation with the IFPMA Director General and his team on *Global Biopharmaceutical Industry's Efforts to Address the Coronavirus Public Health Crisis*. For more information: http://www.cvent.com/d/knq5j3

Contacts: Vanessa Puberty, Grega Kumer (Mission Outreach)

WHO Regulation

Earlier this week, IFPMA's Regulatory Science Committee met with WHO's Regulatory Team to catch up on recent activities and progress to-date. Following the announcement of the ACT Accelerator, WHO anticipates that its role in broadly coordinating regulatory activities, such as clinical research and trials (e.g. enrolment criteria, endpoints, capacity), to expedite development of therapeutics and vaccines will occur under this new partnership. How this will play out in practice and to what extent ICMRA will be involved is yet to be seen. WHO will continue its routine engagement with various regulatory networks, e.g. PAHO, to facilitate best practices and use of regulatory reliance.

In addition, the Prequalification (PQ) Team is poised within WHO to carry out the Emergency Use Listing (EUL) procedure for the use of unlicensed therapeutics and vaccines during a public health emergency. The EUL was revised in January 2020 and is aligned, as much as possible according to WHO, with current principles and thinking of national regulatory authorities (NRAs). EUL begins with the use of limited information, involves the participation of interested NRAs and will be followed by PQ once the product has been further developed and has received its first marketing authorization. WHO envisages that abridged and full review procedures will be available under both EUL & PQ. The EUL is already in use for diagnostics; will be opened soon for therapeutics; and is not yet launched for vaccines. These conversations are part of regular, ongoing dialogue with the WHO Secretariat.

Contact: Janis Bernat

OECD Engagement

The OECD has released two confidential background documents ahead of the virtual OECD Expert Group on Pharmaceuticals and Medical Devices meeting (7 May). As a follow up to Member States input on a wider set of proposals presented at the December 2019 Health Committee, the first document is presenting three project proposals for the OECD to engage in work with the common objective of Increasing Transparency in Pharmaceutical Markets by i) implementing a framework to collect net prices of pharmaceuticals; ii) assessing the collection and use of data collected in managed entry agreements, and; iii) evaluating the availability and access to medicines in OECD countries. The second document, entitled *Managing Pharmaceuticals and Medical Devices in Times of Pandemics*, outlines proposals for potential areas the OECD Pharmaceutical Expert Group can contribute to discussions on COVID-19, including a suggestion to develop innovations in prophylaxis and treatment against COVID-19 as ''global public goods'' to ensure access and affordability. IFPMA is spearheading industry position on these projects and will convey written comments to the OECD through BIAC, and in interventions by IFPMA DG Thomas Cueni in his capacity of Chair of the BIAC Health Committee during the Expert Group virtual meeting.

Contact: Sara Amini

G20 Engagement

On 26 April, the Saudi G20 Presidency welcomed the launch of *Access to COVID-19 Tools (ACT) Accelerator* partnership for speeding up the development, manufacturing and equitable access to

products to tackle the pandemic, as well as mobilizing and dedicating appropriate investments. Paving the way to the coming pledging conference on 4 May, the Kingdom of Saudi Arabia has already committed USD 500 million, calling on all actors to contribute to close the estimated USD 8 billion financing gap. G20 Saudi Presidency has also reiterated its focus on digital health, seeking to position it a cornerstone of actions to tackle the COVID-19 pandemic. IFPMA and PhRMA, together with the Global Business for Health Partnership, have developed a 2-page policy paper calling G20 Officials "*to implement, in collaboration with the private sector, policies to allow more effective and widespread ethical use of digital technologies to diagnose, treat, and pay for healthcare*". The document was sent to the Saudi government ahead of the Extraordinary Digital Economy Ministers Meeting on 30 April, and will be leveraged with G20 Officials when appropriate.

Contacts: Sara Amini and Luka Srot (Digital)

Reinforcing Ethics & Business Integrity amidst COVID-19

On Thursday 7th of May IFPMA will host a special webinar on "Reinforcing Ethics and Business Integrity amidst COVID-19", jointly convened with the *APEC Business Ethics Initiative* (overseen by the US Government), of which IFPMA holds the Industry Co-Chair. As economies around the world actively address the COVID-19 pandemic, we are reminded of the importance of international collaboration to reinforce high standards of business ethics and integrity in the biopharmaceutical sector. IFPMA member associations and companies serve a crucial role in supporting local code of ethics implementation, upholding the IFPMA Code of Practice and facilitating multi-stakeholder collaborations that promote integrity. The webinar will be opened by Thomas Cueni, followed by a roundtable with the Chief Ethics and Compliance Officers from Amgen, Bayer, GSK and Pfizer. The focus will be on actionable recommendations for IFPMA member associations around the world on reinforcing business ethics and integrity during and after the pandemic.

Contact: Sofie Melis

External Meetings and Events (Week of 4 May):

- **May 4:** Coronavirus Global Response Initiative Pledging Event
- **May 5:** IFPMA webinar for Missions in Geneva on "Global Biopharmaceutical Industry's Efforts to Address the Coronavirus Public Health Crisis"
- **May 6**: IFPMA Vaccine CEOs meeting with Seth Berkley, Gavi CEO
- **May 7**: IFPMA Vaccine CEOs meeting with Dr. Tedros, WHO DG
- **May 7:** IFPMA/APEC webinar on "Reinforcing Ethics and Business Integrity amidst COVID-19"
- **May 7**: OECD Expert Group on Pharmaceuticals and Medical Devices
- **May 8:** Weekly IFPMA DG & WHO ADG Call

IFPMA Meetings and Events (Week of 4 May):

- **May 5**: Weekly Covid-19 Heads of Associations
- **May 6**: Weekly Covid-19 Update for Committees
- **May 6**: IFPMA Vaccine CEO Steering Committee meeting
- **May 7**: IFPMA Vaccines Committee meeting

***IFPMA Operating Status**: IFPMA offices remain closed and IFPMA staff continue to work from home. IFPMA is reviewing Swiss Federal Council's latest announced plans to further ease measures from 11 May.*