Let's Talk About Vaccination

The launch of a new Patient Guide to fill in the information and awareness gap

Virtual event 14 January 2021







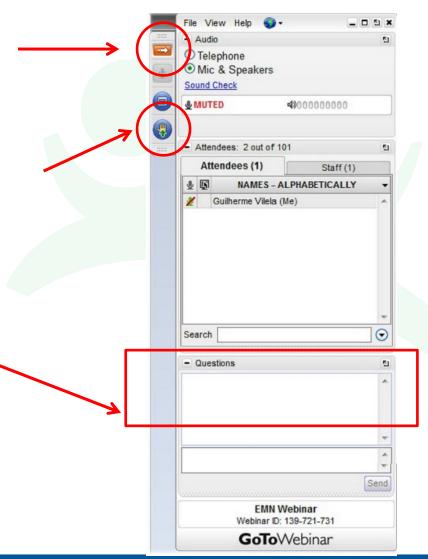
House keeping rules



Do you want to minimise the control panel?

Do you have any questions?

You can leave your comments or questions in this chat box. They will be visible to presenters and organisers only.



Event Agenda



15:00-15:10	Opening
	Marco Greco, President, European Patients' Forum (EPF)
15:10-15:40	Keynote speech Noël Wathion, Deputy Executive Director, European Medicines Agency (EMA)
15:40-16:10	Presentation of Patient Guide 'Let's Talk about Vaccination'
	Kaisa Immonen, EPF's Policy Director
16:10-16:25	Q&A
	Moderated by Marco Greco, President, EPF
	Keynote speech
16:25-16:55	Isabel de la Mata, Principal Advisor for Health and Crisis management European Commission
16:55-17:00	Closing remarks
	Marco Greco, President

Opening Remarks

Marco Greco President EPF

Virtual event 14 January 2021







Participation Certificates



If anyone requires a proof of participation for this event, kindly email our Communications Manager Dante Di Iulio for a certificate.

Dante.diiulio@eu-patient.eu

Keynote Speech

Noël Wathion

Deputy Executive Director

European Medicines Agency (EMA)

Virtual event 14 January 2021









Vaccine confidence in times of COVID-19

Noël Wathion
Deputy Executive Director, European Medicines Agency

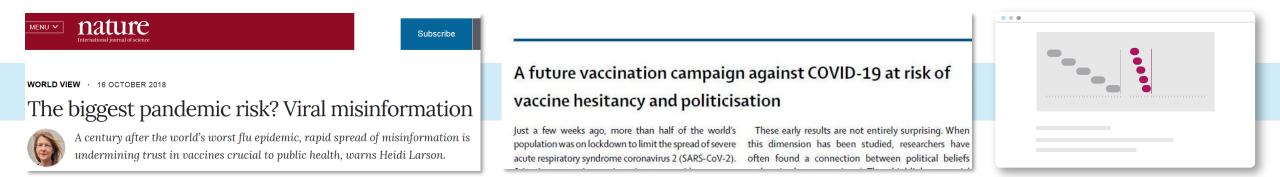


Outline

- Vaccine hesitancy: an ongoing challenge in times of COVID-19
- EMA's vaccine outreach strategy
- Progress on actions from vaccines outreach strategy
- Engaging patient and healthcare professional representatives
- Provision of information on COVID-19 vaccines
- New information materials on COVID-19 vaccines
- Information on studies needed for approval of COVID-19 vaccines
- EMA's extraordinary transparency for COVID-19 medicines
- Conclusions



Vaccine hesitancy: an ongoing challenge in times of COVID-19



- High scepticism on vaccines and safety measles outbreaks
- Global public health threat: bad science rumour 'spreaders' general misinformation

COVID-19 pandemic – additional complexity

- New types of vaccines
- Fast track development and approval
- COVID-19 denialism



EMA's vaccine outreach strategy

In this context it is imperative:

- to listen and understand public concerns on vaccines and vaccination
- that information from reliable sources addresses the need and concerns and supports informed decisions on vaccination

EMA is putting resources and efforts in this direction and welcomes EPF's work to also address this need.





