



**COVID-19**

Global Biopharmaceutical Industry Commitment  
to Address Coronavirus Public Health Crisis

# IFPMA Management of COVID-19 Crisis

Thomas Cueni – Director-General, IFPMA

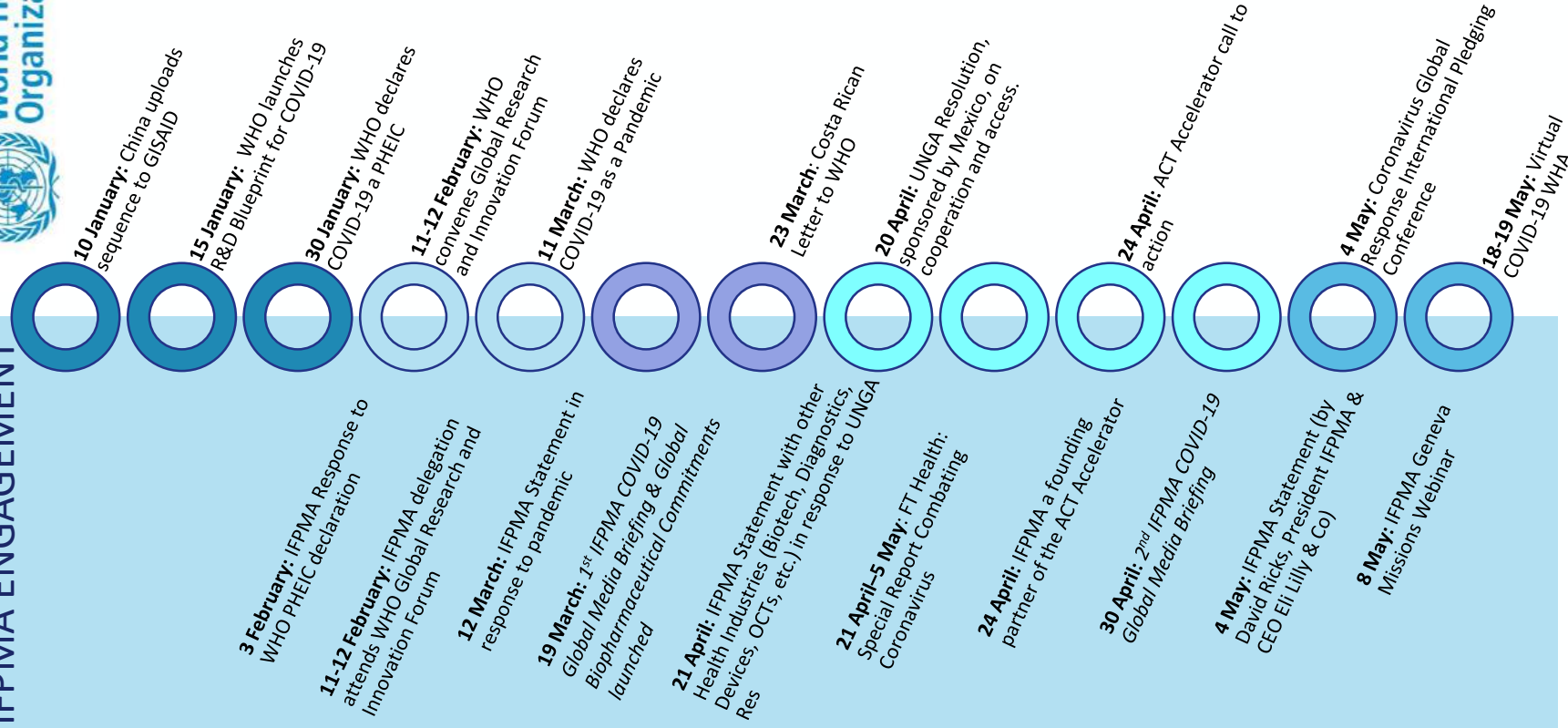
*13<sup>th</sup> May 2020 FIFARMA Annual meeting*

# Agenda

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1. Overview of Key COVID-19 Events to Date
2. Pharma and COVID-19 Diagnostics, Treatments and Vaccines
3. COVID-19: Innovation & Access
4. COVID-19: Regulatory
5. COVID-19: Ethics
6. COVID-19: Anti-Microbial Resistance
7. IFPMA Engagement and Tools
8. What next?

