EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Providing public health advice and communicating during a crisis

PCWP/HCPWP meeting on 2 June 2020

Presented by:
Melanie Carr, Head of Stakeholders and Communication Division
Marie-Agnes Heine, Head of Communication Department

- What has been our approach to communication during this public health crisis?
- Who are we collaborating with?
- What have we communicated about?
- Why and How have we engaged with the media?

What has been our approach to communication during this public health crisis?

EUROPEAN MEDICINES AGENCY

Aim to be: quick –accurate –credible

- Take control of communication – even if not all facts are known
- Be clear and transparent and deal proactively with complicated issues
- Communicate quickly and honestly to protect public health

COVID-19 on www.ema.europa.eu

EMA's regular updates

3 FEBRUARY: first COVID-19 publication

OVER 75 Press Releases, News Items, Public Health Communications or other updates

2 JUNE

Communication on COVID-19: behind the scenes

Weekly strategy meeting with ED and D-ED

Planning: communications log

Lines to take shared internally and across network

Streamlining communications tools and approval processes

Considering transparency principles for COVID-19 vaccines and therapeutics

Media and social media monitoring

Who are we collaborating with?

A coordinated global response to the pandemic

Within the EU we work with:

- National competent authorities in the EU Member States
- European Commission
- Health Security Committee
- ECDC and other sister agencies

Globally we work with:

- International Coalitions of Medicines Regulatory authorities (ICMRA)
- World Health Organization
- FDA, Health Canada, TGA Australia, PMDA Japan

Stakeholder engagement: critical for crisis management

Now more than ever, EMA must engage with patient and healthcare professional organisations

Stakeholder mapping, engagement methodologies, scenario-planning and impact assessment are critical elements in crisis management

Active dissemination of all EMA COVID-19 communications to EMA's stakeholders

Engagement during crisis is not an improvised task:

- requires skills and well-grounded process with defined stakeholder roles
- implement collaborative approach and monitor stakeholder opinions

EMA has proven methodologies to engage rapidly and effectively with stakeholders:

- established network of patients, healthcare professionals, academics
- voice of patients, consumers and healthcare professionals in scientific committees, working parties and task forces

Information sessions to PCWP/HCPWP*

* PCWP: Patients' and Consumers' Working Party; HCPWP: Healthcare professionals Working Party

Consultation to increase effectiveness of public health communications

Personalised service in response to queries/concerns from members of public

What have we communicated about?

What have we communicated about?

COVID-19 vaccines and therapeutics

Availability of medicines during the emergency

Public health advice

Guidance to companies

COVID-19 vaccines and therapeutics

- Overview of vaccines and therapeutics under development

- CHMP call for large-scale clinical trials

- Remdesivir: compassionate use and rolling review

Availability of medicines during the emergency

- Establishment of the EU steering group & regular updates
- Regulatory flexibility
- Launch of iSPOC system

Public health advice

- Use of (hydroxy)chloroquine to treat COVID-19

- Use of certain medicines to treat hypertension and heart failure in patients with COVID-19

- Buying medicines online

Guidance to companies

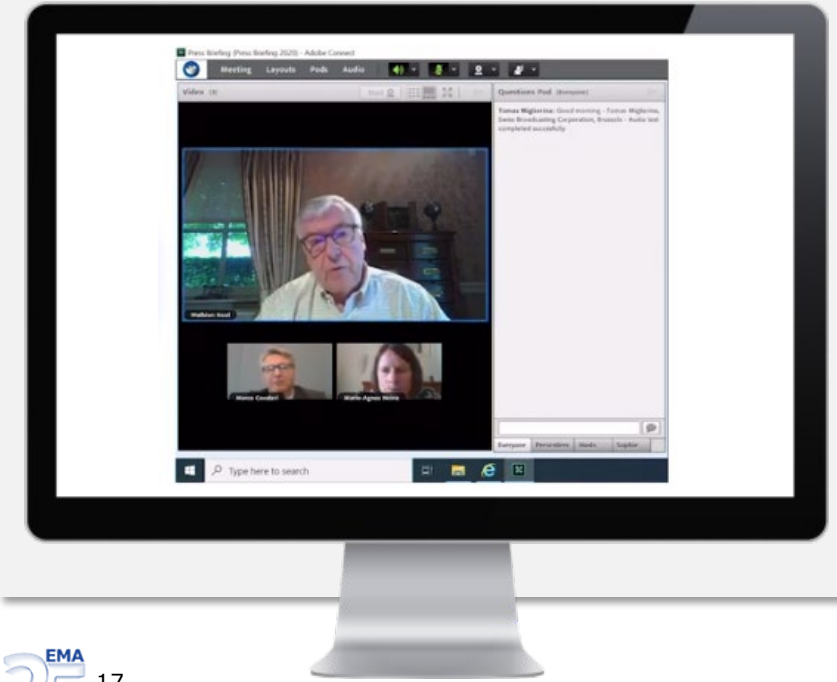
- Support tools for developers of COVID-19 vaccines and therapeutics

- Guidance how pharmaceutical companies can deal with disruptions caused by COVID-19

Why engage with the media?

