



23 October 2020
Virtual meeting

**XIII FORESIGHT TRAINING
COURSE**

*Challenges for Researchers and
Regulators facing the pandemic crisis*

The increased value of the EC consultation to promote the new strategy

Viviana Giannuzzi, Enrico Bosone

Fondazione per la Ricerca Farmacologica Gianni Benzi onlus

Via Abate Eustasio, 30 – 70010 Valenzano (BA) Tel.: +39 080 2052499

www.benzifoundation.org

The crucial value of public consultations

*Public consultation process is a way of working to ensure that political decisions are prepared in an **open and transparent** manner, informed by the best available evidence and supported by the **comprehensive involvement** of citizens and other stakeholders*

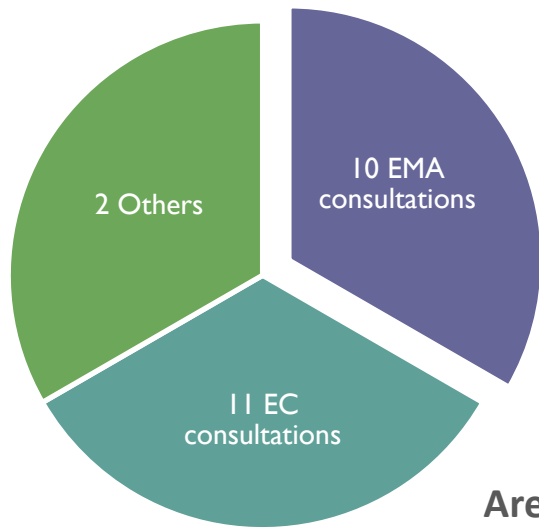


Opportunity to contribute to
policy-making

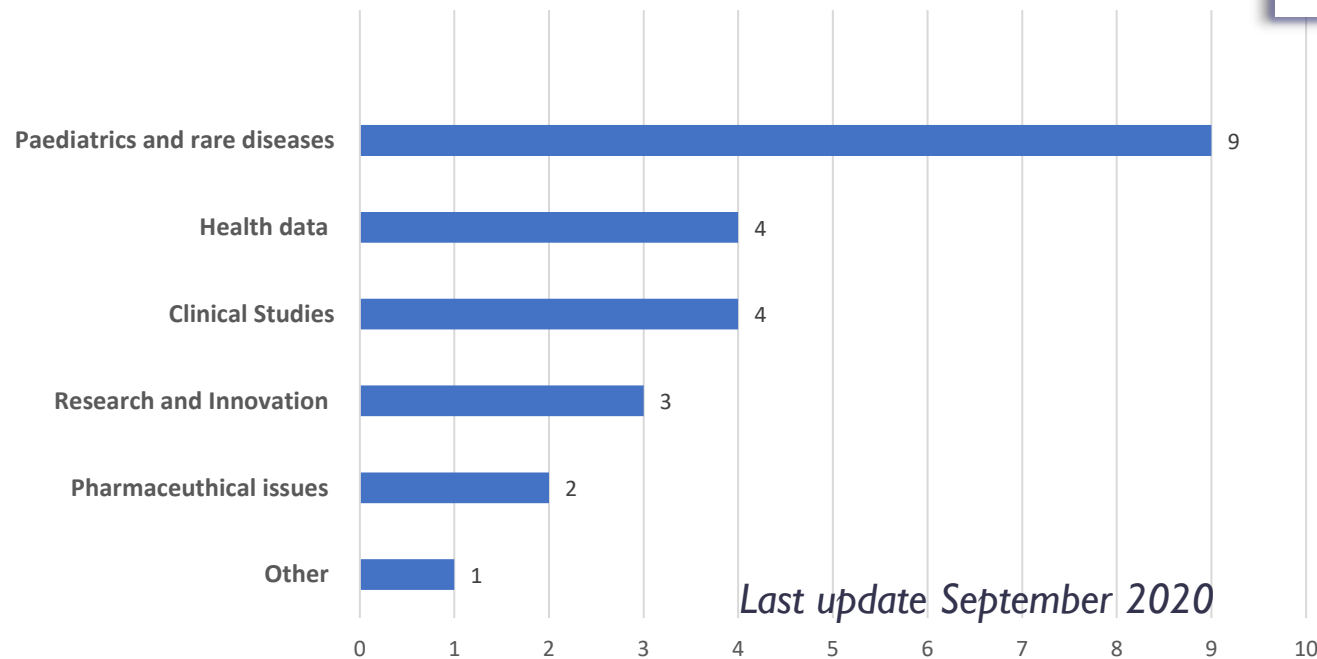
Raising regulators awareness on
specific stakeholders' unmet
needs

