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# IFPMA Weekly COVID-19 Update 17 April 2020

#### **Communications**

IFPMA has an agreement with The Financial Times to produce a special report on combatting COVID-19. Six articles will be published between 21<sup>st</sup> April and 5<sup>th</sup> May. The articles will cover a wide range of topics including status on innovation for COVID-19 treatments and vaccines, intellectual property and COVID-19, challenges for scaling up manufacturing COVID-19 vaccines, hope for a COVID-19 vaccine and possible impact on vaccine hesitancy, pricing and access of COVID-19 treatments and vaccines. While IFPMA is sponsoring the series of articles, IFPMA does not have control on the contents of the articles. The IFPMA Communications team connected the authors of the articles with IFPMA member companies including with their CEOs and relevant external stakeholders for additional insights.

To build on the successful <u>virtual media briefing of 19 March</u>, IFPMA is planning to host two further virtual media briefings with member company CEOs and/or senior executives, end of April (29<sup>th</sup> or 30<sup>th</sup> April) and on early June (2<sup>nd</sup> or 3<sup>rd</sup> June). The next media briefing will focus on new and repurposed treatments for COVID-19 (antivirals, antimalaria, anti-inflammatory and antibodies), and on manufacturing and supply chain challenges. The June media briefing will focus on COVID-19 vaccine development and industry contribution to Gavi, the Vaccine Alliance, coinciding with Gavi replenishment (3<sup>rd</sup> and 4<sup>th</sup> June).

Contact: Morgane De Pol

## World Health Assembly "EU" resolution

The European Union Mission in Geneva has distributed a zero draft for a COVID-19 resolution to be tabled at the upcoming World Health Assembly (WHA). The decision on whether or how to hold the next WHA has not been taken, and a few modalities are still being discussed with Member States. In any case, it is likely going to be the only "substantive" topic for discussion if a shortened virtual meeting takes place. The zero draft is largely positive as it stands, though controversial language may be negotiated in the upcoming weeks. The most sensitive part relates to a request to the WHO DG to "draft a plan (...), in consultation with Member States, (...) with inputs from relevant international organizations including WIPO, GAVI, UNITAID, the Medicines Patent Pool, CEPI, the Global Fund to fight Aids, TB and Malaria, and UNICEF, to achieve equitable access to quality, safe, and efficacious COVID-19 vaccines and other health technologies necessary for COVID-19 response". IFPMA will follow these negotiations very closely and coordinate our advocacy response, including with our national associations and other health innovative health industries. We will also provide a structured feedback to the EU Mission.

Contact: Grega Kumer

#### **United States Announcement to Suspend WHO Funding**

The USG announced funding to the WHO will be halted after the President of the US voiced concerns that WHO had "severely mismanaged" the coronavirus pandemic. Given the fact that the US is the largest contributor to WHO (providing approximately \$893 million for the WHO for its 2018 – 2019

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biennial budget in assessed and voluntary contributions versus WHO's overall biennial budget of \$6 billion in 2018 – 2019), this suspension has the potential to significantly impact WHO's operations in the mid-to longer term. IFPMA is also working with other key collaborators such as PhRMA to further determine the implications of the US's suspension of WHO funding and monitor developments, and to factor this into ongoing engagement with WHO. Given the sensitivity of the situation, IFPMA has prepared an "if asked" reactive statement which has been shared with the Global Health Committee that focuses on the importance of international cooperation in a global health emergency such as the COVID-19 pandemic without overtly criticizing the USG or commending the WHO.

Contact: Vanessa Peberdy

## WHO Covid-19 R&D Blueprint

#### **Therapeutics**

Real-world Evidence & Observational Studies - More than 30 national regulatory authorities met with WHO to talk about the consolidation and sharing of outcomes from RWE and observational studies. Similarly companies are interested in this type of information, and in some cases, have developed applications to create registries around particular treatment regimens. WHO is open to looking at these applications if companies are interested to share this information.