EMA's vaccine outreach strategy

Goal

Increase knowledge of and trust in the quality, safety and effectiveness of vaccines, and empower the EU public and healthcare professionals to take well-informed vaccination decisions

Basis for EMA's work on COVID-19 vaccines





EMA's vaccine outreach strategy

Objectives

- Monitoring & analysis of vaccine concerns
- Science outreach activities
- Collaborate with ongoing initiatives to improve information on vaccines
- Strengthen strategic collaboration with EU & international partners
- Expand evidence on the safety and effectiveness of vaccines, promote research and engagement





Progress on actions from vaccines outreach strategy



- Engagement with EU patients', consumers' and healthcare professionals' organisations
 - Supporting EPF efforts on informing the public on vaccination
- Analysis of public concerns on COVID-19 vaccines
- New information materials on COVID-19 vaccines
- Communication on procedures for COVID-19 vaccines
- Transparency aspects for COVID-19 vaccines
- Contribution to European Vaccination Information Portal content



Engaging patient and healthcare professional representatives

EMA engages with patients and healthcare professionals throughout the medicines regulatory life-cycle

EMA has:

- Proven methodologies to engage effectively, broadly and rapidly with its stakeholders
- Established network of patients and healthcare professionals to involve in discussions and actions and to respond quickly to their needs and to those of the EU regulatory network
- Platforms for exchange of information with organisations: Patients and Consumers Working Party (PCWP)
 / Healthcare Professional Working Party (HCPWP)

Added value has been well demonstrated



Engaging patient and healthcare professional representatives

In a crisis context, engagement with patients and healthcare professionals is more important than ever

- Voices of civil society in scientific committees
- Patient and healthcare professional representatives in EMA COVID-19 Taskforce
- EMAs COVID-19 communications reviewed by patients/healthcare professionals
- Patients and Healthcare professionals disseminate EMAs COVID-19 communications to their communities
- Regular updates on COVID-19 pandemic to PCWP and HCPWP
- EMA responds to queries and concerns from general public



ENGAGING THE PUBLIC

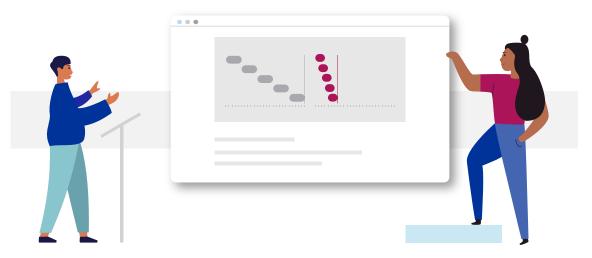
EMA Public stakeholder meetings

11 December 2020

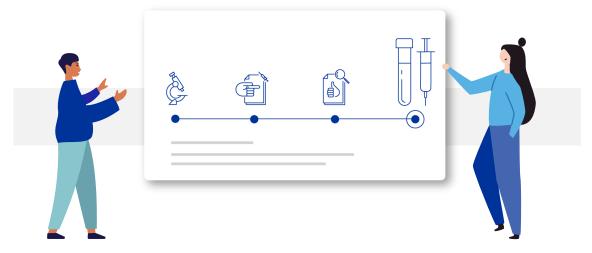
BROADCAST LIVE

8 January 2021

BROADCAST LIVE



Inform the public and stakeholders about EU regulatory process for approval of COVID-19 vaccines and EMA's role in their development, evaluation and approval



Explain the basis for the approval and use of new vaccines, how their safety will be monitored and their roll-out at national level

Listen to the public and stakeholder groups on their needs, expectations and any concerns, so that these can be considered in the relevant regulatory processes.



Engaging patient and healthcare professional representatives

Added value

- Gather critical input into crisis-related activities in the context of COVID-19
- Support specific considerations, such as discussions on vaccines, associated social challenges, vaccine deployment, vaccine hesitancy, etc
- Channel public health messages directly to patients, healthcare professionals and citizens
- Reinforces legitimacy of actions and trust in the scientific outcomes and the EU system





Engaging patient and healthcare professional representatives

Supporting European Patients' Forum activities on vaccination information

- EPF initiative is essential to provide information on vaccination to patients with chronic conditions
- EPF guide consolidates practical guidance and fulfils a need for information for people with chronic conditions to make an informed decision about vaccination
- EMA contributed in an Expert Advisory Group on an EPF project funded by EU:
 - Vaccination Confidence Patients' and Professionals' Awareness, Communication and Trust (VAC-PACT) project to improving uptake and confidence in vaccines for patients with chronic diseases



Provision of information on COVID-19 vaccines

How are we communicating?

