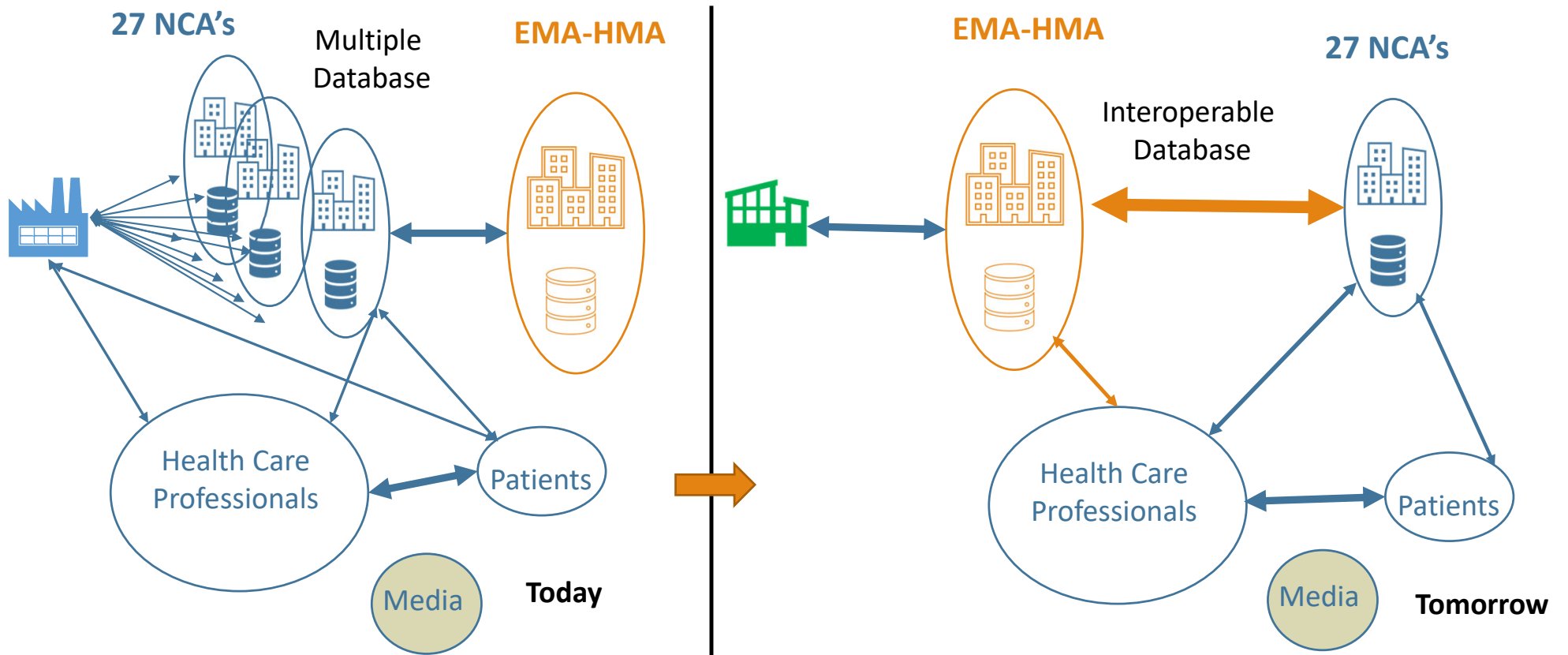




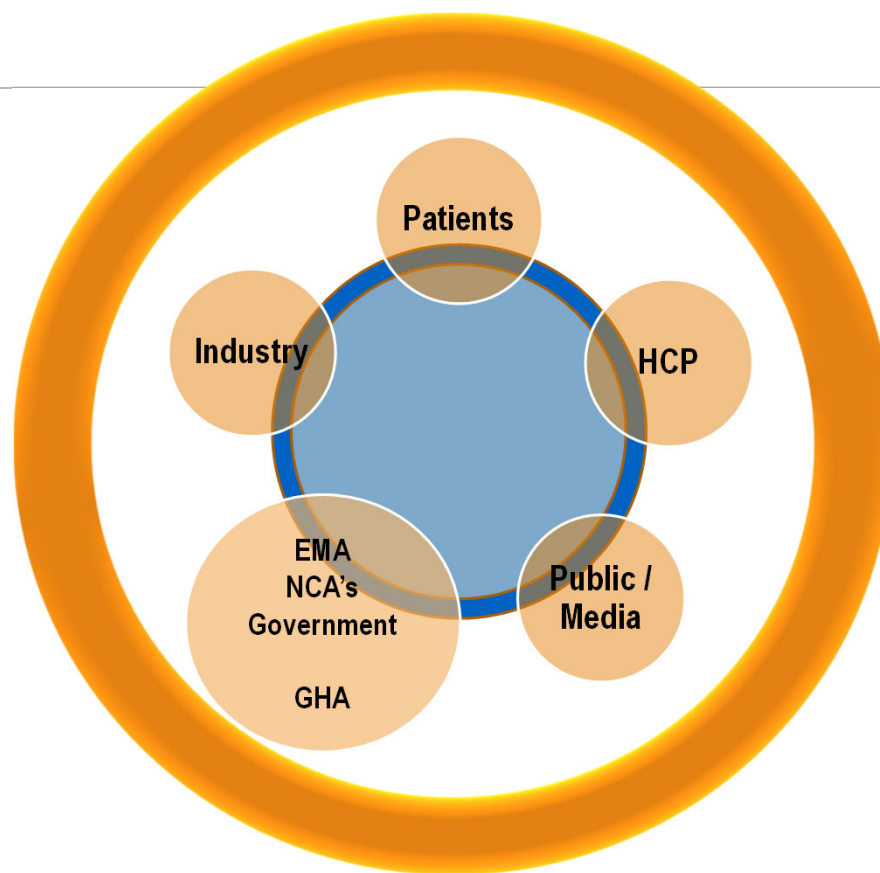
# Session 5: Communication and Transparency