Empowering of patients in
official debates

FGB commitment in public consultations



Areas of interest




PUBLIC CONSULTATIONS

The consolidated regulatory expertise makes the Gianni Benzi Foundation an authoritative voice at European level for everything concerning the regulatory sciences. Such an experience resulted into documents processing and concrete participation in public consultations.

This is the list of the public consultations where the Gianni Benzi Foundation directly participated in:

- Linee guida AIFA per la compilazione del Dossier a supporto della domanda di rimborso e prezzo di un medicinale (September, 2020) [LINK](#)
- Survey on the Pharmaceutical Strategy - Timely patient access to affordable medicines (September 2020) [LINK](#)
- Comments to the EMA Discussion Paper "The General Data Protection Regulation: Secondary Use of Data for Medicines and Public Health Purposes" (July, 2020) [LINK](#)
- Horizon Europe Co-design 2021 - 2024 (September, 2019) [LINK](#)
- Discussion paper: use of patient disease registries for regulatory purposes - methodological and operational considerations (June, 2019) [LINK](#)
- Public Consultation on EMA Regulatory Science to 2025 (June, 2019) [LINK](#)

www.benzifoundation.org/activities/regulatory-sciences/



EU Pharmaceutical strategy: EC public consultation



Law

Pharmaceuticals – safe and affordable medicines (new EU strategy)

[Have your say](#) > [Published initiatives](#) > [Pharmaceuticals – safe and affordable medicines \(new EU strategy\)](#) > [Public consultation](#)

PAGE CONTENTS

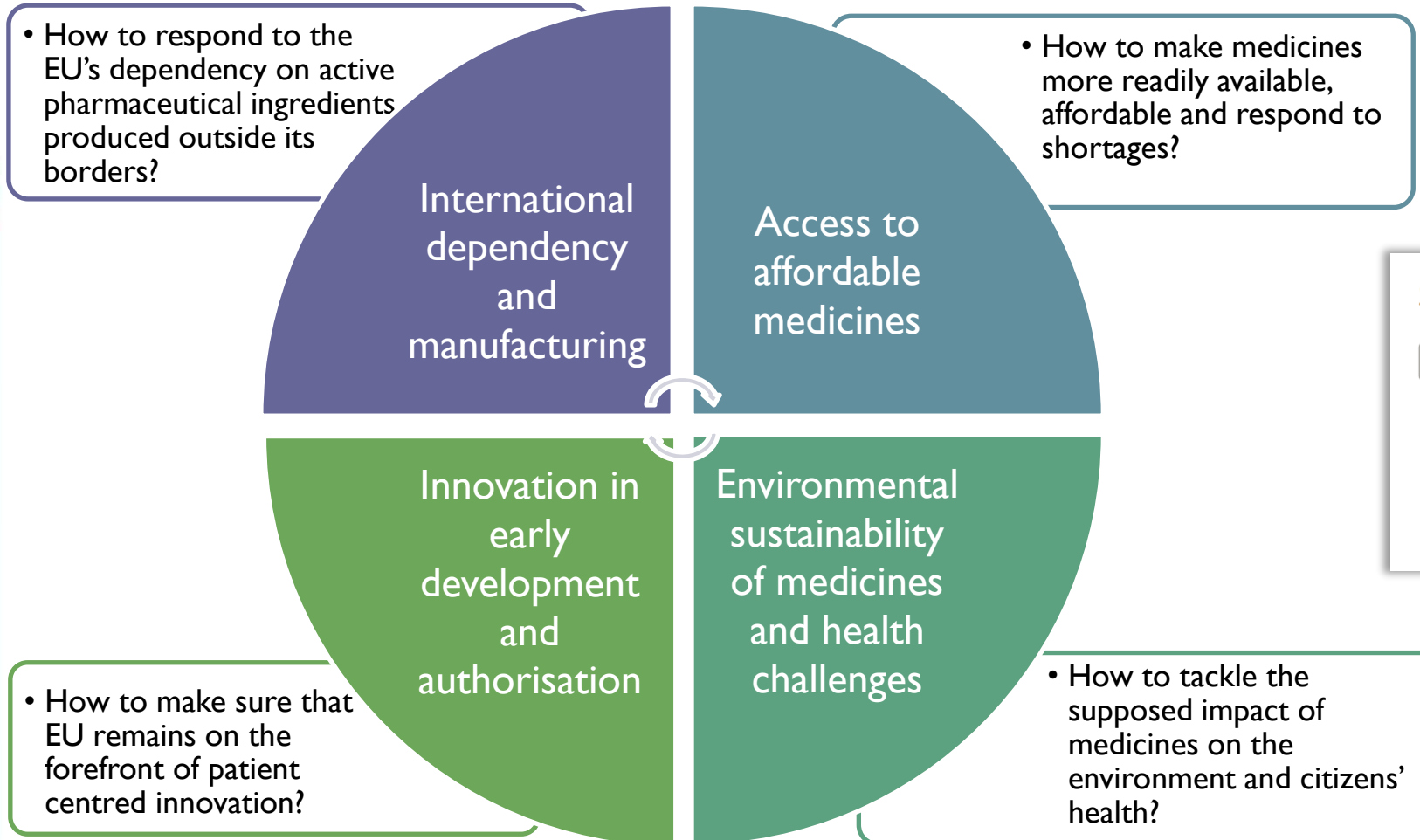
- About this consultation
- Target audience
- Why we are consulting

