FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS

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

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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*

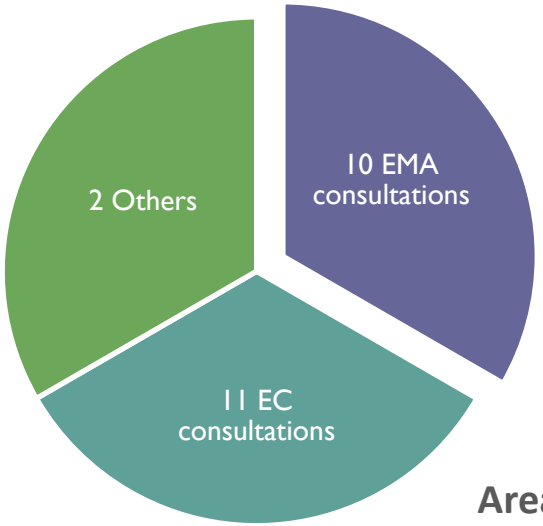
Opportunity to contribute to policy-making

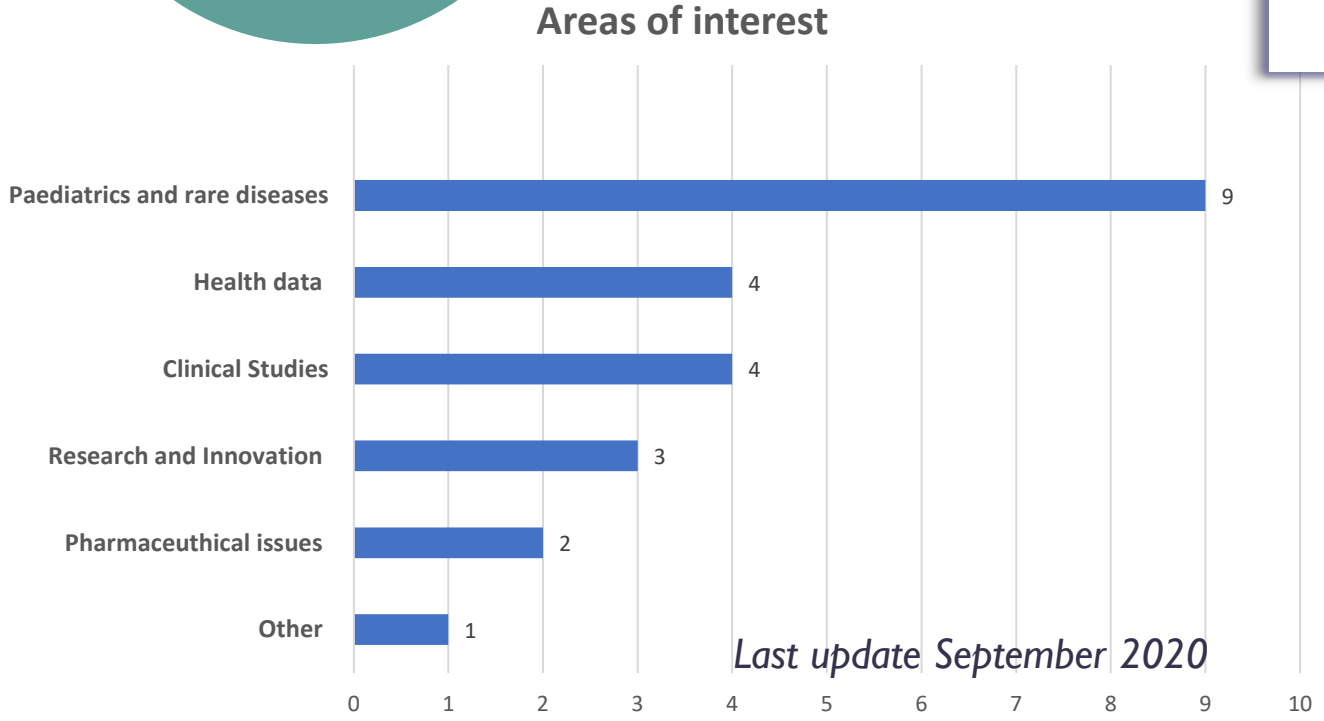
Raising regulators awareness on specific stakeholders' unmet needs

Empowering of patients in official debates

https://ec.europa.eu/info/sites/info/files/better-regulation-guidelines.pdf

FGB commitment in public consultations





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

EU Pharmaceutical strategy: EC public consultation

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EU Pharmaceutical strategy: EC public consultation

- How to respond to the EU's dependency on active pharmaceutical ingredients produced outside its borders?

