

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?





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



Advanced therapies	Coronavirus disease (COVID-19) 💷			
Biosimilars	The European Medicines Agency (EMA) is contributing to global efforts to save lives during the COVID-19 pandemic by expediting the development and approval of safe and effective			
Compliance	the COVID-12 pandamic by exploring the development and approval of size and enterine treatments and vaccines, supporting the continued availability of medicines in the European Union (EU), and providing reliable information to patients and healthcare professionals.			
Data on medicines (ISO IDMP standards)	Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus.			
Fees	On 30 January 2020, The World Health Organization (WHO) declared the outbreak a public health emergency of international concerning. On 11 Narch 2020, WHO characterised COVID-19 as a pandemic			
Medical devices	8-			
Orphan designation	There are currently no authorised vaccines or treatments in the EU to prevent or treat COVID- 19. However, there are ongoing clinical trials evaluating potential treatments.			
Paediatric medicines	The COVID-19 ENA pendemic Task Force is the main tool of ENA and the European medicines regulatory network for enabling EU Namber States and the European Commission to take quick and			
Pharmacovigliance	coordinated regulatory action during the pander			
Plasma master file (PHF) certification	Overview			
Public health threats 💦 👻				
Coronavirus disease (COVID-19) ~	What's new	Guidance for developers and companies		
What's new	Our latest updates on the COVID-19 pandemic, including our news and press releases	Regulatory mechanisms to speed up medicine and vaccine development and approval and advice on clinical trials and regulatory		
Guidance for developers and companies		expectations		
Treatments and vaccines	Treatments and vaccines for COVID-19	Availability of medicines		
Availability of medicines	Information on potential treatments and vaccines under investigation, including ongoing	EU measures to help prevent and mitigate supply disruptions and medicine shortages		
Public-health advice	dinical brials and observational studies in the EU	during the pandemic		
EMA's governance	Public-health advice	EMA's governance		
Antimicrobial resistance	Advice for patients and healthcare professionals on the safe use of medicines during the	Our governance during the COVID-19 pandemic, including the role and activities of		
Biological and chemical threats	pandemic, in particular in patients with or at risk of COVID-19 infection	the COVID-19 EMA pandemic Task Force		
Ebola				
Falsified medicines	Trusted sources of information from our EU and international partners			
Pandemic influenza	World Health Organization (WHO): Coronavirus disease (COVID-19) pandemic g			
Zika Support for early access	European Centre for Disease Provention and Control (ECDC): COVID-19/3 European Commission: Contravinus responses;			



EMA's regular updates



EMA to support development of vaccines and treatments for novel coronavirus disease (COVID-19)

Press release 04/02/2020



To contribute to the global response to the outbreak of the novel coronavirus (2019-nCoV) infections, EMA is taking concrete actions to acciderate the development and availability of <u>medicinal products</u> for the treatment and prevention of the new coronavirus. "EMA has activated its plan for managing emerging health threats," asys Guido Rati, the Apenyc's Exocutive Director. The new

coronavirus has been declared a public health emergency of international concern by the World Health Organization, and we are drawing on the strong expertise of the European medicines network to worke fast track scientific advice an dive concount emetidine devocements."

The Agency is surveying the landscape for potential antivirals or vaccines to treat or prevent novel coronavirus infections. ENA is also analysing all available information on developers' drug pipelines. As with any emerging public health threat, EMA collaborates and exchanges information with EU public health authorities, notably the European Commission (2), the Health Security Committee (2) and the European Centre for Disease

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

Engagement during crisis is not an improvised task:

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

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

EMA has proven methodologies to

established network of patients,

voice of patients, consumers and

stakeholders:

forces

engage rapidly and effectively with

healthcare professionals, academics

healthcare professionals in scientific

committees, working parties and task

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

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

CHMP call for large-scale

clinical trials

Remdesivir: compassionate

use and rolling review

COVID-19 vaccines and therapeutics

Overview of vaccines and

therapeutics under development

Availability of medicines during the emergency

Public health advice

Guidance to companies





COVID-19 vaccines and therapeutics

 Overview of vaccines and therapeutics under development

> EU Medicines Agency ② @EMA_News · Mar 31 ¶Check out EMA's update on treatments and vaccines against #COVID19 under development.

#FactsMatter: At this point, no medicine has yet demonstrated efficacy in treating COVID-19, but we are in contact with many developers.

