



ISPOR Europe 2021 Plenary 2

***Lessons Learned from
EU Collaboration Efforts
During the Pandemic –
The End or the Beginning?
From Vaccines to Orphans and Gene Therapies***

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Lessons Learned from EU Collaboration Efforts During the Pandemic – The End or the Beginning? From Vaccines to Orphans and Gene Therapies



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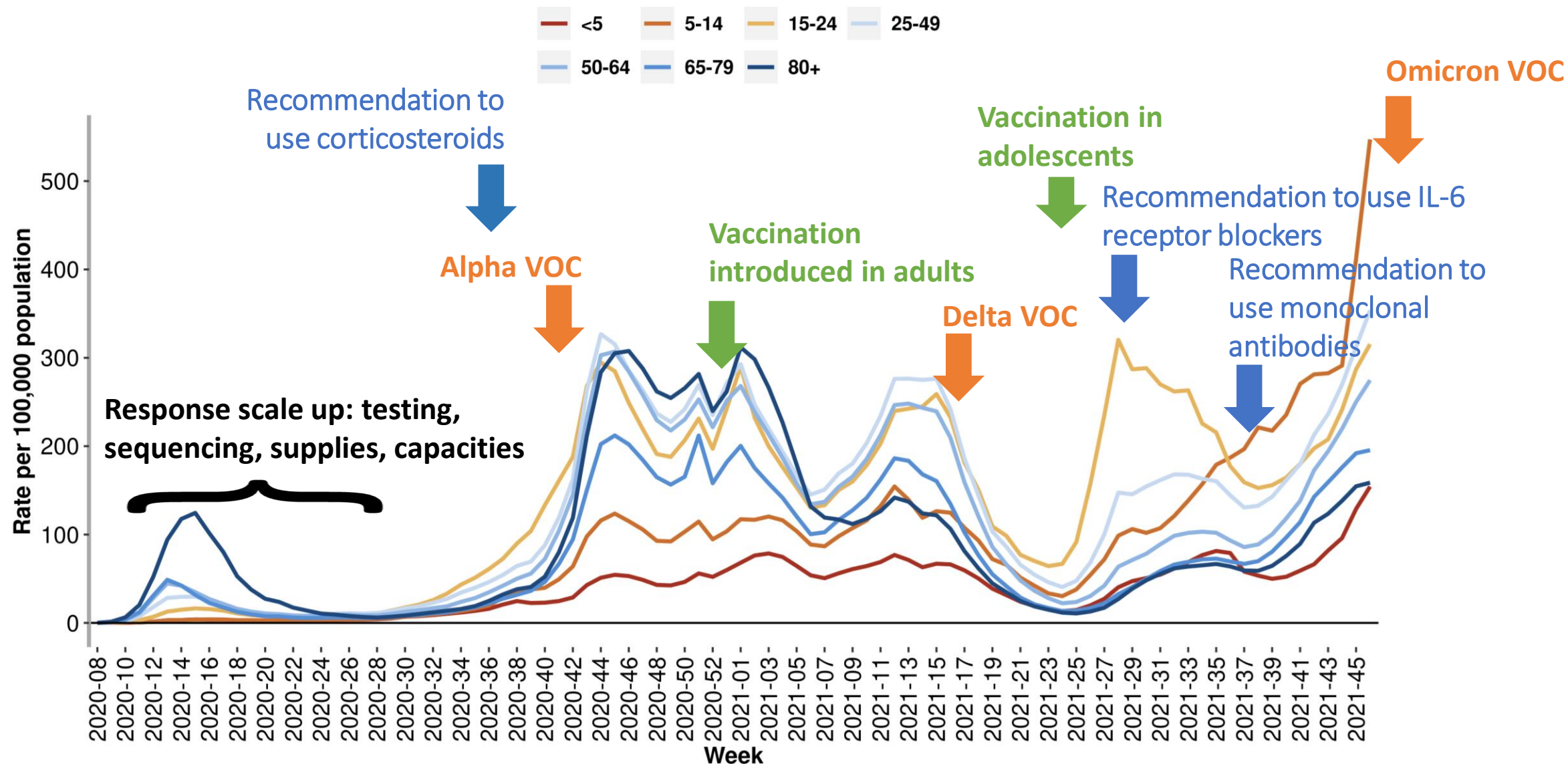
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WHO EURO COVID-19 Incident Management Support Team