International dependency and manufacturing

Access to affordable medicines

- How to make medicines more readily available, affordable and respond to shortages?

Innovation in early development and authorisation

- How to make sure that EU remains on the forefront of patient centred innovation?

Environmental sustainability of medicines and health challenges

- How to tackle the supposed impact of medicines on the environment and citizens' health?

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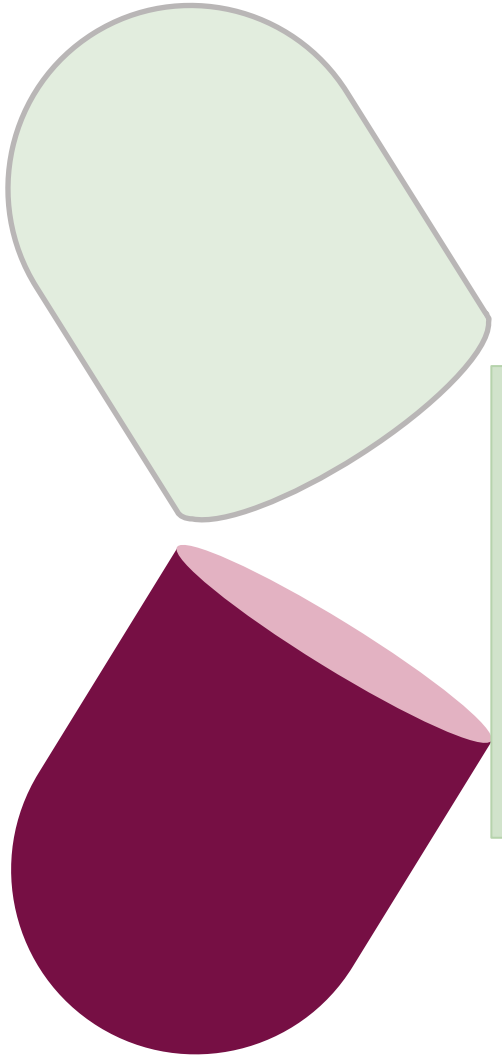
International dependency and manufacturing

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

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Innovation in early development and authorisation

Which actions most effective?