Jean Francois Duliere on behalf of industry

# Communication Organisation



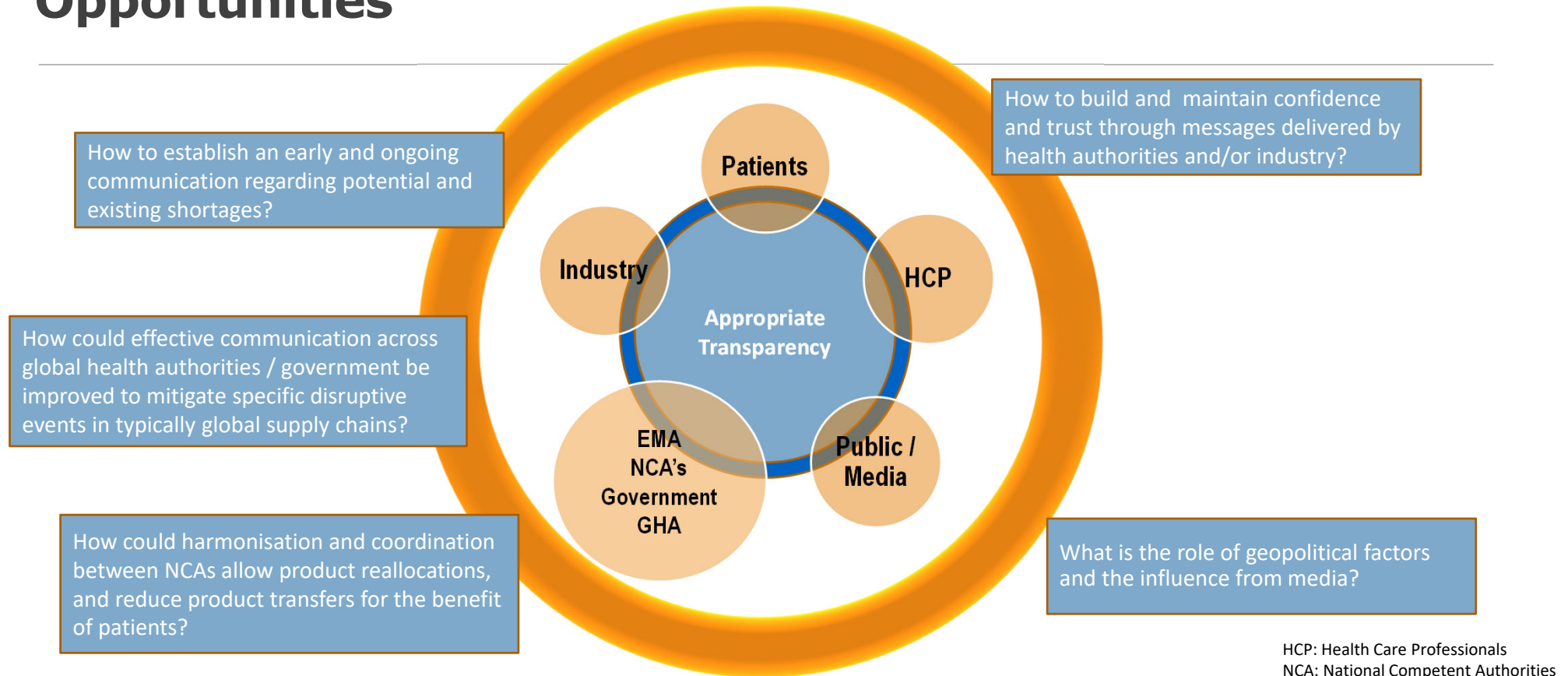
# Stakeholders



HCP: Health Care Professionals  
NCA: National Competent Authorities  
GHA Global Health Authorities

## Communication and Transparency

# Opportunities



HCP: Health Care Professionals  
NCA: National Competent Authorities  
GHA Global Health Authorities