About this consultation

Feedback period	16 June 2020 - 15 September 2020 (midnight Brussels time)
Topic	Public health



EU Pharmaceutical strategy: EC public consultation



Survey on the Pharmaceutical Strategy Timely patient access to affordable medicines

Fields marked with * are mandatory.

Introduction

The EU strives to be a frontrunner in ensuring universal health coverage. In addition, it is a global leader in healthcare research and development and a major trading partner in pharmaceuticals and medical technologies. People across the EU expect to benefit from equal access to safe, state-of-the-art and affordable new and established therapies. Medicines play an important role in this regard, as they offer therapeutic options for diagnosis, treatment and prevention of diseases.

International dependency and manufacturing

How to incentivise the production of active pharmaceutical ingredients for essential medicines in EU and enhancing the high quality of medicines in the EU?

Our point of view

- ✓ To facilitate the set up of **GMP-compliant factories**
- ✓ To simplify the **bureaucratic burden**
- ✓ To increase official controls in the manufacturing and distribution chain



Innovation in early development and authorisation

Which actions most effective?

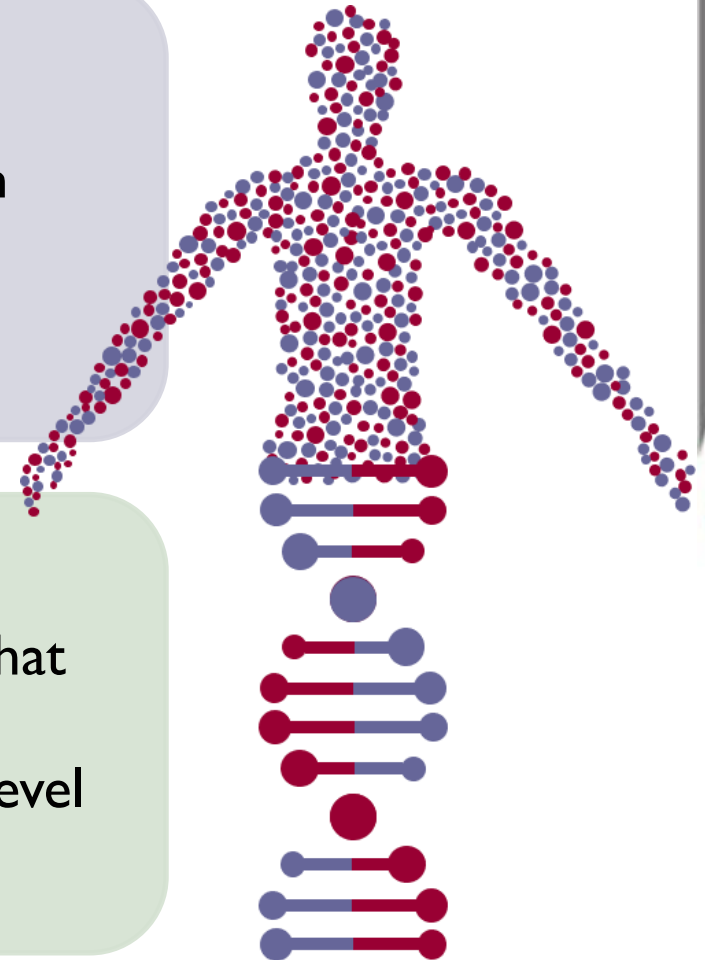
Our point of view

To support innovative
R&D of medicines

- Making the **legislative framework** more adaptive to new technologies
- Fostering research **collaboration** between universities, research centres and industry
- Providing R&D incentives as intellectual property or market exclusivity rights

To support R&D in areas
where there are unmet
needs

- Agree on a common understanding on what are the areas of **unmet need** in EU
- **Funding** more targeted research at EU level