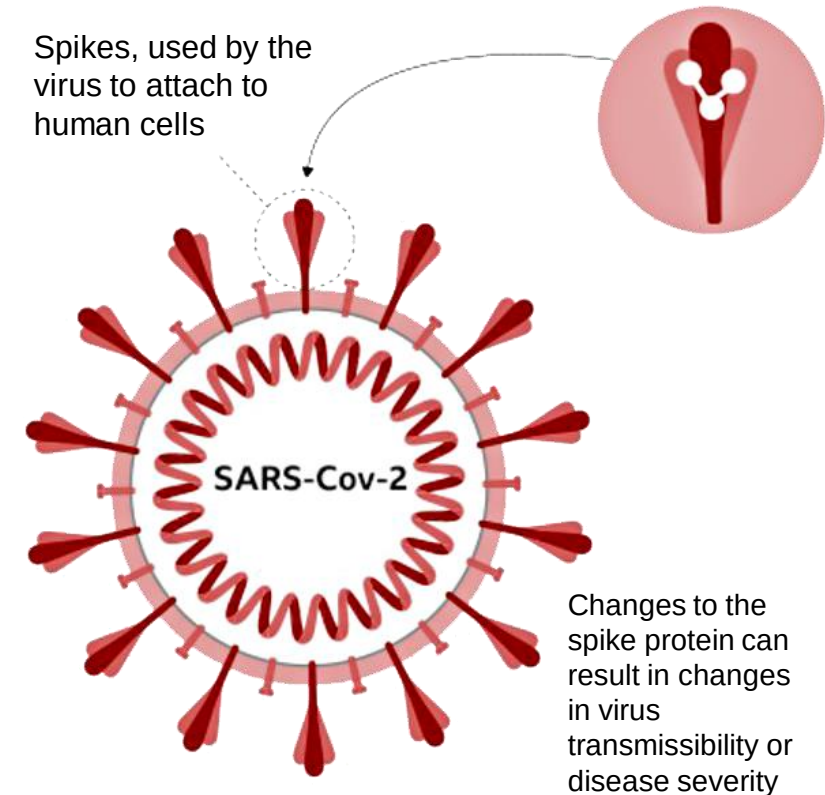
www.euro.who.int

Europe – the pandemic over time



Europe – current situation

- ➔ **Rapid rise in case incidence across European region driven by:**
 - High population susceptibility particularly in children/young adults due to varying rates of prior infection; vaccine uptake and vaccine waning
 - Replacement by more transmissible Delta variant
 - Relaxation of PHSM/change in behavior
- ➔ **Rapid rise in severe disease, particularly in Eastern part of region:**
 - High rates of population transmission
 - Low vaccine uptake in vulnerable populations
- ➔ **Public Health Response needed:**
 - Reduce transmission now – strengthen PHSM
 - Increase vaccination of priority groups
 - Strengthen health care system



Europe is Delta dominant now,
but will the future be Omicron?



THANK YOU

HEALTH
EMERGENCIES

programme



Andrzej Rys, MD
European Commission
Brussels, Belgium

Virtual

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NO SLIDES FOR THIS PRESENTER



Francis Arickx, PharmD

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*Lessons Learned from EU Collaboration
Efforts During the Pandemic – The End or
the Beginning? From Vaccines to Orphans
and Gene Therapies*