## What to share, with whom?

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### Requirements for transparency:

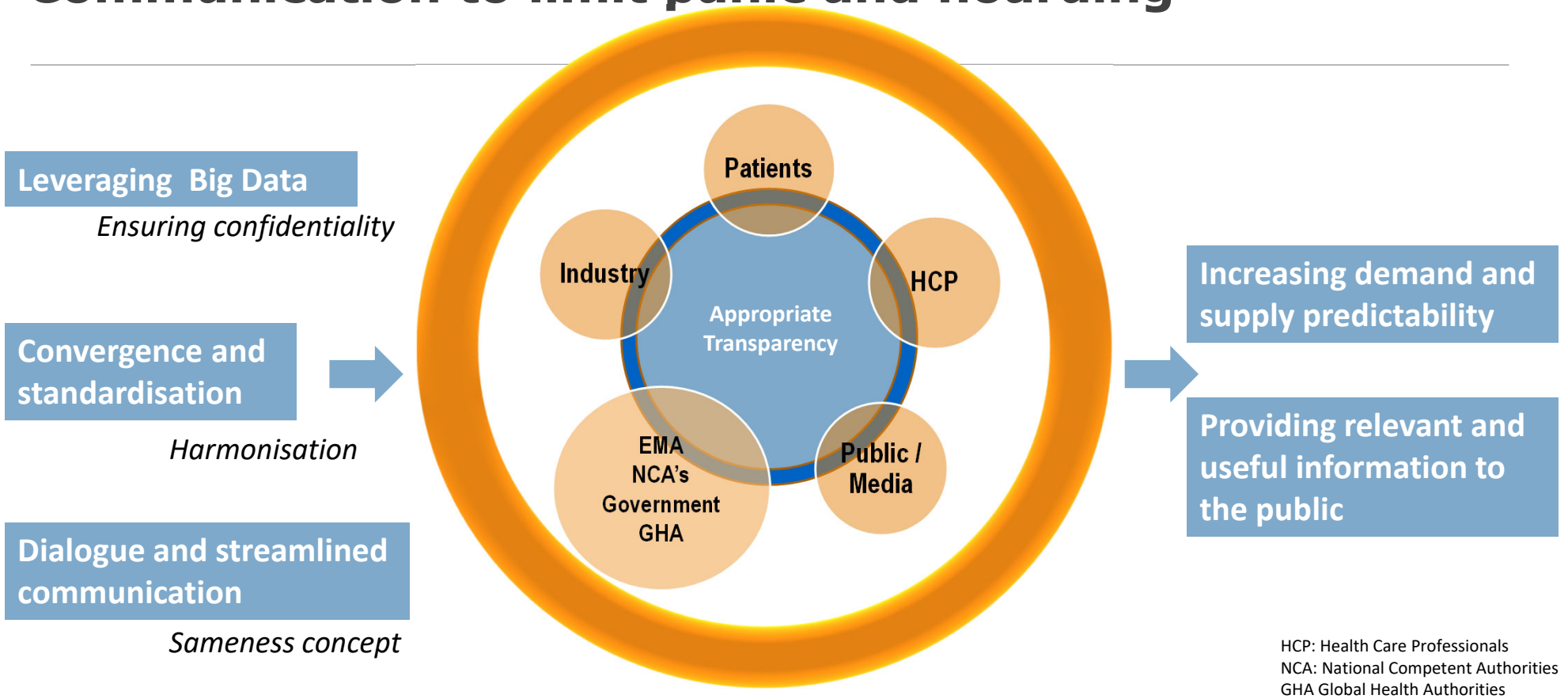
- Consistent definitions and their interpretation
- Alignment on **same** reporting expectations (e.g., impact, timelines, volumes,) in Member States
- Confidentiality of the data submitted (volumes, sales, forecasts)