*The media serve as an important **emergency information system** during a crisis and EMA has a duty to engage with them as part of an **effective crisis response**.*

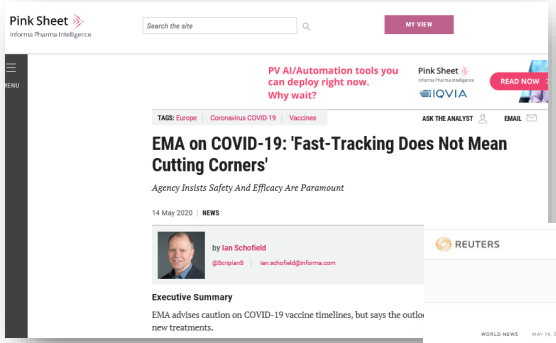
Press briefing – 14 May 2020



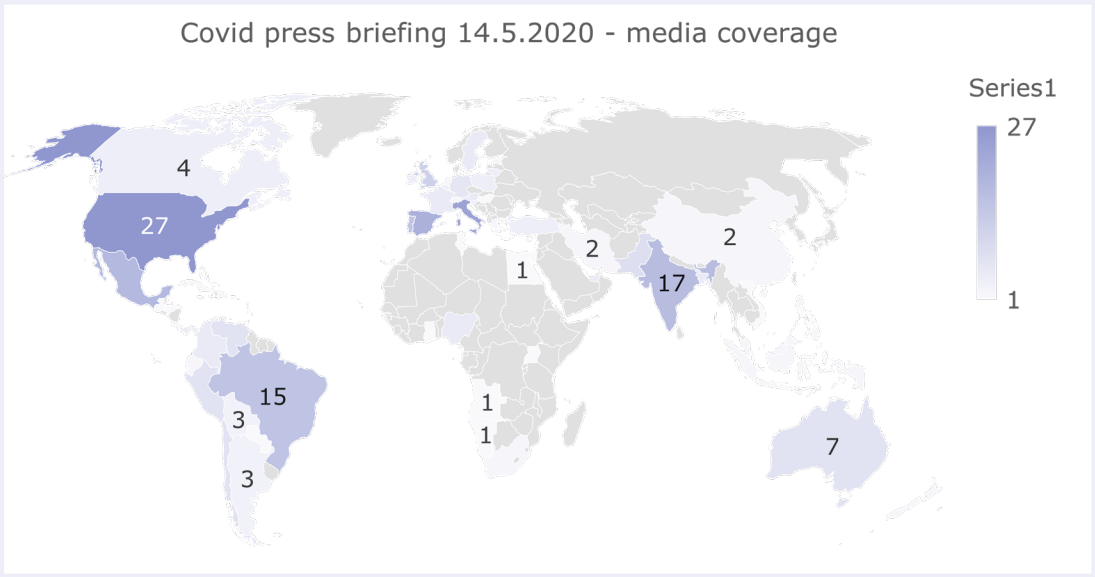
23 Journalists from news wires, large national and international newspapers and broadcasters

326 Unique articles published in the first 24 hours after the event

EMA in the news



Worldwide coverage of press briefing



Coverage by media type

News...	1
Television Station	1
Other	186
Online Version*	80
News Web Site	44
Magazine	2
Daily Newspaper	11
Blog	1

*Online version of a daily newspaper or TV

We have seen unprecedented coverage of the press briefing on the Covid-19 pandemic held on 14.5.2020.

326 unique articles all over the world were published in 24 hours after the event. Most articles were publish in USA, followed by Italy (24), Spain and Mexico (18).

The coverage was mainly about an optimistic forecast that a vaccine may be available in one year. Several newswires (Reuters, AFP) have reported on the issue.

We have seen coverage in the usual publications like APM, Pink Sheet and Politico but also in important international outlets like AlJazeera, The New York Times, Namibia Press Agency, The Times of Israel and large daily newspapers and news outlets across Europe.

On social media (Twitter & LinkedIn)

Any questions?

Further information

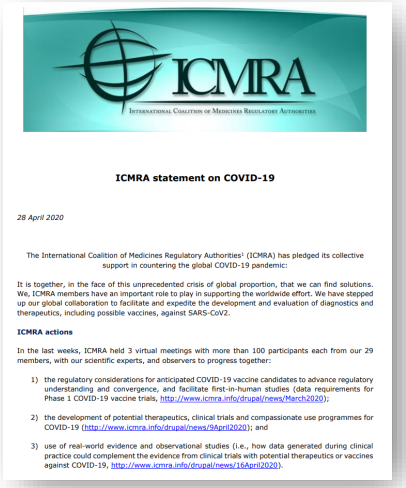
Melanie.Carr@ema.europa.eu
Marie-Agnes.Heine@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Send us a question Go to www.ema.europa.eu/contact
Telephone +31 (0)88 781 6000