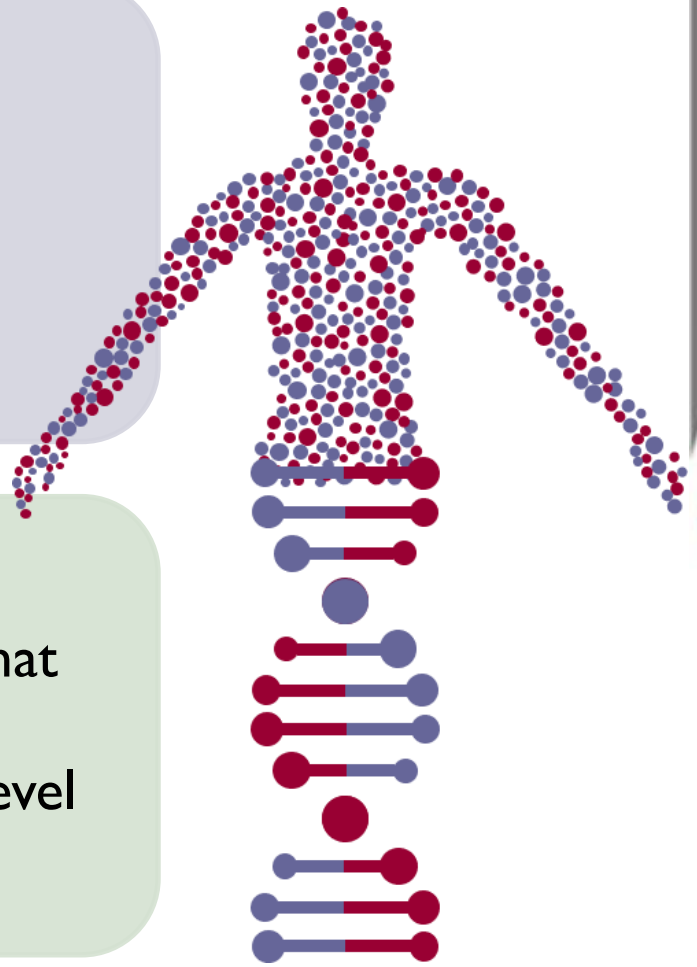
Our point of view

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



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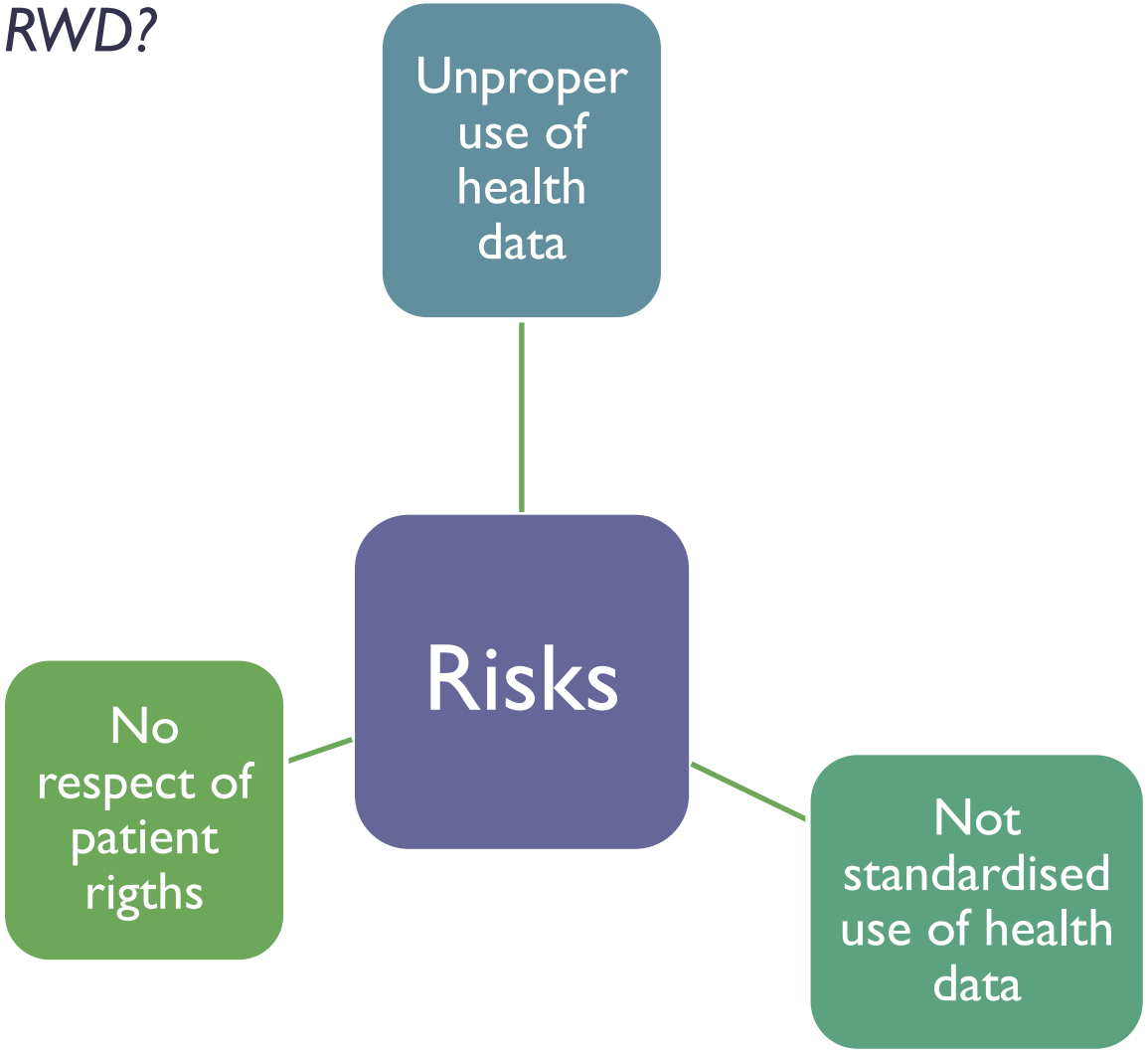
Innovation in early development and authorisation