# 1. Overview of Key COVID-19 Events



## 2. COVID-19 Diagnostics, Treatments and Vaccines

“ The biopharmaceutical industry is acutely aware of the enormous responsibility we have to patients and society to engage in unprecedented levels of collaboration to find a solution to COVID-19.

We stand ready to bring to this partnership our unique knowledge and expertise in the discovery and development of medicines and vaccines, as well as our experience building manufacturing capacity and distribution networks.”

The background of the slide features a teal-to-blue gradient with a microscopic image of virus particles. Overlaid on this is a large, white, stylized logo consisting of three curved, overlapping shapes that form a central circular void. Below this logo, the letters "IFPMA" are written in a large, bold, white, sans-serif font.

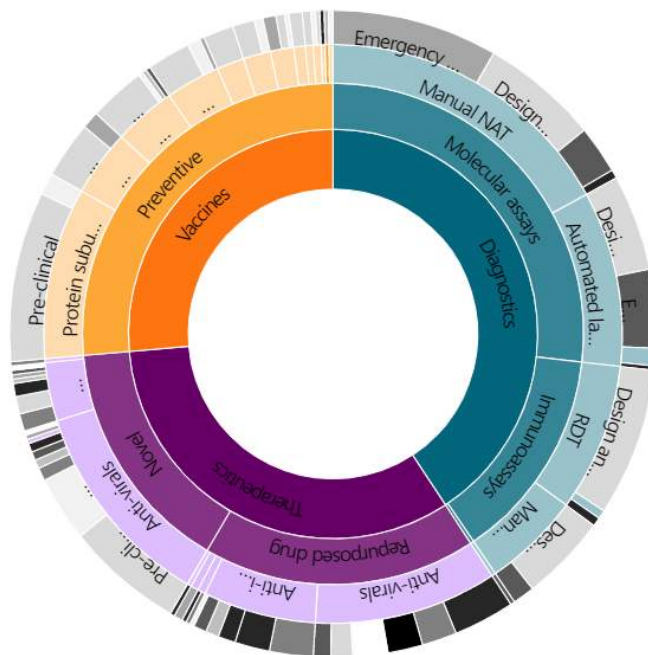
IFPMA

## 2. The Pipeline of COVID-19 Therapeutics, Vaccines and Diagnostics – Since 10 January 2020

121 Vaccines

187 Diagnostics

151 Therapeutics



## 2. IFPMA Members' Activities - COVID-19 Therapeutics, Vaccines and Diagnostics



**>20**  
COMPANIES  
INVOLVED IN R&D

for therapeutics,  
vaccines and  
diagnostics

### Collaborations

11 Big pharma and **biotech**

13 Big pharma and **academia**

6 Big pharma and **big pharma**

And with **Health Innovation Industries**



**35**  
CLINICAL TRIALS  
evaluating the  
effectiveness of  
therapeutics



**\$700M**  
IN MONETARY  
DONATIONS



**\$40M**  
NON-MONETARY  
DONATIONS



**25M**  
DONATED UNITS  
OF MEDICINES AND  
PERSONAL  
PROTECTIVE  
EQUIPMENT



## 2. IFPMA Member Companies Stepping up to Tackle COVID-19

### Treatments:

- Experimental antivirals: Gilead's remdesivir
- Combination HIV treatment: AbbVie's Kaletra
- IL-6 inhibitors: Roche's Actemra and Sanofi and Regeneron's Kevzara
- Malaria treatment: chloroquine and hydroxychloroquine: Sandoz/Novartis, Bayer
- Blood treatments/ hyperimmune immunoglobulin: Takeda
- .... And many more

Major collaborations: WHO Solidarity Trials, COVID-19 Therapeutics Accelerator initiative, CoVlg-19 Plasma Alliance, IMI

### Vaccines:

- **Pfizer and BioNTech** mRNA vaccine
- GSK AS03 adjuvant system for vaccines
- J&J AdVac
- Sanofi for severe acute respiratory syndrome (SARS) & mRNA vaccine