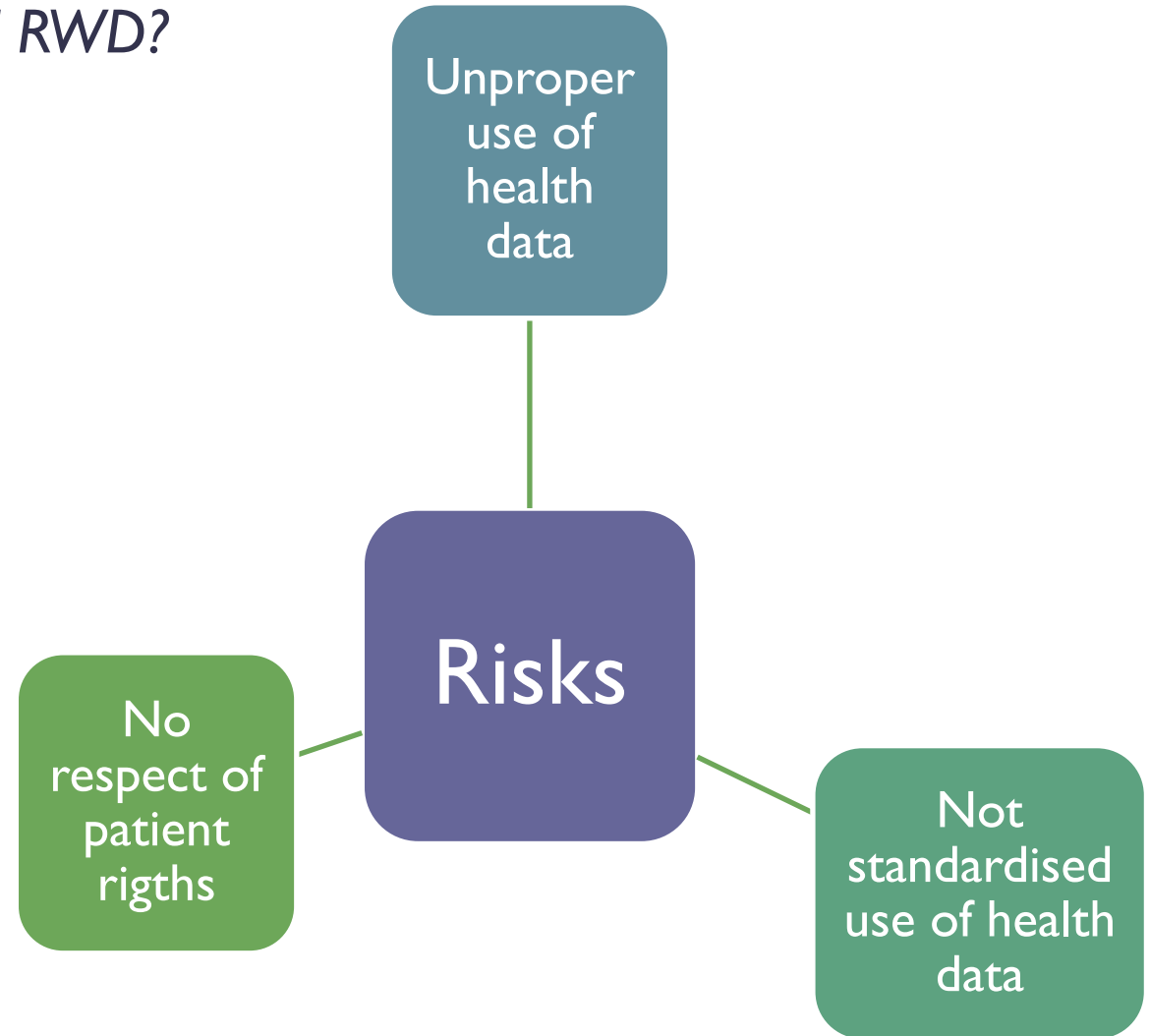


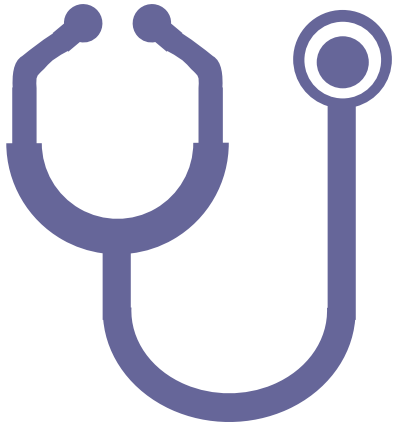
Innovation in early development and authorisation

Which opportunities in Artificial Intelligence and RWD?

Our point of view

- *A great opportunity to foster the development of medicines, to exploit large amount of data for a proper use of medicines*
- *Their use for regulatory purposes should be effectively supported*





Innovation in early development and authorisation

Clinical trials in the EU be driven more by patients' needs while keeping them robust, relevant and safe for participants

Our point of view



By providing support for **non-commercial organisations** to conduct clinical trials in fields where financial interest is weaker



By involving **patients' experiences** in early phases of medicine design