 CHMP call for large-scale clinical trials

EU Medicines Agency @ @EMA_News · Mar 19 EMA's human medicines committee (#CHMP) urges EU research community to prioritise large randomised #ClinicalTrials as they are most likely to generate conclusive evidence for rapid development & approval of potential #COVID19 treatments: ema.europa.eu/en/news/call-p...

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• Remdesivir: compassionate use and rolling review

EU Medicines Agency @ @EMA_News · May 12 II EMA recommends expanding #remdesivir compassionate use to patients not on mechanical ventilation: ema.europa.eu/en/news/ema-re... #COVID19 #coronavirus







Availability of medicines during the emergency

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

Launch of iSPOC system

EU Medicines Agency @ @EMA_News · Apr 6 Supply of medicines is a critical concern for medicine regulators. What are the new measures taken by EU authorities to support availability of used in the #COVID19 pandemic? ¶ Check out our communication: ema.europa.eu/en/news/eu-aut...



EU Medicines Agency @ @EMA_News · May 4 .@EU_Commission, EMA & national competent authorities have issued guidance on regulatory flexibility to ensure availability of #veterinary medicines @during #COVID19: ______eme.europa.eu/en/news/regula...









Public health advice

 Use of (hydroxy)chloroquine to treat COVID-19

EU Medicines Agency @ @EMA_News · 5m II EMA is reminding #HealthcareProfessionals to closely monitor patients with #COVID19 who are receiving #chloroquine or #hydroxychloroquine, given the serious side effects that can result from treatment with these medicines.

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



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

EU Medicines Agency @ @EMA_News · Mar 18 What is EMA's advice on the use of non-steroidal anti-inflammatories like #ibuprofen for #COVID19? #NSAIDs #SafetyOfMedicines @rema.europa.eu/en/news/ema-gi...



· Buying medicines online

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EU Medicines Agency @ @EMA_News · Mar 24 EMA advice: II Do not buy medicines from unauthorised websites and other vendors aiming to exploit fears and concerns during the #COVID19 pandemic, #SafetyOMedicines

fema.europa.eu/en/news/covid-...







Guidance to companies

 Support tools for developers of COVID-19 vaccines and therapeutics



EU Medicines Agency @ @EMA_News · Mar 13 #COVID19: developers of medicines or vaccines will benefit from free scientific advice: ema.europa.eu/en/news/covid-...



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



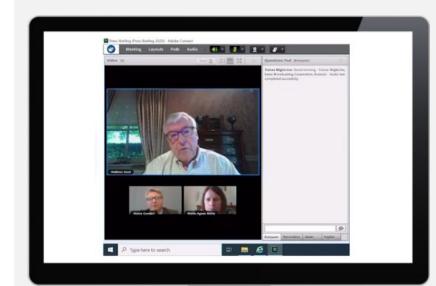


Why engage with the media?

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





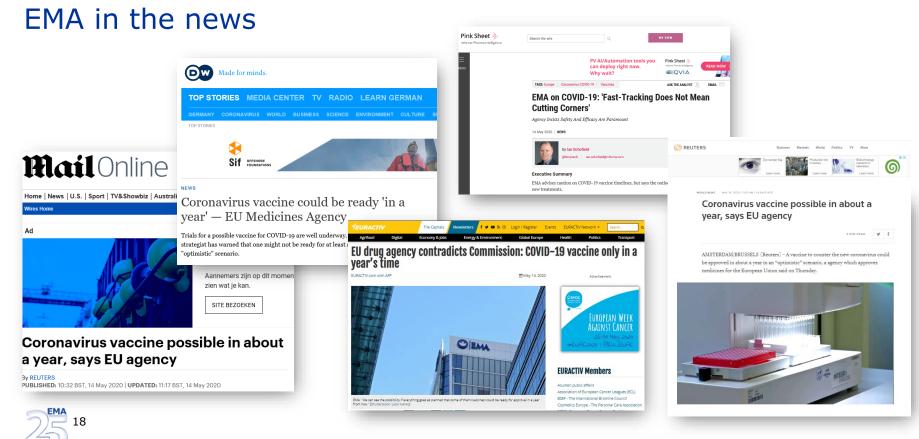
23 Journalists Included and wires, large national and Journalists from news international newspapers and broadcasters