- New information on development & approval of COVID-19
 vaccines specifically targeting the general public
- Responding to queries from members of the public and media
- Press, public meetings & social media on key developments
- Media interviews with experts
- Providing content for <u>European Vaccination Information Portal</u> and supporting the European Commission
- EMA/Member States' safety communications





New information materials on COVID-19 vaccines

https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-diseasecovid-19/treatments-vaccines/covid-19-vaccines-key-facts



COVID-19 vaccines: key facts share



Table of contents

- Why are vaccines to prevent COVID-19 urgently needed?
- Is there a vaccine to protect against COVID-19?
- What process and methods are being used to develop and approve COVID-19 vaccines?
- · Why did development only start after the pandemic was declared?
- When will the vaccines be approved?
- What type and amount of data is needed for approving a safe and effective vaccine?
- How long will immunity from a vaccine last?
- Will vaccines protect vaccinated people if the virus mutates?

There are currently no authorised vaccines for COVID-19 in the European Union (EU). The European Medicines Agency (EMA) is liaising closely with developers of potential COVID-19 vaccines, mobilising its own resources and cooperating with regulatory partners, to ensure safe and effective vaccines reach patients as soon as possible.

Published √

- Questions and answers format
- General public
- Addresses commonly received questions



New information materials on COVID-19 vaccines

https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-development-evaluation-approval-monitoring

COVID-19

COVID-19 vaccines: development, evaluation, approval and monitoring share

Table of contents

- Development
- · Scientific evaluation and approval
- · Monitoring vaccine safety and use in real life

The European Medicines Agency (EMA) plays an important role in enabling the development, scientific evaluation, approval and monitoring of COVID-19 vaccines in the European Union (EU).

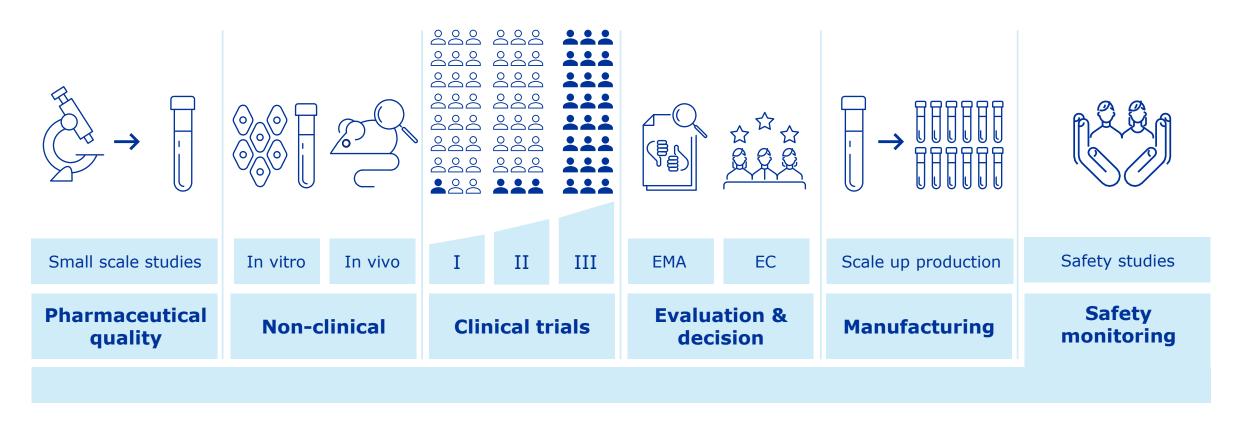
Vaccines for COVID-19 are being developed, evaluated and approved according to current regulatory guidelines and legal requirements.

Published √

- More detailed information on how COVID-19 vaccines are developed, evaluated, approved and monitored post-marketing
- Professional audiences and general public
- Addresses commonly received questions
- Graphics to illustrate concepts