Major collaborations: BARDA, CEPI, Access to COVID-19 Tools (act) Accelerator

## 2. Our Commitments



EXISTING & TEST NEW TREATMENTS



SHARE REAL-TIME CLINICAL TRIAL DATA  
WITH GOVERNMENTS & OTHER COMPANIES



SPEED UP R&D OF SAFE & EFFECTIVE  
VACCINES



DEVELOP DIAGNOSTIC TESTING & SECURE  
CONTINUOUS SUPPLY



SECURE ESSENTIAL SUPPLIES FOR MEDICINES &  
VACCINES



INCREASE & SHARE MANUFACTURING  
CAPACITY FOR MEDICINES & VACCINES



SUPPORT GLOBAL HEALTHCARE SYSTEMS



### Global Biopharmaceutical Industry Commitment to Address Coronavirus Public Health Crisis

**As part of the global health community, biopharmaceutical companies are committed to playing the greatest possible role in the global response to COVID-19.**

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is the global association of the world's leading biopharmaceutical companies. Our members have a breadth of expertise (research, clinical development, manufacturing) that uniquely positions our industry to support the fight against the spread of COVID-19.

We have a strong sense of responsibility to act together, as well as in partnership with the World Health Organization (WHO), governments and health systems across the world in a concerted, collective response.

Already, our industry has responded on an unprecedented scale to the current pandemic.

*And here we commit to...*

- rapidly screen the industry's vast libraries of medicines to identify potential treatments and undertake numerous clinical trials to test new and existing therapies
- share real-time clinical trial data to advance the development of new medicines
- use our expertise and know-how to prevent COVID-19 in partnership with governments and health systems
- use our medical expertise to secure the supply of medicines and medical devices in the face of an increase in pressure they are experiencing
- share tools and insights to test and increase the capacity of diagnostics testing
- increase our manufacturing capacity for successful vaccine or treatment
- work to secure continuity of supply of medicines and medical devices in the face of disruption with other life-threatening diseases to facilitate access for all those in need



19 March 2020 | Thomas Cueni, Director General, WHO

#### About IFPMA

IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees discover, develop, and deliver medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

To find out more, go to [ifpma.org](https://ifpma.org)

[@IFPMA](https://twitter.com/IFPMA) [in /ifpma](https://www.linkedin.com/company/ifpma)



## 2. IFPMA and COVID-19 Diagnostics, Treatments and Vaccines



*news release*

David Ricks, Chairman and CEO of Eli Lilly and Co and IFPMA President, said: "We are sending a clear signal of how seriously industry is taking the pandemic and the need to act as one team. So, we are sharing today our commitments on how we, as an industry, are stepping up to do all we can to fight this pandemic".



### Global Biopharmaceutical Industry pulling out all the stops to address Coronavirus public health crisis

19 March 2020, Geneva - The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), representing the world's leading biopharmaceutical companies, confirmed that having already mobilized on an unprecedented [scale](#) to respond to the pandemic, they commit to do more. The biopharmaceutical industry commits to act to use its skills, technology and resources to bring safe, effective diagnostics, treatments and vaccines to patients around the world as a matter of urgency.

David Ricks, Chairman and CEO of Eli Lilly and Co and IFPMA President, said: "We are sending a clear signal of how seriously industry is taking the pandemic and the need to act as one team. So, we are sharing today our commitments on how we, as an industry, are stepping up to do all we can to fight this pandemic".

The commitments demonstrate the combined will of leading companies in the field to use their scientific expertise, technical skills and manufacturing capabilities to bring forward treatments and vaccines to protect humankind from this escalating pandemic. The biopharmaceutical industry is uniquely positioned to work in partnership with governments, the WHO and health systems to deliver the world in a concerted, collective response.

<https://www.ifpma.org/resource-centre/ifpma-president-david-ricks-on-global-pledge-committing-to-work-together-to-beat-covid-19-video/>

### Big Pharma steps up **FINANCIAL TIMES**

Thomas Cueni, head of the International Federation of Pharmaceutical Manufacturers and Associations, says coronavirus is a pivotal moment for his members. He argues that the sector is rising to the challenge with [initiatives](#) to develop the tools required and make them available affordably through unprecedented co-operation, donations and pledges on prices.