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*



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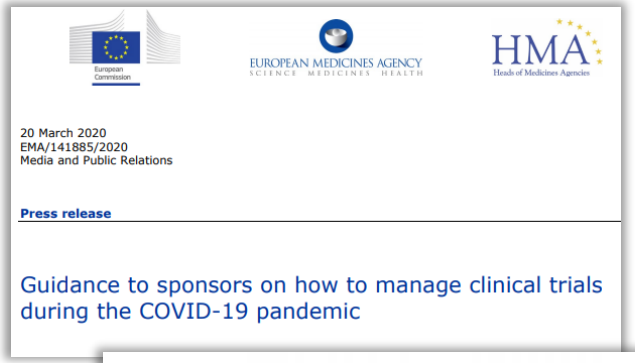
Innovation in early development and authorisation

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

Our point of view


European Commission
EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH
HMA Heads of Medicines Agencies

20 March 2020
EMA/141885/2020
Media and Public Relations

Press release

Guidance to sponsors on how to manage clinical trials during the COVID-19 pandemic


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2020
EMA/158330/2020 Rev. 1
Committee for Human Medicinal Products (CHMP)

Points to consider on implications of Coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials

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

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Innovation in early development and authorisation

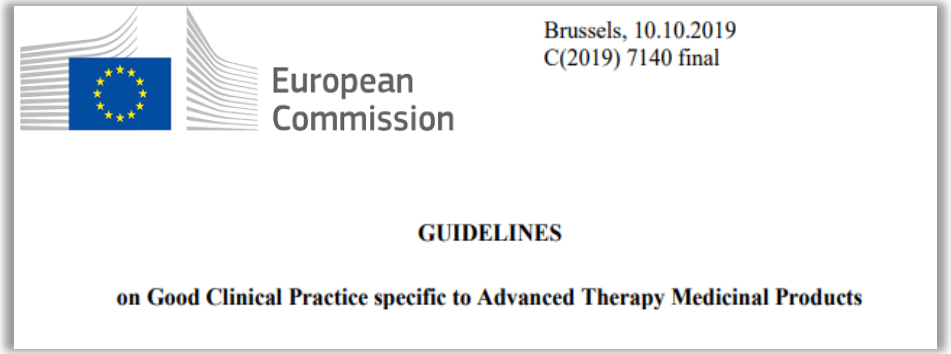
Advanced therapy medicinal products *(ATMPs) are developed based on genes, cells or tissue engineering*

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



European Commission

Brussels, 10.10.2019
C(2019) 7140 final

GUIDELINES

on Good Clinical Practice specific to Advanced Therapy Medicinal Products

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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

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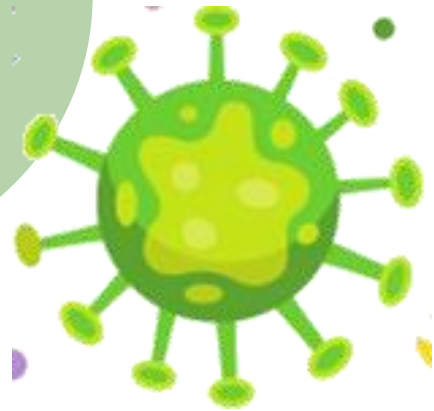
Environmental sustainability of medicines and health challenges

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

- More prudent use of antimicrobials
- Raise citizens' and healthcare practitioners' awareness on antimicrobial use
- Introduce an obligation to use diagnostic tests before prescribing antimicrobials
- Support academia and industry for researching/discovering new antimicrobials or their alternatives