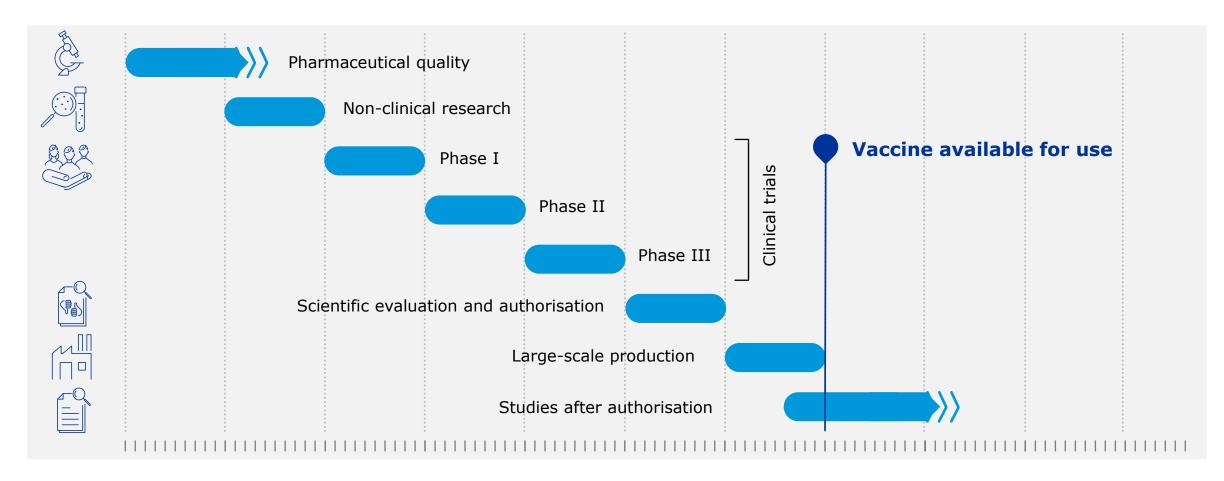


Covid-19 vaccine development, evaluation, approval and monitoring - Overview



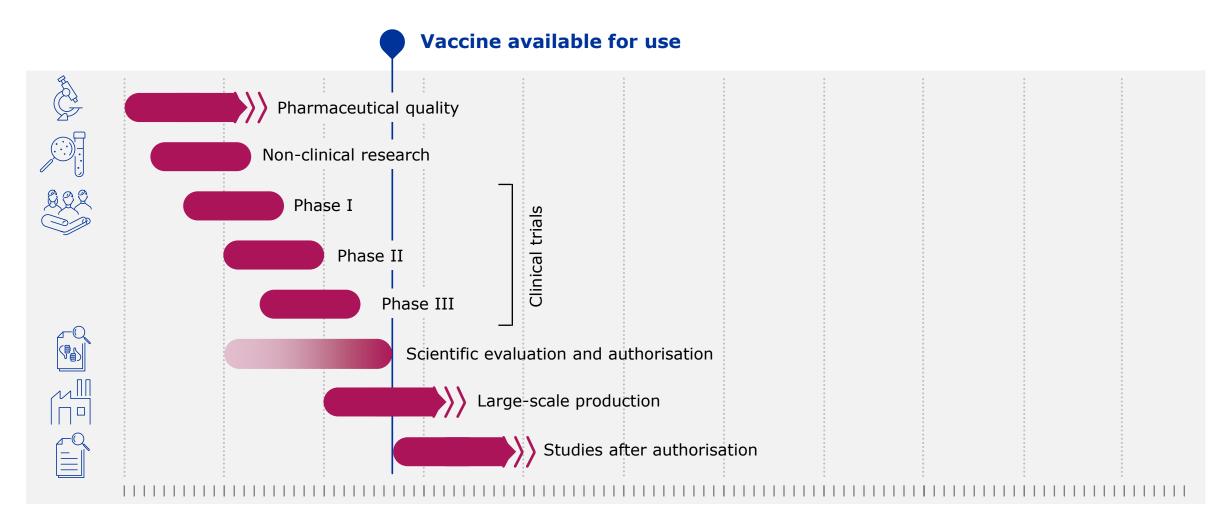


Standard vaccines compared with covid-19 vaccines





Standard vaccines compared with covid-19 vaccines





Rapid approval processes in the EU

Early support for vaccine developers:

EMA provides scientific advice and a dedicated Task Force (COVID-ETF)





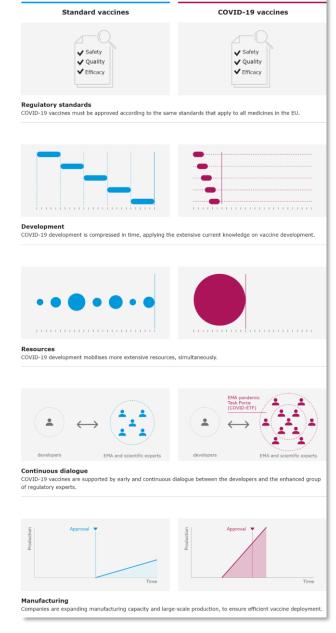
Explaining regulatory standards will be maintained

Same requirements for pharmaceutical quality, safety and efficacy as other medicines in the EU

subject to scientific evaluation

Speed of development and approval is much faster due to the public health emergency

- development is compressed in time
- simultaneous mobilisation of human resources EMA Task Force
- combining clinical trial phases or conducting some studies in parallel, instead of carrying them out sequentially - where safe to do so