"Everybody feels this is the moment when the industry needs to do the right thing," he says. "It holds the keys to ending Covid-19. This is 1919 and 1929 combined: the Spanish flu with the Great Depression. I'm extremely pleased to see industry reacting as society would hope, without being coerced or forced."

## 2. ACT Accelerator Founding Partners

BILL & MELINDA  
GATES foundation

dcvmn  
Developing Countries Vaccine  
Manufacturers Network

CEPI

Gavi  
The Vaccine Alliance

The Global Fund



International Federation  
of Pharmaceutical  
Manufacturers & Associations



Unitaid  
Innovation in Global Health



World Health  
Organization

### ACCESS TO COVID-19 TOOLS (ACT) ACCELERATOR

A Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 diagnostics, therapeutics and vaccines

24 April 2020

10

### COMMITMENT and CALL TO ACTION

#### Our Vision and Mission

Grounded in a vision of a planet protected from human suffering and the devastating social and economic consequences of COVID-19, we, an initial group of global health actors (BMGF, CEPI, Gavi, Global Fund, UNITAID, Wellcome Trust, WHO) and private sector partners and other stakeholders, are launching a landmark, global and time-limited collaboration to accelerate the development, production and equitable global access to new COVID-19 essential health technologies.

We know that as long as anyone is at risk from this virus, the entire world is at risk – every single person on the planet needs to be protected from this disease.

We agree that alongside evidence-based public health measures, innovative COVID-19 diagnostics, therapeutics and vaccines are needed – in record time and at record scale and access – to save millions of lives and countless trillions of dollars, and to return the world to a sense of 'normalcy'.

We recognize the significant amount of critical work, investment and initiatives already ongoing around the world to expedite the development and deployment of innovative COVID-19 related products and interventions.

We appreciate that while development and deployment of innovative products is essential, it will not be enough. We must simultaneously and urgently accelerate the strengthening of sustainable health systems and capacities to enable delivery of the new COVID-19 tools to those who need them and to mitigate the knock-on impact on other diseases.

We remember lessons from the past, which have shown that even when effective tools are available to the world, too often some are protected, while others are not. This inequity is unacceptable – all tools to address COVID-19 must be available to all. In the fight against COVID-19, no one should be left behind.

We understand we cannot do this alone, and that we need to work together in unprecedented and inclusive partnership with all stakeholders – political leaders, public and private sector partners, civil society, academia, and all other stakeholders across society – jointly leveraging our comparative strengths and respective voices to drive towards collective solutions, an accelerated path, and access for all. We are stronger, faster and more effective working together.

Our Mission is not only accelerated development and availability of new COVID-19 tools – it is to accelerate equitable global access to safe, quality, effective, and affordable COVID-19 diagnostics, therapeutics and vaccines, and thus to ensure that in the fight against COVID-19, no one is left behind.

#### Our Commitment

1. We commit to the shared aim of equitable global access to innovative tools for COVID-19 for all.
2. We commit to an unprecedented level of partnership – proactively engaging stakeholders, aligning and coordinating efforts, building on existing collaborations, collectively devising solutions, and grounding our partnership in transparency, and science.
3. We commit to create a strong unified voice to maximize impact, recognizing this is not about singular decision-making authority, but rather collective problem-solving, interconnectedness and inclusivity, where all stakeholders can connect and benefit from the expertise, knowledge and activities of this shared action-oriented platform.
4. We commit to build on past experiences towards achieving this objective, including ensuring that every activity we undertake is executed through the lens of equitable global access, and that the voices of the communities most affected are heard.
5. We commit to be accountable to the world, to communities, and to one another. We are coming together in the spirit of solidarity, and in the service of humanity, to achieve our mission and vision.

#### Our Call

We ask the global community and political leaders to support this landmark collaboration, and for donors to provide the necessary resources to accelerate achievement of the objectives of this global collaboration, capitalizing on the opportunity provided by the rolling pledging campaign that will start on 4 May 2020.