and (missed) opportunities

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Joined HTA

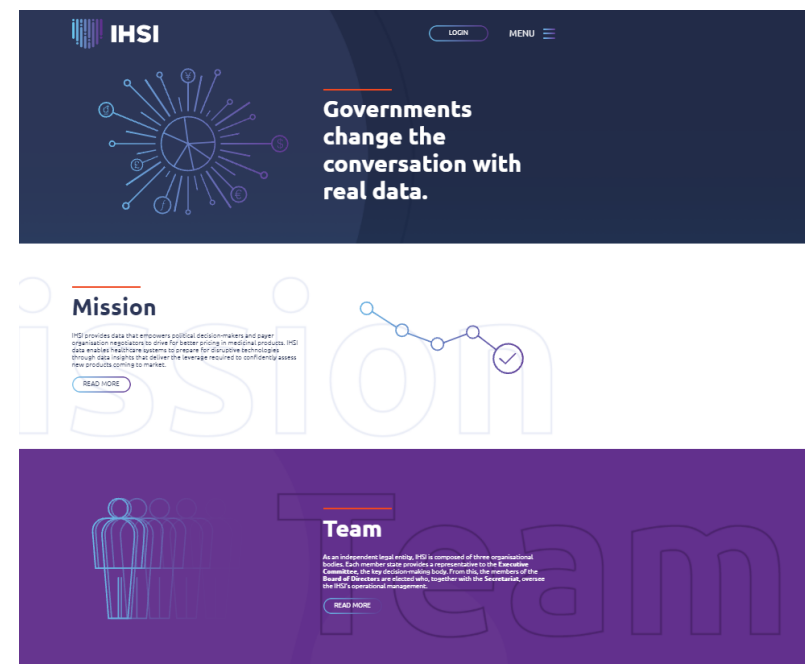
Joined Reimbursement and Contracting

Information Sharing

Horizon Scanning

Good Neighbours

Expert Network and Capacity



- + Joint HTA assessment of ZYNTEGLO
- + Outcome of joint negotiations for Zolgensma
- + [Assessment of COVID-19 monoclonal antibodies is needed](#)
- + Archive

Assessment of COVID-19 monoclonal antibodies is needed

The Beneluxa Initiative considers value assessments of medicines prior to reimbursement in their respective countries, to be essential in quantifying the potential added benefit of treatments relative to the price requested. This concept was reaffirmed in a recent joint statement with the Nordic Pharmaceutical Forum.¹

The urgency of the pandemic had required some changes to normal medicine regulatory processes to tackle the global pressure on health systems; for the EMA this has resulted in the introduction of rolling reviews. Rolling reviews involve a real time examination of evidence to establish if sufficient information is available to support a marketing authorization. This allowed countries to prepare early on for joint procurement of e.g. vaccines at an exceptional time.

More recently the EMA has begun rolling reviews on monoclonal antibodies to treat some patients with COVID-19 (September 2021)². However the Beneluxa considers it appropriate at this stage of the pandemic that these therapies³ are assessed for value within established national processes, before decisions on reimbursement or procurement are made. Informed decision making in this matter includes exchange of available HTA information within Beneluxa.

¹ <https://amgros.dk/4889/>

² <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/treatments-covid-19/covid-19-treatments-under-evaluation>

³ <https://www.bmj.com/content/374/bmj.n2231>

Last update: 01 October 2021

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INFO

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Deputy Prime Minister
and Minister of Social Affairs
and Public Health

Frank Vandenbroucke



Ministry of Health, Welfare and Sport



LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de la Santé



An Roinn Sláinte
Department of Health



Federal Ministry
Republic of Austria
Social Affairs, Health, Care
and Consumer Protection

managing fragile balances

Solidarity

Science

Health Priorities

Urgency

Politics

Economics

and Investments Infrastructure, Employment, Education,..

Solidarity

Cost of Individualization

and Freedom, Vax Reluctancy, Postponed Care,..