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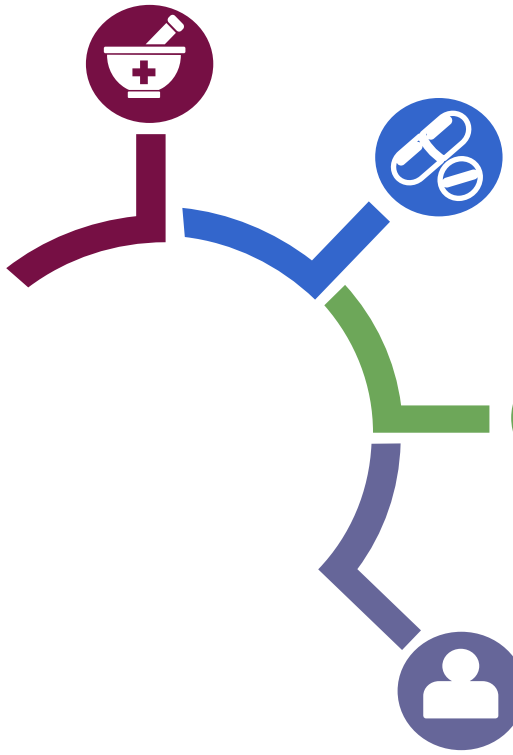
Access to affordable medicines

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



Stronger obligations on medicines producers and other players in the supply chain to ensure medicines are available

Increased cooperation among public authorities/national governments on shortages

Inform on and make available to patients suitable substitutes for medicines that are at risk of shortage

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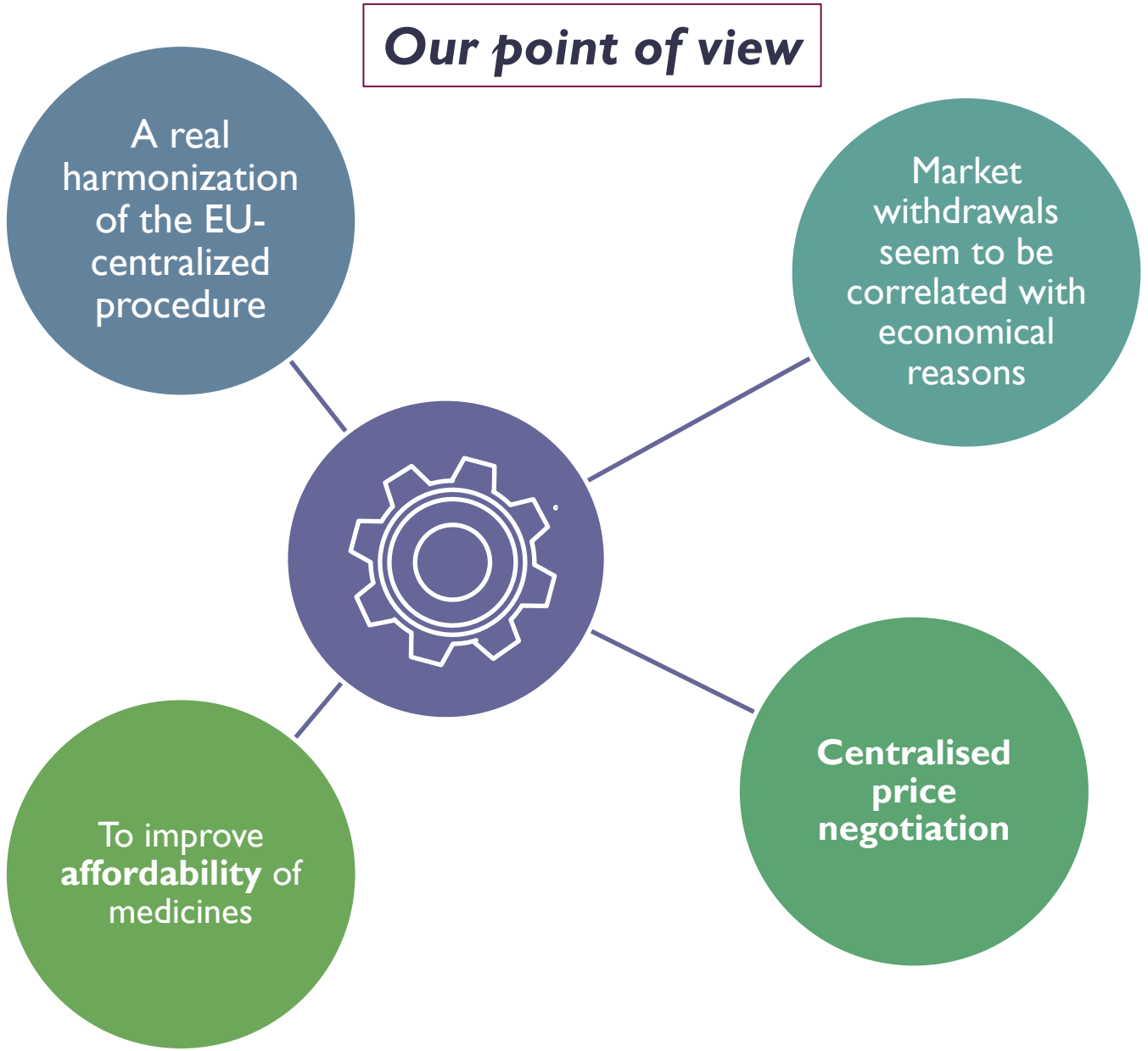
Access to affordable medicines