## 2. ACT Accelerator: Three Pillars



**Vaccines  
Partnership**

CEPI



**Therapeutics  
Partnership**

Therapeutics  
Accelerator



**Diagnostics  
Partnership**





## 2. ACT Accelerator: Global Pledging Conference



### 3. COVID-19: Innovation & Access



San José, 23 de marzo de 2020  
DP-P-024-2020

Dear Dr. Tedros,

Costa Rica in the spirit of contributing to global actions to fight the pandemic, respectfully requests to the World Health Organization (WHO) to undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic.

This pool, which will involve voluntary assignments, should include existing and future rights in patented inventions and designs, as well rights in regulatory test data, know-how, cell lines, copyrights and blueprints for manufacturing diagnostic tests, devices, drugs, or vaccines. It should provide for free access or licensing on reasonable and affordable terms, in every member country.

Given the urgency of this matter, Costa Rica proposes that the WHO develop an initial concise memorandum of understanding on the intent to share rights in technologies funded by the public sector and other relevant actors, and reach out to WHO Member States, non-profit institutions, industry and others, to sign such an MoU. The specific technologies and the terms of the assignments can be determined later, in the implementation stage of the pool, in consultation with R&D funders and rights holders.

**Dr. Tedros Adhanom Ghebreyesus**  
Director-General  
World Health Organization



## statement

#### IFPMA remarks on intellectual property management and the global response to COVID-19

**6 April 2020, Geneva** - In the fight against the novel coronavirus (COVID-19), biopharmaceutical companies are focusing significant amounts of their resources on the immediate task [ahead](#), which requires pushing the boundaries of science, developing workable solutions and ensuring there is capacity to scale up manufacture once solutions are found, while at the same time ensuring continuity of global supply for critical products. This approach is bearing fruit, with a large number of competitive leads for treatments and vaccines already identified for testing in just a matter of a couple of months<sup>1</sup>.

Since the emergence of virus, [biopharmaceutical companies have stepped up their efforts](#) and are engaged in multiple research projects to develop vaccines and treatments in order to contain it. The private R&D business model, underpinned by sound intellectual property protection, has contributed with most of the treatments that are now being tested for additional uses, and also enabled companies to make bold investments in R&D for new products. Moreover, there is a strong commitment across the biopharmaceutical industry to work with governments, insurers and other stakeholders to make these medicines and vaccines accessible and affordable to those who need them.

"We recognize that a flexible approach is needed to accommodate and support different R&D and access efforts, and that no easy 'one size fits all' solution exists" said Thomas Cueni, Director General, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). He adds: "In this spirit, we are open to explore innovative approaches and partnerships to facilitate further R&D to develop new medicines and vaccines for patients suffering from COVID-19 and to expand access."

Cueni concludes: "While we are not aware of any instance to date where intellectual property management has been an impediment in the global response to this pandemic, proposals for voluntary pooling of intellectual property assets, including [the decision of the Medicines Patent Pool \(MPP\)](#) to temporarily expand its mandate to include health technologies related to COVID-19, adds to the arsenal of options available to companies when establishing access to any potential COVID-19 product."

#### About IFPMA

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### 3. COVID-19: Innovation & Access

*“There does not appear to be any evidence that IP is a barrier to access to vital medical preventive measures, such as vaccines, or to treatments or cures.”* Francis Gurry, DG World Intellectual Property Organization WIPO

[https://www.wipo.int/about-wipo/en/dgo/news/2020/news\\_0025.html](https://www.wipo.int/about-wipo/en/dgo/news/2020/news_0025.html)



Thomas Cueni, Health Policy Watch: “The main policy challenge is to encourage the innovation that may lead to COVID-19 vaccines, treatments and cures, as well as innovation that assists in managing the coronavirus crisis.”



The industry views such moves with alarm. Severin Schwan, chief executive of Roche Holdings, says waiving IP “would be a disaster”. “If we don’t have IP, no one will take care of developing anything . . . Who would ever invest if there was no incentive?”