Payer

QOL

Awareness and Trust

Digitalization

Buyer

QO Wellbeing

Fatigue

e-vulnerability



Lieven Annemans, PhD

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Virtual

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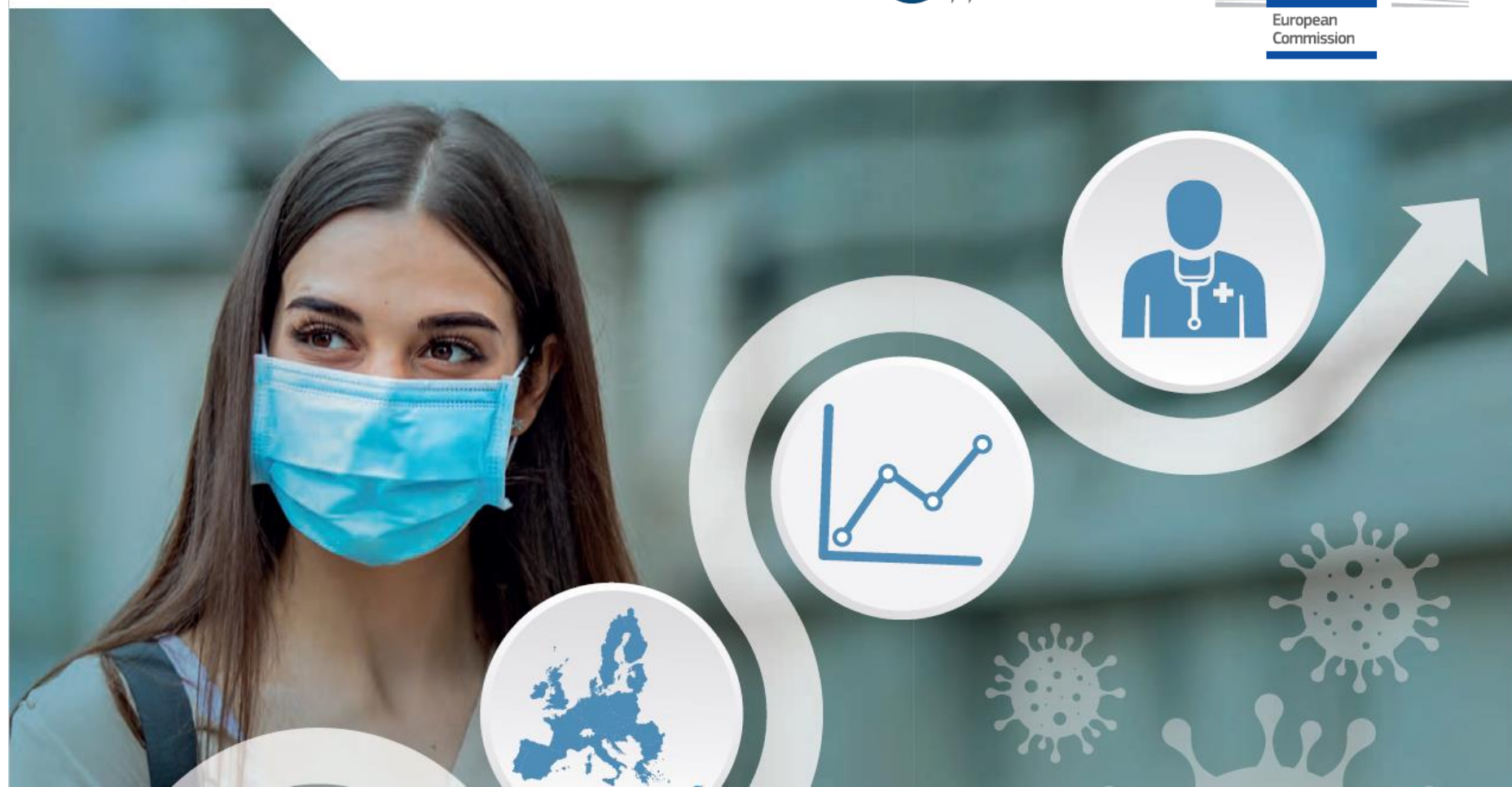
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Health at a Glance: Europe 2020

STATE OF HEALTH IN THE EU CYCLE



STATE OF
HEALTH IN
THE EU
CYCLE

The pandemic has abruptly brought public health back to the top of the policy agenda

- “The virus has disproportionately hit the elderly and those with underlying health conditions”
- “The pandemic highlighted the shortages of health workers”
- “There has been a clear social gradient in COVID-19 deaths”
- “Only a few countries have managed to limit the health and economic impacts”
- “The pandemic has highlighted the need to consider the resilience of our health systems”
- ...