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

Our point of view



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Emergency support instrument

- 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

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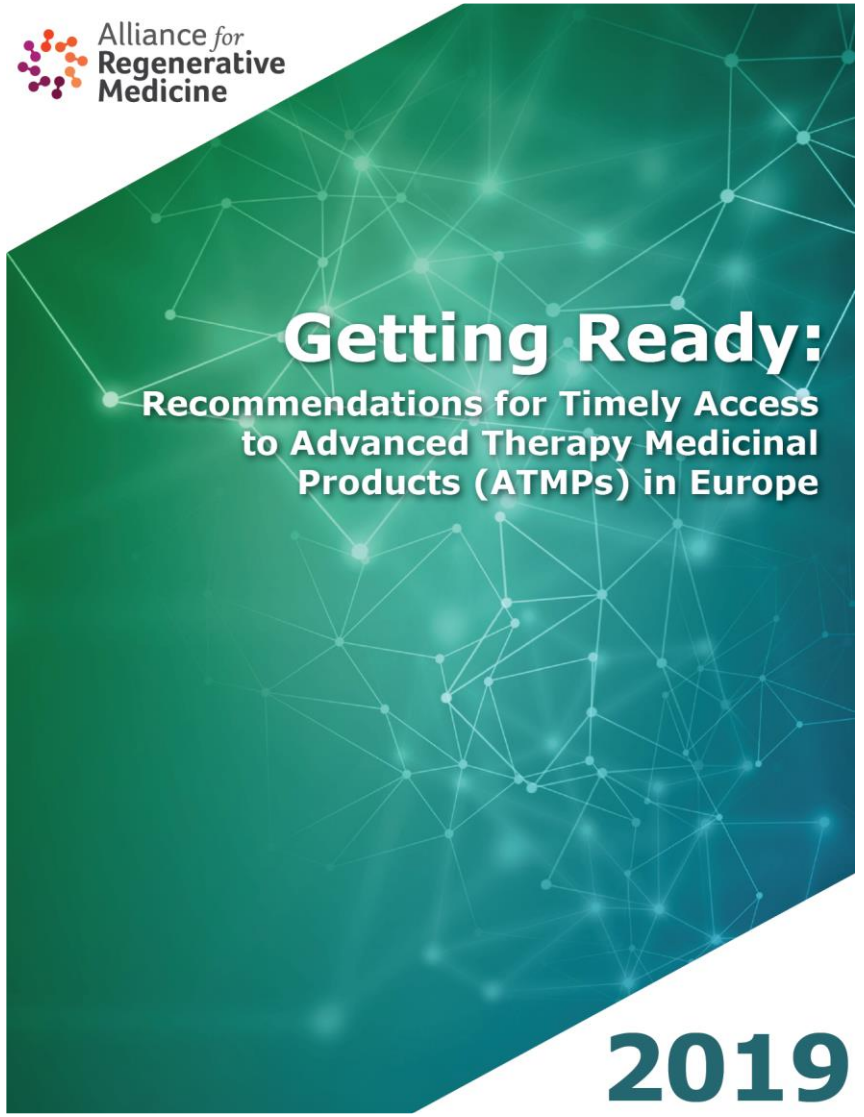
Access to affordable medicines

- 14 approved ATMPs ⇨ 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



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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**

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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

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A special acknowledgment to

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