### Transparent and timely communication should:

- Inform all stakeholders to minimize the impact of actual supply disruptions.
- Focus on aligned industry/associations/regulatory communications that share relevant and useful information to the public to counter:
  - misdirecting media reports
  - unnecessary hoarding
  - patient confusion or decreased confidence in their medicines

Communication and Transparency

# Communication to limit panic and hoarding









# Additional Details

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Different stages in communication models and transparency are different and could lead to different solutions

# Participating Associations

Logo	Abbreviation	Stands for	Link
	EFPIA	European Federation of Pharmaceutical Industries and Associations	<a href="https://www.efpia.eu/">https://www.efpia.eu/</a>
	GIRP	European Healthcare Distribution Association	<a href="https://www.girp.eu/">https://www.girp.eu/</a>
	ISPE	International Society for Pharmaceutical Engineering	<a href="https://www.ispe.org/">https://www.ispe.org/</a>
	-	Medicines for Europe	<a href="https://www.medicinesforeurope.com/">https://www.medicinesforeurope.com/</a>
	PDA	Parenteral Drug Association	<a href="https://www.pda.org/">https://www.pda.org/</a>
	VE	Vaccines Europe	<a href="https://www.vaccineseurope.eu/">https://www.vaccineseurope.eu/</a>



# Abbreviations

Abbreviation	Stands for
API	Active Pharmaceutical Ingredient
ATMP	Advanced therapy medicinal products
CMC	Chemistry, Manufacturing, Control
ECDC	European Centre for Disease Control
ESMP	European Shortages Monitoring Platform, provided by EU Regulation 2022/123
ICH	International Council of Harmonisation
IP	Intellectual property
MAH	Marketing Authorisation Holder
MoH	Ministry of Health
NCA	National Competent Authority
RUP	Repeat Use Procedure
SPP	Shortage Prevention Plan

# Key points by associations

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Different stages in communication models and transparency are different and could lead to different solutions

*EEFPIA; GIRP; ISPE; Medicines for Europe; PDA; VE*



# Communication

## Prevention: Dialogue on epidemiology data to anticipate demand surges

- Amoxicillin demand increased +300-500% for paediatric formulations, +50-70% for adults between 2021 and 2022
- Supply chain adjustments take many months
- There should be dialogue between ECDC, EMA/HMA, and industry including sharing of data to plan infectious surges 1 year ahead

## Mitigation: Communication to limit panic and hoarding

- Hoarding undermines good allocation in a shortage
  - **Of note: media attention on a shortage will exacerbate it!** (See COVID19 peak and end-2022 shortages) How can this be dealt with?
- Regulators and Industry to communicate to reduce hoarding
- Outreach to wholesalers and pharmacies: improve data sharing and anti-hoarding policies
- Outreach to patient organisations if treatment will be impacted



# Transparency

**Greater transparency in the Supply Chain will increase its resilience, and the capacity of NCA's to improve Shortage Prevention/Mitigation action. This could take two forms:**

- Better visibility of patient demand (epidemiology) to all supply chain stakeholders, e.g. by empowering ECDC to share consolidated data, including forecasts.
- Leveraging existing databases and ensuring their interoperability, e.g. EMVS, SPOR, IRIS.

**NOTE: MAHs run a unilateral, confidential quota system to ensure the availability of treatments across countries**

This allows adequate allocation across countries according to patient needs, as opposed to allocation based on purely economic drivers, which can increase economic demand (orders) several-folds higher than patient needs (patient demand), threatening availability of medicines.