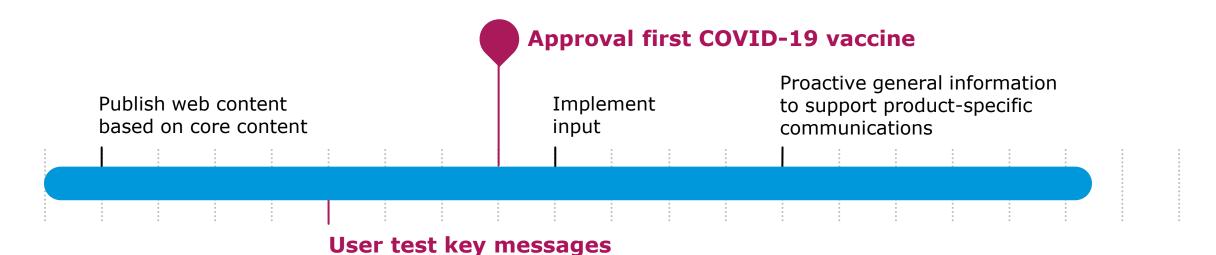


User testing

Ongoing √

- User-testing of key messages/graphics
- Consulting on best channels/tools
- Patients, consumers, healthcare professionals and learned societies

and graphics





Information on studies needed for approval of COVID-19 vaccines

https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-diseasecovid-19/treatments-vaccines/covid-19-vaccines-studies-approval



COVID-19 vaccines: studies for approval share



Table of contents

- What types of studies are needed to approve a COVID-19 vaccine?
- What are efficacy studies?
- How is the efficacy of COVID-19 vaccines studied?
- How many participants take part in efficacy studies and for how long?
- What is the level of efficacy that can be accepted for approval?
- Which benefits might not be known when a COVID-19 vaccine is initially approved?
- How is safety studied before approval?
- What data have to be provided for special populations and age groups?
- · What studies are needed after approval?
- How are clinical studies carried out in other parts of the world?

The European Medicines Agency (EMA) needs many detailed studies to confirm that a vaccine is safe, provides adequate protection and is of suitable quality. As a public-health body safeguarding medicines in the European Union (EU), EMA will only approve a vaccine for COVID-19 after a thorough evalutation demonstrating the same high standards of quality,

Published √

- Pharmaceutical quality, non-clinical and clinical studies
- Focus on clinical aspects, e.g.:
 - Efficacy levels for approval:
 - Uncertainties on long term benefits when vaccines first approved
- Includes safety studies before and after approval

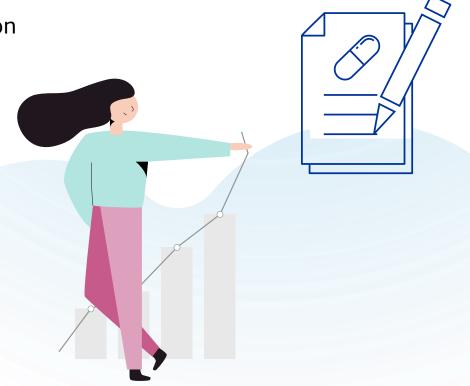


Enhanced transparency for COVID-19 vaccines

What information is being published?

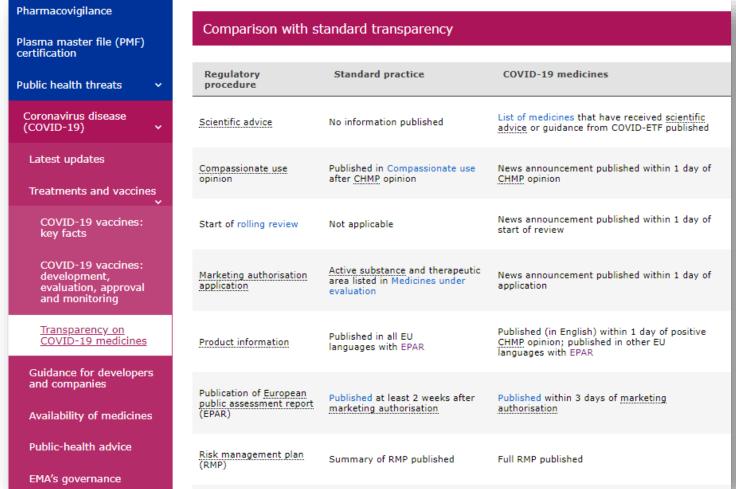
- Medicines that have received EMA advice during their development
- Committee meetings highlights, minutes and agendas
- Start of rolling review and applications for marketing authorisation
- Product information (all EU languages)
- An overview of the vaccine and why it is approved in plain language (all EU languages)
- European Public Assessment Report
- Full Risk Management Plan
- Clinical data supporting marketing authorisation
- Changes post-authorisation and regular safety updates