Coronavirus puts Big Pharma’s IP regime to the test, The Financial Times, 21 April 2020  
<https://www.ft.com/content/5a364eb0-780c-11ea-bd25-7fd923850377>



<https://healthpolicy-watch.org/wha-resolution-on-covid-19-political-football-polarized-global-health/>

## 4. COVID-19: Regulatory



Weekly calls WHO



### Focus of IFPMA action

- “Working in partnership and collaboration with NRAs to define the best science-based regulatory strategies for ensuring the availability of COVID-19 medicines and vaccines
- Progressing research into new treatments and prevention of other conditions
- Shortages/Maintaining supply of medicines and vaccines
- Ensuring all our medicines and vaccines continue to meet appropriate standards for quality and safety

## 5. Reinforcing Ethics & Business Integrity Amidst COVID-19

- While operating in these uncharted territories, we must demonstrate to the world that it can count on our **integrity** to win this fight.
- COVID-19 will be a long ride, meaning that the need for our industry's ethical foundation (the "**Ethos**") is ever more clear.
- The core values of our Ethos – **Care, Fairness, Respect and Honesty** – provide the framework to ensure that especially in the face of this crisis, we act with integrity and with patient's trust in the center.
- Long **after the crisis** has ended, society will see and applaud the integrity of industry's decisions and actions.



**Rady Johnson**

Chief Compliance, Quality & Risk  
Officer, Pfizer

Chair of IFPMA Ethics & Business  
Integrity Committee

## 5. APEC/IFPMA Webinars May 7: Key messages for Associations

The screenshot shows a GlobalMeet webinar interface. At the top, the GlobalMeet logo is on the left, and a 'TC Speaking' indicator for Thomas Cueni is on the right. Below the header, a 'Meeting Type' section indicates 'File Presentation'. A video gallery shows five participants. A red banner prompts users to submit questions via email. The main content area displays the following text:

**Special Webinar / Teleconference Session for APEC Biopharmaceutical Industry Associations: Reinforcing Business Ethics and Integrity amidst COVID-19**

Thursday, 7 May 2020 [8:00 (U.S. EDT) / 20:00 (Singapore) / 22:00 (Sydney)]

Introduction  
Mr. Andrew Blasi  
Technical Secretariat, Business Ethics for APEC SME's Initiative

**Chief Ethics and Compliance Officers Roundtable: Recommendations for APEC Biopharmaceutical Industry Associations**

<b>Ms. Cynthia Patton</b> Senior Vice President and Chief Compliance Officer Amgen	<b>Mr. Nick Hiron</b> Senior Vice President, Global Ethics and Compliance GlaxoSmithKline
<b>Mr. Thomas Pfennig</b> Global Head of Compliance and Data Privacy Bayer	<b>Mr. Rady Johnson</b> Executive Vice President, Chief Compliance, Quality and Risk Officer Pfizer

Comments & Dialogue by APEC Biopharmaceutical Industry Associations  
Mr. Andrew Blasi

Concluding Remarks  
Mr. Thomas Cueni  
Chair, APEC Biopharmaceutical Working Group on Ethics  
Cooperation of Pharmaceutical Manufacturers and Associations (IFPMA)

The Discussion & Suggested Actions  
Mr. Andrew Blasi

At the bottom, there is a 'Recording' indicator, a 'SM' logo, and various control icons (mute, video, chat, settings). An 'Exit Meeting' button is in the bottom right corner.



“In addition to the U.S. Government and company representatives, leaders from 47 associations across 33 economies plus several regions participated in our two webinar sessions”.





## 6. AMR & COVID-19

Parallel between the devastating health and economic impact of Covid-19 on the global community, and a rising death toll of over 200,000. With AMR, we have a public health threat, which already kills 700'000 people a year, and we know it could have as great, if not bigger an impact on our health, health systems and economically as COVID-19.

We know about AMR, and we know what needs to be done: create a viable environment that fosters a fertile environment for R&D and ensures that the growth of resistance is sustainably managed and controlled.

Companies in AMR field lose less money when they fail, as they can write off their research investment. This has to change.