- Enhanced transparency (leveraging existing IT databases) will make actual allocations per country visible to NCAs, while preserving commercial confidentiality and competition across players.
- For competition law reasons (see Bayer/Adalat), quotas information is a commercially sensitive information with the potential to distort competition and should not be made available to economic players.



### Leveraging big data

- Interoperable data systems (SPOR, EMVS, ESMP)
- Use EMVS data and AI to predict supply/demand imbalances
- Industry collaboration (in line with competition rules) under EMA/HMA leadership to mitigate shortages

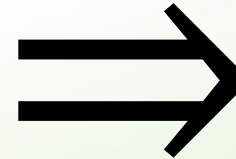
### Dialogue and streamlined communication

- Dialogue with ECDC, EMA about surge risks (infectious surges, prescribing protocols, etc) - prevention
- Two-way communication between EMA-HMA and industry, leveraging shortage reporting – mitigation
- Rapid information about manufacturer shortage so other manufacturers can adapt

### Harmonisation and standardisation

- EU-harmonised shortage reporting, avoiding duplication (national/EU)
- Standard requirements and protocols

will translate in



Increased Demand predictability

Increased Supply predictability

Note: Extending notification periods to 6 months is not an efficient way of preventing/mitigating shortages

- MAHs will report minor supply chain blips: i.e., Canada 10X increase in possible shortage reporting
- The vast majority of shortages are not reported within the current 6-month timeline, because they result from unforeseen incidents occurring in later stages of the supply chain.



# Abbreviations

- ECDC: European Centre for Disease Control
- EFPIA: European Federation of Pharmaceutical Industries and Associations
- EMVS: European Medicines Verification Systems
- ESMP: European Shortages Monitoring Platform, provided by EU Regulation 2022/123
- MAH: Marketing Authorisation Holder
- MfE: Medicines for Europe
- SPOR: Substance, Product, Organisation and Referential
- VE: Vaccines Europe

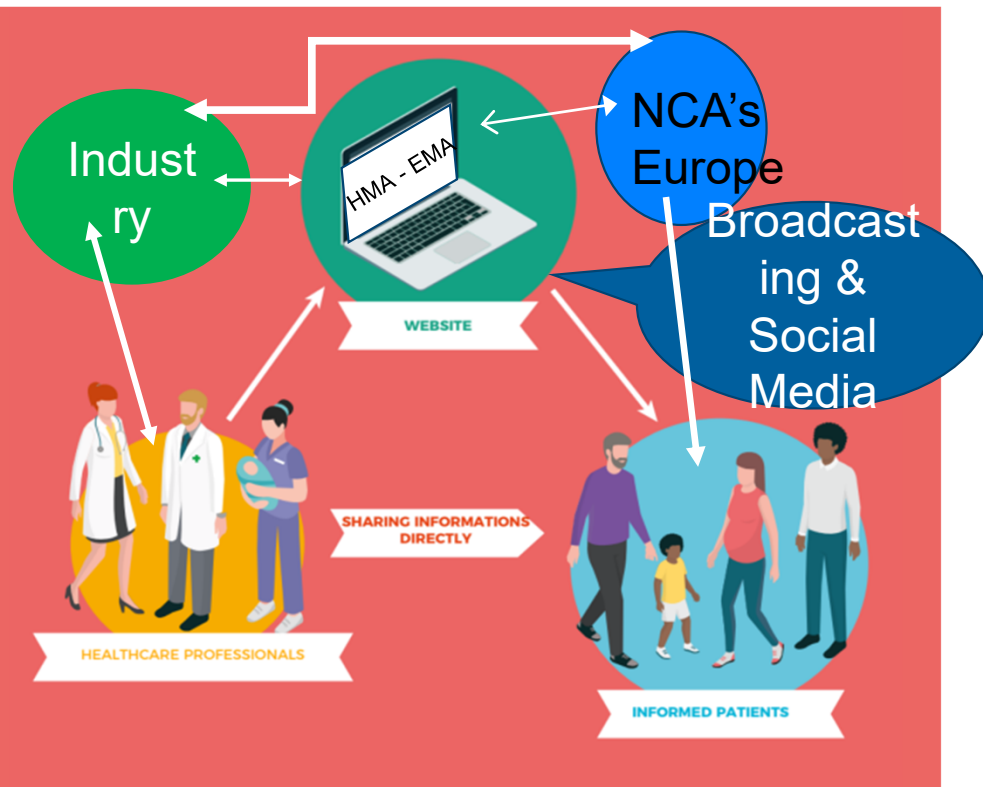
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# GIRP recommendations for communication and transparency