EMA's extraordinary transparency for COVID-19 medicines

Transparency for COVID-19 medicines vs standard practice





Conclusions

- More than ever, reliable information, good communication and transparency on vaccines remain priorities
- The public needs to be able to access data and understand the rationale behind important decisions on vaccines
- Transparency requires extra effort to communicate better, put the data into context and explain the science in plain language
- Efforts by patients to support dialogue on vaccines are key
- Engagement remains crucial:
 - actively listening to the public and our stakeholders
 - involving them in our activities





Latest updates on EMA's corporate website: COVID-19 pandemic





ema.europa.eu



@EMA News



European Medicines Agency





Presentation of Patient Guide 'Let's Talk about Vaccination'

Kaisa Immonen
Policy Director
EPF

Virtual event 14 January 2021







In this presentation



- 1. Acknowledgments
- 2. About EPF
- 3. EPF's engagement on vaccination
- 4. About the guide

Acknowledgments and thanks



Ruth Wilson / Person Before Patient

Dr Hanne Nøkleby / Norwegian Institute of Public Health

Rosa Gonzalez-Quevedo / European Medicines Agency

Vaccines Europe for the unrestricted grant that enabled this work

Our dedicated advisory group of patient advocates:

Saskya Appelman, Autoinflammatory Alliance (NL)

Konstantina Brousa, Panhellenic Association for Patients with

Autoimmune Rheumatic Disease (EL)

Ovidiu Covaciu, independent patient advocate (RO)

Ricardo Fonseca, Nat'l Association Against Fibromyalgia and CFS (PT)

Vera Gomes, Inflammatory Bowel Diseases (PT)

Tunde Koltai, HAPO the Hungarian National Patient Coalition (HU)

Filipa Monteiro, Portuguese Multiple Sclerosis Society (PT)

Helga Ovens, Lupus Europe (UK)

Annemarie Sluijmers, Lupus Europe (NL)

Thomas Smith, independent patient advocate (UK)

Plamen Taushanov & Reneta Ilieva, Association for Patients' Defence (BG)

About the European Patients' Forum



- Independent, non-governmental umbrella organisation
- Founded in 2003
- 75 national coalitions & EU disease-specific organisations

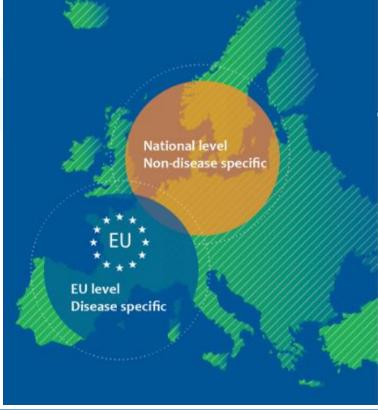


A Europe where patient organisations are valued partners in creating equitable, person-centred, accessible, and sustainable healthcare systems, based on patients' unique expertise

Our mission

To advance the interests of patients and patients' communities by strengthening their collective impact across Europe through effective advocacy, education, empowerment and partnership



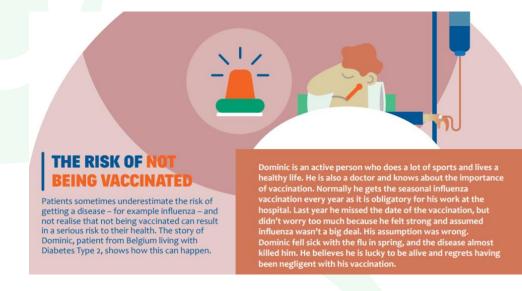


Why vaccination matters for patients



Patients are more vulnerable than baseline-healthy people

- Underlying health condition increased risk of vaccine-preventable diseases
- Some patients may not have all kinds of vaccines
- Some patients cannot be vaccinated at all ... so general vaccination coverage matters even more
- Take up of recommended vaccinations by patients is not optimal for various reasons
- Little data specifically in chronic disease groups



"We are no longer used to seeing infectious diseases ... so we are no longer afraid [of them]."