Regulatory Flexibility - WHO is sharing best practices amongst NRAs and met with PAHO NRAs recently. The idea for this regular communication by WHO is to promote regulatory reliance and cooperation to help NRAs be more efficient and effective at this time. In addition, WHO shared several alerts regarding falsified and/or substandard chloroquine.

Contact: <u>Janis Bernat</u>

### **Vaccines**

On 13 April WHO published a <u>statement for collaboration on COVID-19 vaccine development</u> and will be conducting an international randomised trial of candidate vaccines against COVID-19. WHO held a meeting with vaccine developers to provide an update on the work they are doing. They presented the <u>outline of the Solidarity vaccine trial</u> and <u>Target Product Profile for COVID-19 vaccines</u> that operate within the WHO R&D Blueprint, and outlined for the trial protocol to be updated in the coming days. It was stated that since the announcement of the trial 4 weeks ago, WHO has a note of 9 different manufacturers, 91 different countries and nearly 1000 hospitals worldwide who wish to enrol in the trial and 6 countries are already randomising patients in hospitals. Regulatory oversight will be done by each NRA and a similar trial protocol will be used in each enrolled country. Each site will evaluate all the vaccines against a placebo and a vaccine will be able to enter the trial at any time. WHO believes that within the period of 3-6 months this trial will enable to evaluate a vaccine candidate and point out which vaccines to deploy.

Contact: Laetitia Bigger

#### **Substandard & Falsified Medicines**

WHO has issued a <u>Medical Product Alert</u> targeting falsified medical products, including in vitro diagnostics, that claim to prevent, detect, treat or cure COVID-19. WHO advises on exerting due diligence when procuring, using and administering any medical product at this time, in particular those affected by the current crisis of, or related to, COVID-19.

IFPMA together with partners of Fight the Fakes (FtF) has released a <u>statement COVID-19</u> and <u>emerging reports of falsified treatments and rumours of cures</u>. The statement recognizes that disruptions in supply and general feelings of insecurity caused by COVID-19 create the perfect environment for falsified medicines to flourish. It also addresses concerns with what WHO has called an *infodemic* of misleading and fake information on COVID-19 circulating on social media and media. A dedicated <u>Fight the Fakes website</u> gathers information on reported case of falsified COVID-19 medical products. Other partners of FtF such as the Alliance of Safe Online Pharmacies (ASOP) have also published a <u>statement focused online sales</u>.

Contact: Cyntia Genolet

## **API/Supply**

The supply of intermediates from China may cause some issues moving forward as several manufacturers have gone out of business. India estimates that only 40% of capacity is available for manufacture due to the recent federal health measures. However, several export restrictions have been lifted, and the government is committed to supply patients in need as much as possible. IFPMA inquired about the results of WHO's work pertaining to the collection of information on potential shortages/stockouts of essential medicines. WHO is currently updating their information based on what they hear from partners, however the organization is finding it hard to gather needed data from additional sources.

Contact: <u>Janis Bernat</u>

## UN Resolution on Access to COVID-19 products ("Mexican Resolution")

The President of the UN General Assembly has circulated on 15 April the final draft of a resolution on "International Cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19". This off-cycle "emergency" resolution is a concise and largely positive call for solidarity and concerted international action. Of particular relevance is its call for partnerships with the private sector and for Member States to avoid undue stockpiling. Countries have until Monday to express any eventual opposition to the resolution. IFPMA is coordinating a joint response ICBA, GSCF, GMTA and DITTA to welcome the resolution.

Contact: Guilherme Cintra

# **G20** engagement

The G20 Health and Development Partnership hosted a meeting with WHO DG Dr Tedros on 6 April, as part of their **H20 Digital Dialogue Series**. IFPMA took part in the discussion where Dr. Tedros recognized the "outstanding leadership of the private sector" in the crisis, and welcomed continued partnership with the industry. He called on companies to prioritize the supply of products needed to address the pandemic, and underscoring the importance of equitable access and distribution of future COVID-19 health products.