Follow us on **@EMA_News**

Global collaboration in the fight against COVID-19

- International regulators pledge collective support to combat COVID-19
- Global regulatory workshops on COVID-19 medicine and vaccine development
- Bi-weekly strategic meetings on COVID-19 policies and regulatory flexibility



ICMRA

International Coalition of Medicines Regulatory Authorities

ICMRA statement on COVID-19

28 April 2020

The International Coalition of Medicines Regulatory Authorities[1] (ICMRA) has pledged its collective support in countering the global COVID-19 pandemic:

It is together, in the face of this unprecedented crisis of global proportion, that we can find solutions. We, ICMRA members have an important role to play in supporting the worldwide effort. We have stepped up our global collaboration to facilitate and expedite the development and evaluation of diagnostics and therapeutics, including possible vaccines, against SARS-CoV2.

ICMRA actions

In the last weeks, ICMRA held 3 virtual meetings with more than 100 participants each from our 29 members, with our scientific experts, and observers to progress together:

1) the regulatory considerations for anticipated COVID-19 vaccine candidates to advance regulatory understanding and convergence, and facilitate first-in-human studies (data requirements for Phase 1 COVID-19 vaccine trials, http://www.icmra.info/drupal/news/March2020);

2) the development of potential therapeutics, clinical trials and compassionate use programmes for COVID-19 (http://www.icmra.info/drupal/news/9April2020); and

3) use of real-world evidence and observational studies (i.e., how data generated during clinical practice could complement the evidence from clinical trials with potential therapeutics or vaccines against COVID-19, http://www.icmra.info/drupal/news/16April2020).

EU Medicines Agency @EMA_News · Mar 19

EMA & FDA co-chaired the first regulatory workshop on COVID-19, held under the umbrella of #ICMRA. It brought together medicines regulators & experts from WHO & the EU Commission to facilitate global collaboration on vaccine development against #COVID19.

ema.europa.eu/en/news/first-...

3 66 99

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Search

Medicines | Human regulatory | Veterinary regulatory | Committees | News & events | Partners & networks | About us

Global regulators work towards alignment on policy approaches and regulatory flexibility during COVID-19

Share

News 05/05/2020

In a high-level meeting on COVID-19 policies, organised by EMA under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA), international regulators from around the world discussed strategic issues and regulatory approaches to ensure a coordinated response to the pandemic. They stressed the need for alignment on pre- and post-authorisation regulatory requirements to facilitate the rapid development, evaluation and availability of medicines for the treatment and prevention of coronavirus disease.

The participants focused on regulatory considerations and challenges related to the development of medicines and vaccines for the prevention and treatment of COVID-19. They raised concerns about multiple small, rather than large clinical trials and stressed the need for the development of priority criteria for planned trials. In addition, they called for the inclusion of vulnerable or neglected populations, such as pregnant women, children and elderly people in COVID-19 studies. The regulators reiterated that it is crucial to align on common study protocols to ensure that the results meet regulatory requirements and allow the evidence to be used to support the approval of medicines or vaccines.

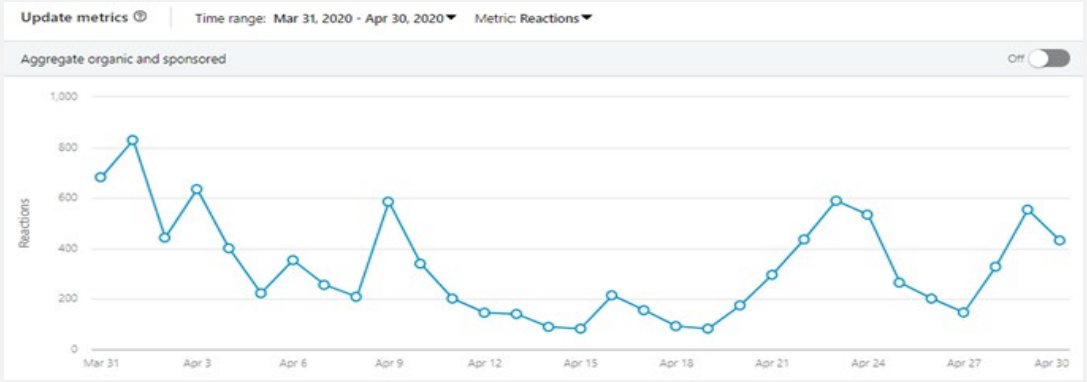
Comparative statistics Twitter (February vs April)

Due to the COVID-19-related communication, there was a 45% increase in number of impressions* in April compared to February.

More importantly, the engagement rate** more than doubled in April compared to February.

*Impressions represent the number of times content is displayed on the news feed of Twitter users, no matter if it was clicked or not.
** Twitter engagement refers to the retweets, follows, replies, favourites, and click-throughs a tweet gets. Twitter Engagement Rate is equal to EMA's tweets' engagement divided by the number of impressions those tweets have made.

Comparative statistics LinkedIn



In April, our LinkedIn followers reacted to the EMA posts 9,442 times, a 23% increase compared to the total reactions in February (7,668).