– Valentina, 44, Diabetes T1

Vaccination as an EU policy priority

- 2017: Commission President Juncker mentioned equal access to vaccines as specific priority in the State of the EU address – in line with EU objectives on reducing the burden of chronic diseases
- 2018: Commission Communication and Council Recommendation on Strengthened Co-operation against Vaccine-Preventable Diseases
- 2018: European Parliament Resolution on Vaccine hesitancy and the drop in vaccination rates in Europe
- 2018: EU Joint Action (EU-JAV) kicked off with 20 Member States + stakeholders







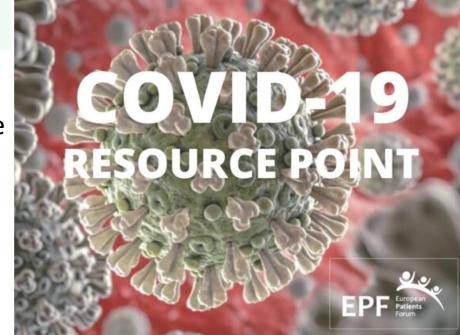
COVID-19 – vaccination becomes urgent



- Safe and effective vaccines against coronavirus are key to control of the pandemic in the long term
- Need to develop and approve vaccines in "record time" –
 while keeping same high level of safety and efficacy
- Need to address hesitancy and misinformation, and foster public trust
- EPF actively engages with and participates in activities of the EMA regarding vaccines approval-related public health communication + with the European Commission → EPF regularly provides information updates to our members







EPF – vaccination from the perspective of patients



EPF aims to support patients, patient organisations and

advocates

- Patient survey (2018)
- Report
- Communication resources and tools
 - Video with patient stories
 - Background report
 - Fact sheets
 - PPT presentation
- 4. Three national workshops (Romania, Germany)
- 5. Manifesto



We call for action to improve patients' access to vaccination; provision of evidencebased, lay-friendly information on vaccination for patients; and involvement of patient organisations in shaping policies, programmes and actions on vaccination at national and European levels.

- Robust, evidence-based information that enables people to understand and contextualise the benefits and risks of vaccination should be made available, specifically for patients with different chronic conditions. Information should be co-developed with patients. Ideally it should be available through a 'one-stop' EU-level online portal
- 2. Vaccination should be included as a part of chronic disease management plans and clinical
- Healthcare professionals should incorporate routine assessment of their adult patients' vaccination needs during all clinical encounters to ensure that patients are aware of the recommendations for needed vaccines and are either offered these vaccines or referred for
- In countries where patients hold a social
- Healthcare professionals should be trained the relevant scientific facts to help then

ORGANIZAȚIILE DE PACIENȚI POT CONTRIBUI LA CREȘTEREA RATEI VACCINĂRII

IMPORTANT THAT MOST

RE VACCINATED?

Organizațiile de pacienți sunt sursele principale de informare ale pacientilor cu privire la vaccinare. Acestea pot sprijini și coordona campanii naționale și internaționale de conștientizare asupra eficienței și

Pot distribui informații științifice, verificate și experiențe ale pacienților, contracarând mituri și dezinformări, abordând ezitarea privind vaccinarea în cadrul comunităților de pacienți. Organizațiile de pacienți doresc să lucreze cu profesioniștii din Sănătate pentru a informa mai bine adultii cu boli cronice cu privire la vaccinare.

WITH CHRONIC DITIONS **S VACCINATION** nesses. The term originates in v). The first vaccinations used a pox, to produce immunity ous disease, smallpox, xist to prevent a great number cinal products that contain d forms of the disease-causing n to get the body's defensive nd produce immunity, but

80%

VACCINATION FOR PATIENTS

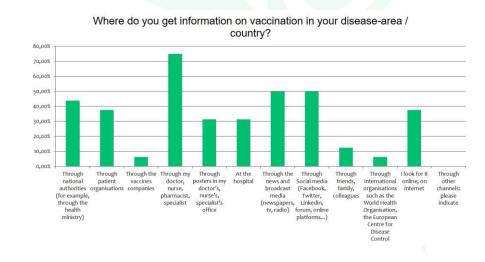
Există un nivel ridicat de vaccinare în populația HIV/SIDA, datorită, în parte, sentimentului puternic al comunității în care pacienții vorbesc