Better coordination of multi-national trials and unload **bureaucratic processes** to be made faster

Innovation in early development and authorisation

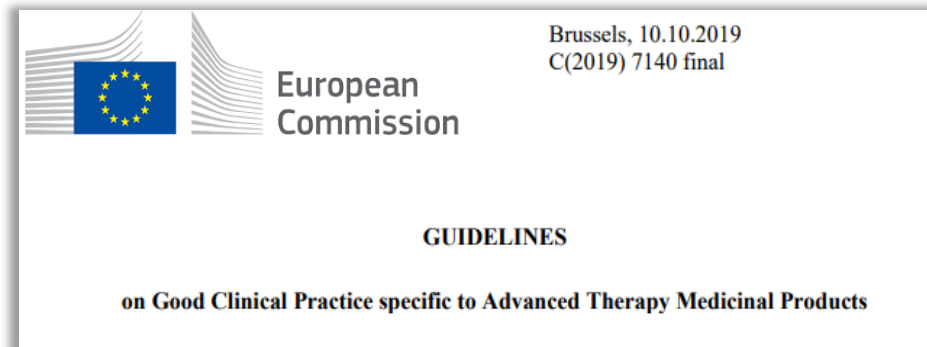
Advanced therapy medicinal products (ATMPs) are developed based on genes, cells or tissue engineering

Our point of view

The current legal framework results suitable as provides safeguards for patients to receive proper and safe products

HOWEVER

Requirements to be fulfilled by hospitals are challenging and should be reconsidered while keeping the due safety and quality



Environmental sustainability of medicines and health challenges

Residues of several medicines have been found in surface and ground waters, soils and animal tissues