The G20 **Health Ministerial is set to take place on 19 April** to discuss national best practices and develop a roadmap for strengthening the G20 response to the pandemic. IFPMA will issue a statement

to communicate the biopharmaceutical industry contribution and role in the international joint action to tackle the crisis.

Contacts: Sara Amini

## **OECD** engagement

IFPMA, through *Business at OECD* (BIAC), conveyed its **trade policy priorities** to minimize supply chain disruptions and to address the COVID-19 outbreak. These were captured in a <u>press release</u> and a BIAC <u>statement</u> on 7 April, outlining the business community's calls for OECD to prioritize three overarching objectives for the OECD – 1) establishing necessary, effective, and evidence-based measures; 2) safeguarding that governments do not adopt or keep arbitrary, discriminatory or protectionist policies; 3) urging open trade and global value chains as fundamental drivers to recover from this global crisis. OECD has since released a <u>policy brief</u> on *Covid-19 and International Trade: Issues and Actions*, which reflect the contribution made during this consultation with business. Further OECD trade policy briefs are being planned on 1) trade facilitation; 2) government support; 3) global value chains for essential goods; and 4) services trade.

The OECD also issued a <u>Joint Statement by the Development Assistance Committee of the OECD</u>, recognizing the critical role of the private sector in tackling the COVID-19 crisis, underpinned by calls to strengthen transparency, governance, and financial support (among other). Finally, IFPMA continues to engage with the OECD through the BIAC Health Committee to identify how the organization can leverage its expertise to formulating a strategic response to the COVID-19 pandemic.

Contacts: Sara Amini and Komal Kalha (Trade)

#### **Africa**

IFPMA has been invited to participate in a WHO-UNCTAD webinar on April 23 on the topic of local production as a response to COVID-19 "Diversifying the supply chain: The role of investment in local production in Africa to address supply bottlenecks during the pandemic crisis". Currently listed participants include representatives from FAPMA, DCVM, East African Community Secretariat, and USP.

Contact: Cyntia Genolet

#### **Intellectual Property**

IFPMA issued a public statement of <u>Intellectual Property Management</u> in response to the Costa Rica proposal and the expansion of MPP's ambit.

Contact: Komal Kalha

#### **Code of Practice and the Ethos**

The IFPMA Ethics & Business Integrity Committee (eBIC) has launched a <u>video message</u> by its new Chair, Rady Johnson, Executive VP and Chief Compliance, Quality & Risk Officer at Pfizer. In the current pandemic, the Chair underlines 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

## External Meetings and Events (Week of 20 April):

- 20 April: Business at OECD Health Committee Zoom Conference
- 23 April: WHO-UNCTAD webinar on local production

## IFPMA Meetings and Events (Week of 20 April):

- 20 April: Africa Engagement Committee Webex Meeting
- 21 April: Weekly HOA COVID-19 Update
- 21 April: Global Health Committee Teleconference
- 22 April: Weekly Cross-Committee COVID-19 Update
- 20-22 April: Regulatory Science Committee & Working Group Virtual Meetings

**IFPMA Operating Status**: IFPMA offices remain closed and all IFPMA staff are working from home until further notice. IFPMA is reviewing Swiss Federal Council's announced plans to <u>gradually ease measures against the new coronavirus</u>: "On 27 April, hospitals will be able to resume all medical procedures, including non-urgent procedures, and outpatient medical practices, hairdressing salons, massage practices and cosmetic studios will be allowed to reopen. DIY stores, garden centres and florists will also be allowed to reopen. The protection of the public and of staff must be assured. These are the steps decided by the Federal Council at its meeting on 16 April. If the situation allows, schools for children of compulsory school age and shops will be able to reopen on 11 May. On 8 June, uppersecondary schools, vocational schools and higher education institutions, as well as museums, zoos and libraries may reopen. The Federal Council also issued further details with regard to protecting workers at especially high risk... The Federal Council has not yet determined further phases. A decision as to when large-scale events will again be allowed to go ahead will be taken at one of its next meetings."