Unhealthy lifestyles

Inequalities

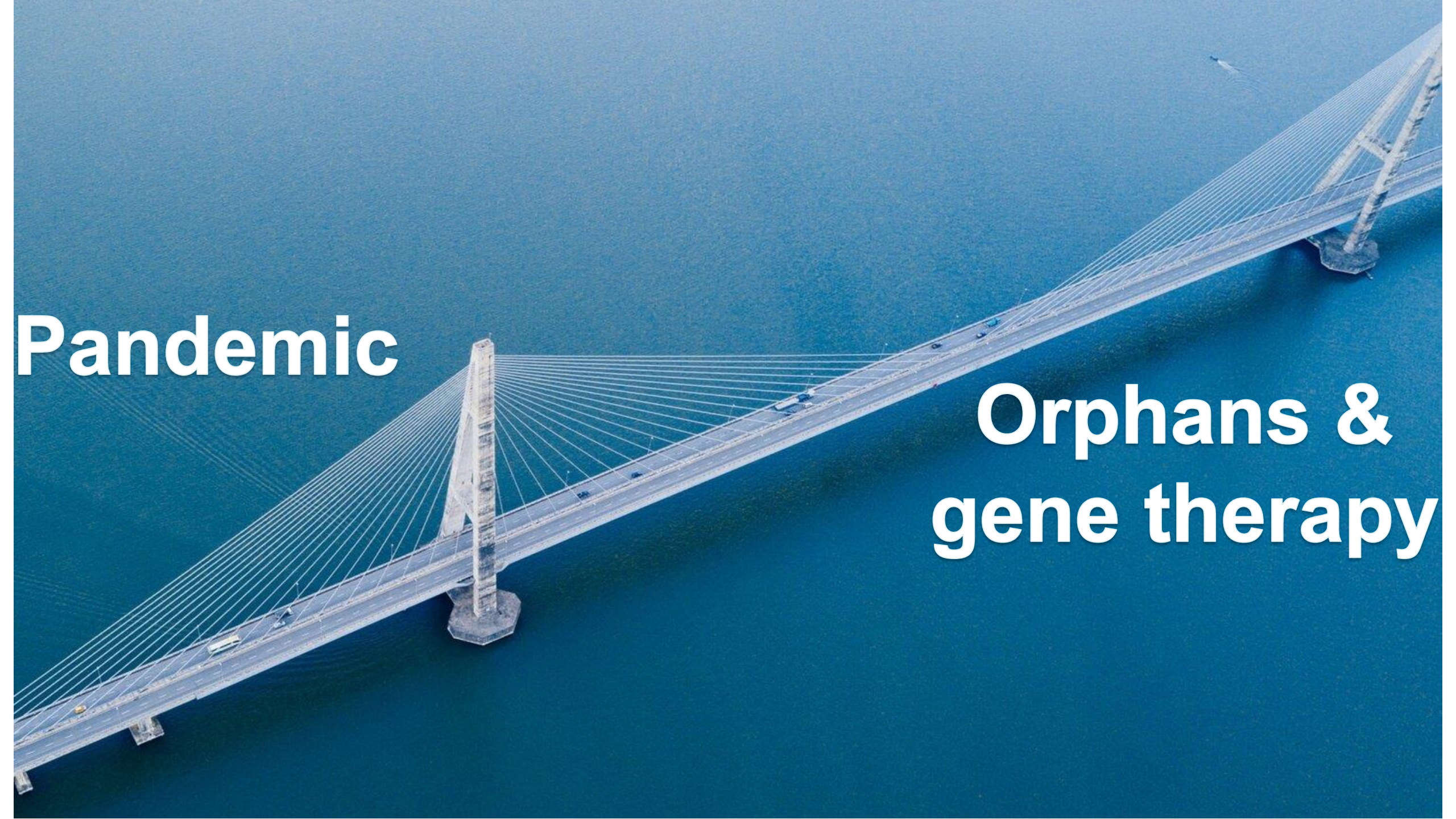
QoL health
workers
ignored

Lacking
the broad
picture

Mental
health
ignored

Lack of trust in
policy makers
No perspective

**Lack of respect
for elderly**

An aerial photograph of a large cable-stayed bridge spanning a wide body of water. The bridge features two prominent concrete pylons with numerous stay cables fanning out to support the deck. Several vehicles are visible traveling across the bridge. The water is a deep blue, and the sky is a lighter blue. The text 'Pandemic' is overlaid on the left side of the image.

Pandemic

**Orphans &
gene therapy**



**LEAVE
NO ONE
BEHIND**

10 opportunities for the EU and its member states

1. Improved information gathering and coordinated data governance
2. Joint scientific consultations and clear advice, involving *all* stakeholders
3. From horizon scanning to horizon shaping: preparedness!
4. Public-private partnerships for developing innovations
5. Move towards assessments from a broader societal perspective
6. Be transparent about how much evidence is enough
7. Joint Value based Procurement together with differential EU prices
8. Modulated thresholds – how far do we go?
9. Transparent outcomes based agreements and payment models
10. Treat the whole patient, not the hole in the patient

A vibrant field of yellow poppies in full bloom, set against a clear, bright blue sky. The flowers are in various stages of opening, with some fully open and others as buds. The background is slightly blurred, emphasizing the sharp details of the flowers in the foreground.

**Keep a cool head and a
warm heart.**

Mike Love

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