Our point of view

To limit the negative environmental impact of medicines

Enhanced application
of the polluter pays
principle

Reference to
environmental risks in
advertising for over-
the-counter medicines

Medicines dispensed
to patients in the
quantity actually
needed

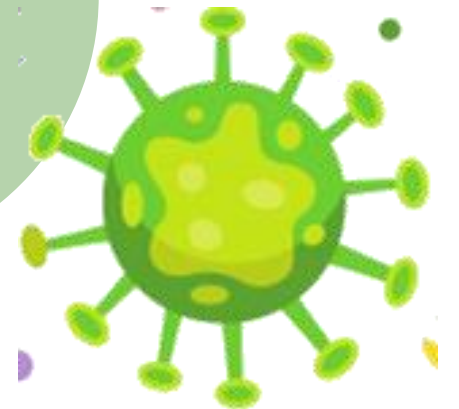
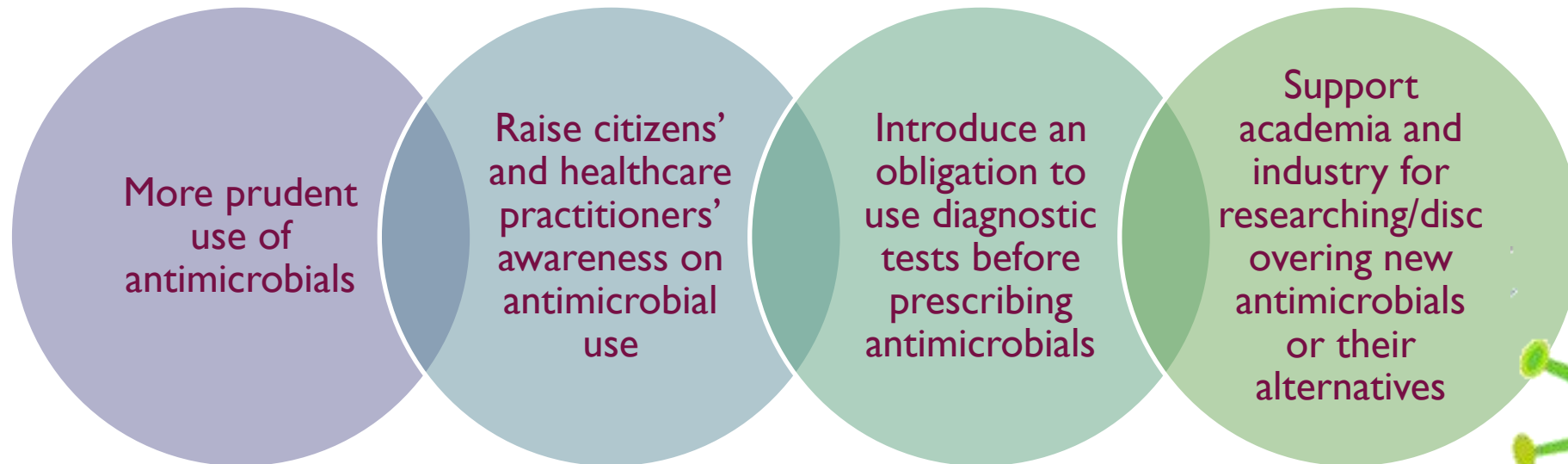


Environmental sustainability of medicines and health challenges



Antimicrobial resistance is one of the most serious and urgent public health concerns. Innovation in antimicrobials is limited. No new classes of antibiotics have been discovered for decades

Our point of view

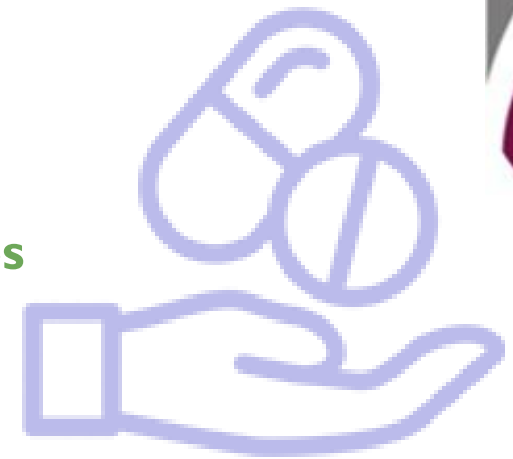


Access to affordable medicines

Medicine shortages occur when there are not enough medicines in a country to treat every patient with a given condition. Shortages can have a big impact on patients if their treatment is delayed