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

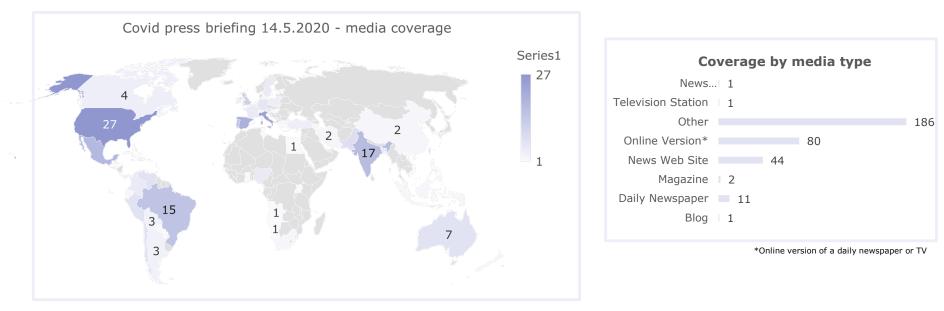








Worldwide coverage of press briefing



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.





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On social media (Twitter & LinkedIn)



1 Comment

Any questions?



Further information

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Global collaboration in the fight against COVID-19

 International regulators pledge collective support to combat COVID-19



ICMRA statement on COVID-19

28 April 2020

The International Coalition of Medicines Regulatory Authorities¹ (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 threapeutics, 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:

- 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, <u>http://www.icmra.info/drupal/news/Nach2020</u>);
- the development of potential therapeutics, clinical trials and compassionate use programmes for COVID-19 (<u>http://www.icmra.info/drupal/news/9April2020</u>); and
- 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.icma.info/drupal/wexs/16April2020).

- Global regulatory workshops on COVID-19 medicine and vaccine development
- Bi-weekly strategic meetings on COVID-19 policies and regulatory flexibility

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-...





Global regulators work towards alignment on policy approaches and regulatory flexibility during COVID-19 $\eqref{constraint}$

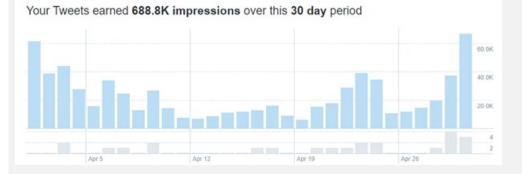
News 05/05/2020

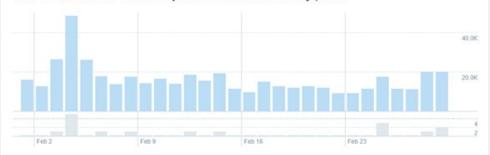
In a high-level meeting on COVID-19 policies, organised by EMA under the unbrella of the International Caalition of Medicines Regulatory Authorities (ICMRA), international regulators from around the world discussed strategic issues and regulatory approaches to ensure a coordinated response to the pandemic. 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 corrorativita disease.

The participants focused on regulatory considerations and challenges related to the development of medicines and vaccines for the prevention and treatment of COVID-10. They raised concerns about multiples multi, rather than large <u>clinical trials</u> and stressed the need for the development of priority criteria for planned trials. In addition, they called for the inclusion of vulnerable or neglicted populations, such as pregnant women, childrian and eldery people in COVID-15 dudies. The regulatory requirements and allow the evidence to be used to support the approval of medicines or accines.



Comparative statistics Twitter (February vs April)





Your Tweets earned 475.0K impressions over this 29 day period

23

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

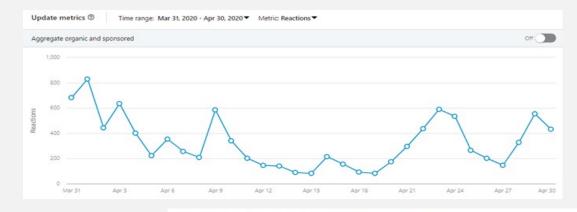
More importantly, the engagement rate** more than doubled in April compared to February.

*Impressions represent the number of times content is displayed on the news feed of Twitter users, no matter if it was clicked or not.

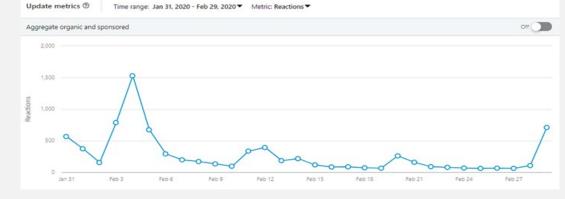
** Twitter engagement refers to the retweets, follows, replies, favourites, and click-throughs a tweet gets. Twitter Engagement Rate is equal to EMA's tweets' engagement divided by the number of impressions those tweets have made.



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).



Classified as public by the European Medicines Agency



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