What we found during our work *



Patients perceived an information gap

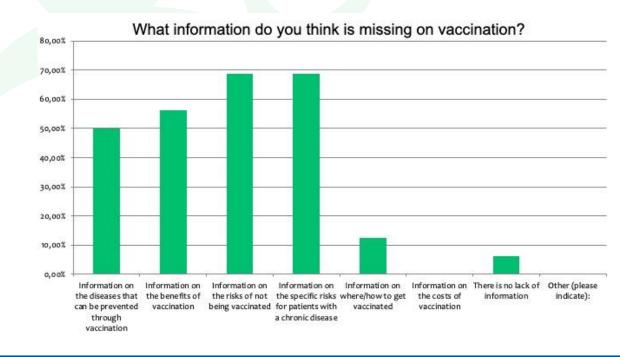
- Lack of information on vaccination for specific chronic conditions
- Good information not easy to find on the Internet
- Low engagement in patient community though some interest
- Health professionals key providers of information generally trusted – but patients do not always get enough information from them
- Sometimes patients get contradictory information from different professionals
- Hesitancy was seen as a problem in various countries



What information patients want



- Comprehensive, reliable, patient-friendly
- Disease-specific information on vaccination
- Information on benefits and risks of vaccines communicated in a careful way that lay person can understand and relate – in context and balanced with other risks (e.g. risks of diseases, risk of not vaccinating)
- **COVID-19** is resulting in new information needs – EPF works with our members to identify and address these



Patient organisations play an important role



- Top source of information on vaccination for patients
- Can support and coordinate national and international awareness campaigns
- Can share scientific, evidence-based information
- Can share patient experiences on why it matters to vaccinate
- Can help counter myths and mis-information and address vaccine hesitancy in patient communities and among the public
- Would like to work with professionals more to inform and share knowledge on vaccination for patients

"There is a high level of vaccination in the HIV/AIDS population, thanks, in part, to the strong sense of community in which patients speak and share among themselves, including on the importance of vaccination."

Peter, HIV-AIDS advocate, Germany



... This is why we developed our Guide:

'Let's Talk About Vaccination' –

for patients and patient advocates

EPF guide: what it is and who it is for



- Based on insights from previous work, developed in collaboration with Person Before Patient
- Patient advisory group representing a variety of chronic conditions and countries engaged online and once in physical workshop to identify needs and shape content
- → What do I need to know to make better informed decisions about vaccination?
- → How can I have better conversations about vaccination?
- A tool patient advocates can use individually, in conversation with others, and in advocacy
- Can be useful to all who wish to strengthen their knowledge and confidence on vaccination

THE ART OF CONVERSATION

LET'S TALK ABOUT VACCINATION

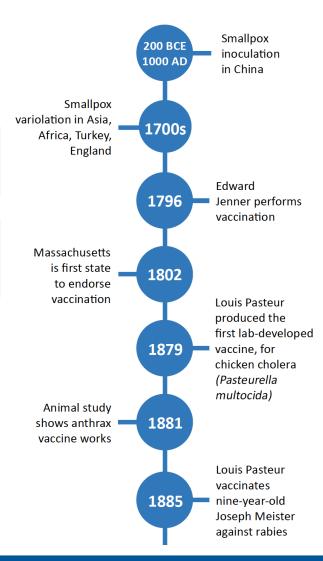


Inside the guide



Part 1: Information about vaccination and immunity

- The history of vaccines and different types of vaccines
- How vaccines work and how immunity works
- How vaccines are developed and approved step-by-step
- How their quality, efficacy and safety is ensured in the EU
- Basic information for patients with chronic conditions (Nb. NOT medical advice)
- Discussion of risks in context and explanation of adjuvants
- Brief info on COVID-19 vaccines and links to up-to-date information from EMA
- List of trustworthy information sources online



Inside the guide



Part 2: Conversation guide

- Why it is sometimes difficult to talk about vaccination
- How to reframe a conversation
- How to focus on other person's concerns
- Understanding, engaging not blaming
- Some practical tips
- Patient voices can change the conversation links to powerful testimonials



Conclusion

EPF European Patients Forum

We hope you enjoy the guide

Please let us have feedback on how you have used it, and how we can improve it further

Thank you!



Q&A

Moderator: Marco Greco

Virtual event 14 January 2021







Keynote Speech

Isabel de la Mata
Principal Advisor for Health and Crisis management
European Commission

Virtual event 14 January 2021







Closing Remarks

Marco Greco President EPF

Virtual event 14 January 2021







SAVE THE DATE – 28 JAN 2021 (15:00-16:15 CET)



A virtual event on all things related to the **COVID-19 vaccines**.

EPF Special Advisor **Nicola Bedlington** will moderate a lively discussion with:

- Prof. Jean-Michel Dogne, Member of WHO Global Advisory Committee on Vaccine Safety,
- Prof. Guido Rasi, former
 Executive Director of
 European Medicines Agency
 (EMA) and;
- Marco Greco, President of European Patients' Forum.



THANK YOU FOR YOUR ATTENTION!

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