Our point of view

Access to healthcare, including medicines, is a fundamental patients' right

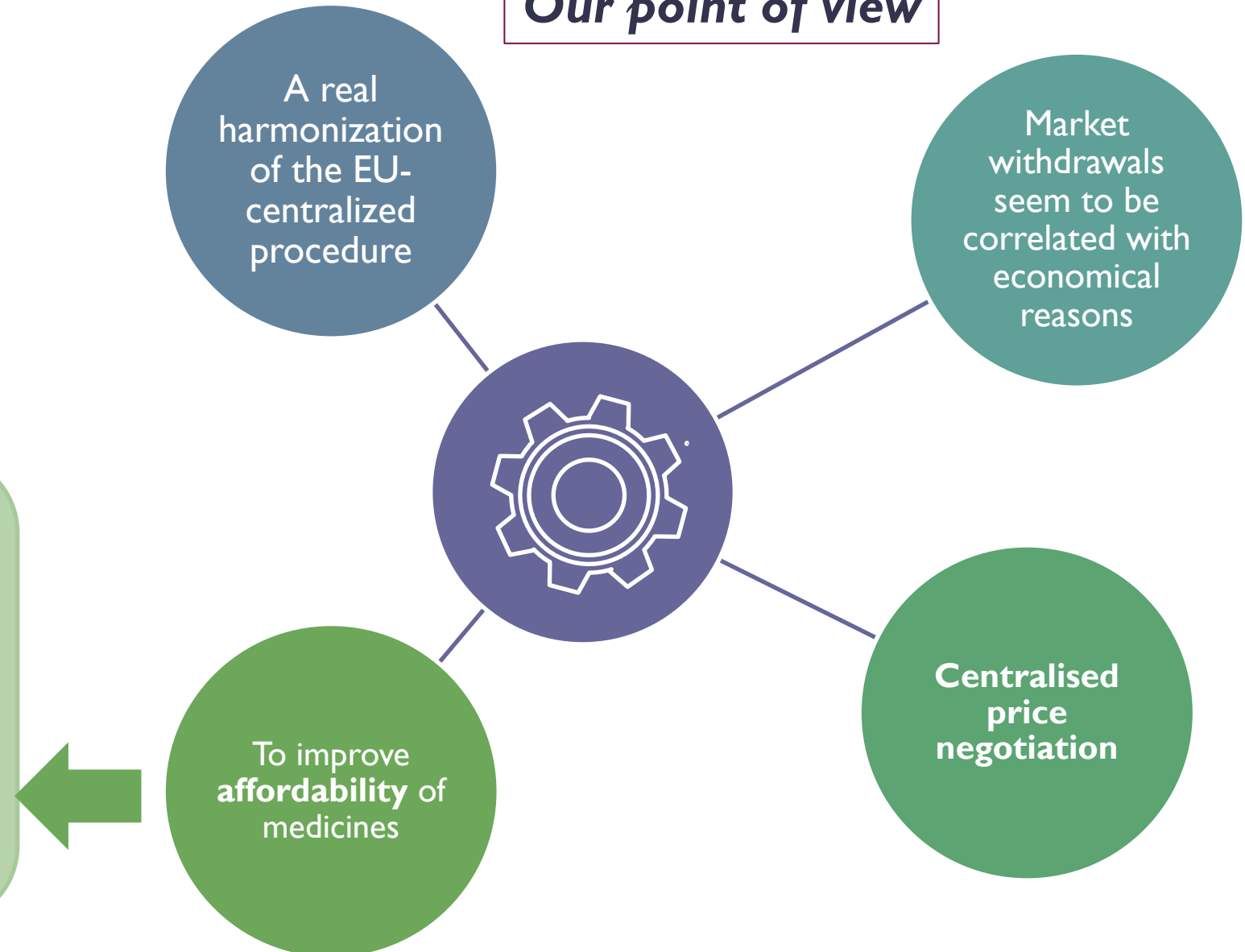


Access to affordable medicines

Our point of view

Innovative medicines have to undergo a centralised MA. Companies often initially market them in a limited number of EU countries. It can take several years before patients in the other EU countries have access to those products...

- More transparency on how the cost of a medicine relates to the cost of its R&D
- A fair return on public investment when public funds were used to support the R&D of medicines



Emergency support instrument



Questa foto di Autore sconosciuto è concesso in licenza da [CC BY-NC](#)

- EU funds directed to logistics, medical supplies, testing, vaccines, treatment, emergency aid, healthcare facilities and staff, industrial preparedness
- Procurement of essential medicines, transfer of patients within the EU and from the EU to third countries, supported
- Used during the COVID pandemic for drugs and medical devices supply in EU