More reading: Coronavirus lessons for the fight against 'superbugs' - The world needs to act now to avert the threat from antimicrobial resistance <https://www.ft.com/content/84f50406-82ee-11ea-b6e9-a94cfd1d9bf>



## 7. IFPMA Engagement and Tools

### LEADERSHIP - commitments



### INFORMATION

IFPMA member & IFPMA COVID19 activities:  
<https://www.ifpma.org/covid19/> &  
 coordination with membership



### POLICY SHAPING

- IFPMA Founding partner ACT Accelerator
- IFPMA policy positions

### ADVOCACY

- Statements (8 since 3 February)
- Vaccines CEO meeting with Dr Tedros 7 May
- Member States/Geneva mission webinar 8 May

**RESOURCES**  
 Support for



.... AND COMMUNICATIONS

# 7. IFPMA COVID-19 Flagship Communications

## IFPMA COVID MEDIA BRIEFINGS

19 March 2020

30 April 2020: on treatments

28 May 2020: on vaccines



### Special Report FT Health: Combating Coronavirus

As researchers race to develop a coronavirus vaccine, we look at efforts to ensure that the world's poor are not left behind — and ask whether the pandemic will jolt policymakers into confronting the looming threat from antimicrobial resistance

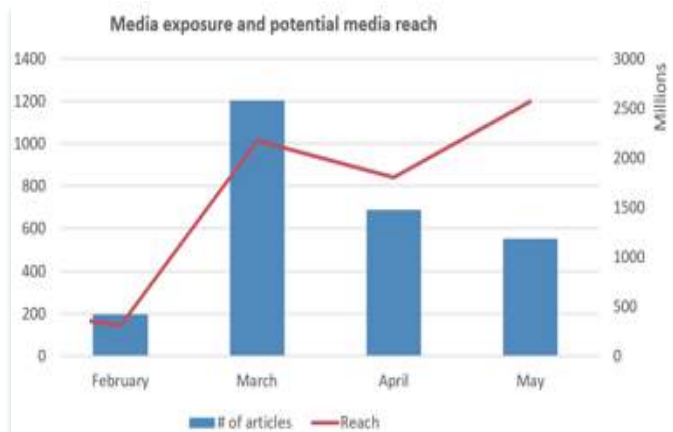


## SIX ARTICLES QUOTING PHARMA

- Will poor countries get the treatments they need?
- Coronavirus lessons for the fight against 'superbugs'
- Drugmakers race to scale up vaccine capacity
- The pandemic is moment of truth for anti-vaxxers
- Big Pharma calls for 'billions' in upfront coronavirus funding
- Coronavirus puts Big Pharma's IP regime to the test

## 7. Media Coverage (Editorial / Non-paid)

- **Articles** (Factiva) - **600%** increase (1096 articles during 01 January -11 May 2020 compared to only 157 articles same period 2019).
- **Hits** (Meltwater) - **58%** increase compared to same period 2019
- Potential reach from distribution: **2,500,000 million**
- Mainly **positive** (otherwise neutral)
- IFPMA, and member companies mentioned alongside, World Health Organization and European Union
- Top countries/regions coverage: **USA, Spain, France, China, Switzerland, UK, Germany, Mexico**



## 7. Top-Tier Media Share of Voice



- **Newswires** including Reuters, Agence France Presse, Belga, Deutsche Presse Agentur, EFE, Nominext, SDA, etc
- **International media**, including Financial Times, Wall Street Journal, New York Times, STAT News, etc..
- **Major national papers** such as Die Welt, Dunya News, FAZ, Le Figaro, El Mundo, NRC, NZZ, CGTN, Nikkei, etc
- TV/Radio: BBC, CNN, RTVE,
- **Development and health policy media:** Devex, Health Policy Watch, Kaiser Foundation, etc.
- **And pharma trade media..**



## 8. What Next?

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- May – June:
  - Virtual Walk the Talk – 16-17 May
  - ACANU (Geneva UN Press core) Media Briefing – 18 May
  - Virtual COVID-19 WHA – 18-19 May
  - Third IFPMA media briefing on vaccines – 28 May 2020
  - GAVI replenishment – 3-4 June
- UNGA – September 2020
- World Health Summit – 25-27 October 2020
- F2F WHA – Q4 2020 (TBC)



# Thank you

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Director General

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