Our point of view

Use the European negotiation of price also for ATMPs and OMPs for children

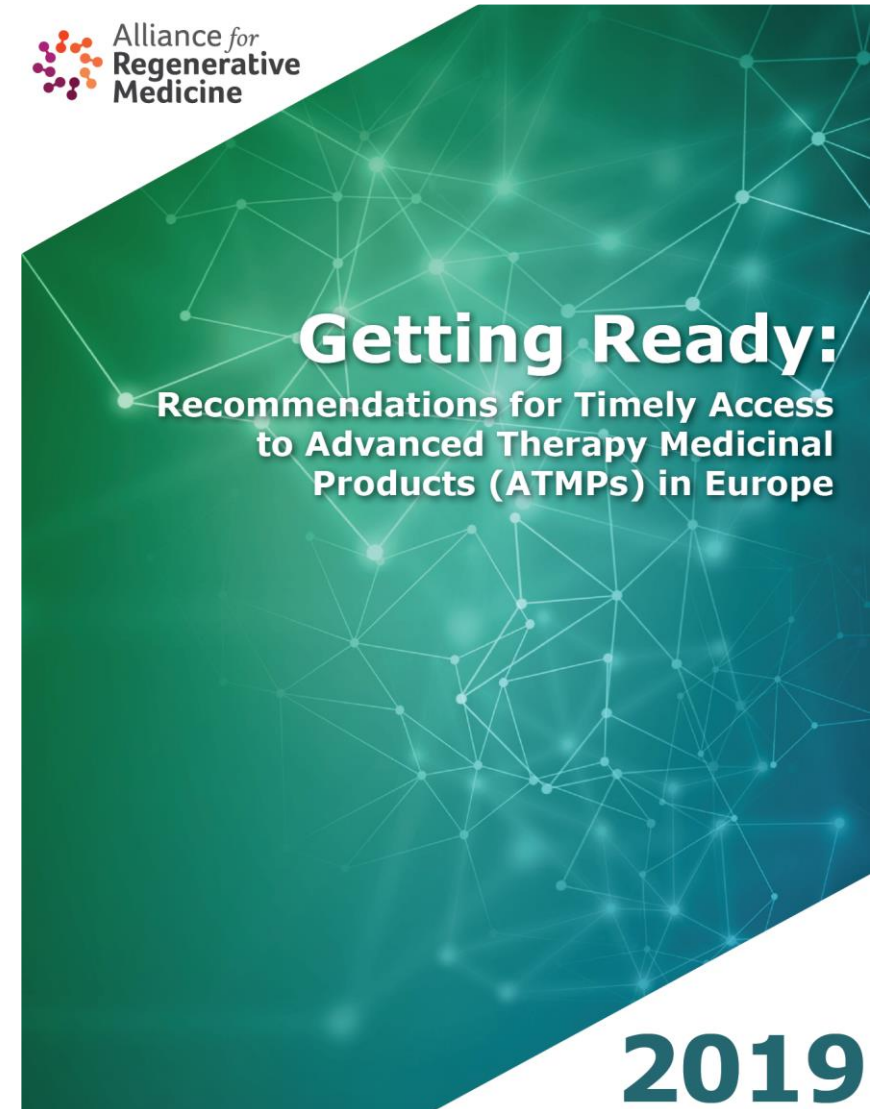
To improve
affordability of
medicines

**Centralised
price
negotiation**

Access to affordable medicines



- 14 approved ATMPs \Rightarrow 4 withdrawn for commercial reasons
- different availability: 6 in Germany, 5 in the UK, 4 in France, 3 in Italy, 1 in Spain, none in Sweden



COVID-19 impact on EU pharmaceutical framework

COVID-19 pandemic revealed the need for modifying the EU regulatory system in order to properly meet patients' needs and ensure them timely access to medicines under all circumstances

Our point of view



Speeding the authorization and reimbursement of medicines while keeping efficacy, safety and quality ensured

Investigating the possible attitude to reduce the 'burden' of the already implemented rules against **patient's rights**

Conclusions

- Public consultations represent a unique opportunity for citizens and stakeholders to contribute to policy-making
- The new pharma strategy will face
 - the need for simplification of the bureaucratic burden while keeping quality
 - the adaptation of the legislative framework to new technologies
 - the support of the use of new technologies for regulatory purposes
 - the need to address unmet needs
 - the speed of medicines availability and the equal access as revealed by the COVID-19 pandemic, at least for ATMPs and OMPs in paediatrics

*A special acknowledgment to
Antonella Didio*



Viviana Giannuzzi

PharmD, PhD

Coordinator of Benzi Foundation
Research Department

vg@benzifoundation.org

Enrico Bosone

ChD

SIARV President

Benzi Foundation Scientific Committee Member

presidenza@siarv.it

The views expressed in this presentation are the personal views of the speakers