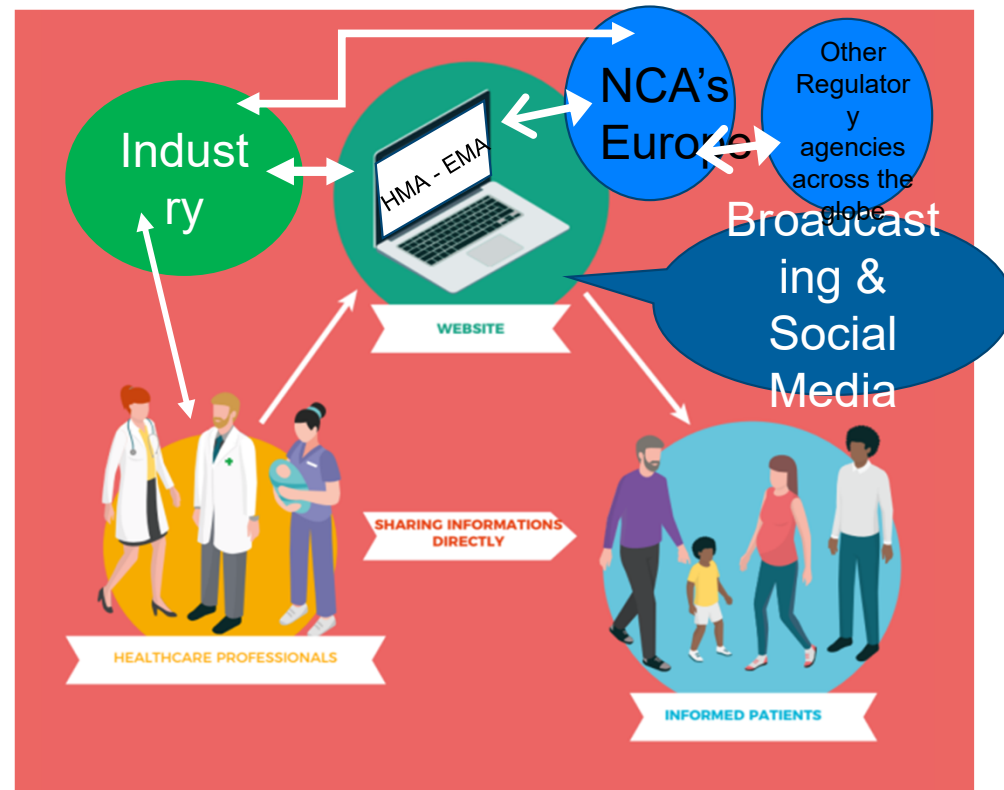
- 1 Legal basis for an EU-wide early warning system for critical medicines, connecting available national shortages monitoring systems, involving:
  - Manufacturers
  - Pharmaceutical full-line wholesalers
  - Hospitals
  - Community pharmacists
  - Prescribers
  - National Competent Authorities
  - EMA for coordination at EU level.
- 2 Ensure EU system is based on data readily available and fit-for-purpose
- 3 **Request for early notification of shortages by MAHs**
  - To NCAs
  - To pharmaceutical full-line wholesalers
- 4 Supply quotas are justified in case of shortages or if orders exceed national demand. Allocation schemes should be made transparent to NCAs and pharmaceutical full-line wholesalers

## Communication and Transparency

# What is Communication and Transparency?



Today



In the Future

Connecting Pharmaceutical Knowledge





## Communication and Transparency

# What is important for communication?

1. Early and ongoing communication between **manufacturers and health authorities** regarding potential and existing shortages
2. Robust communication and alignment between **National Competent Authorities (NCAs) and global health authorities**
  - NCAs have important roles (measures for supply restrictions, support to find alternative products...). Harmonization and coordination between NCAs is necessary to reallocate products for the benefit of patients.
  - Supply chain organizations are typically global and complex. As a result, effective communication across global health authorities could be needed to mitigate specific disruptive events. And, global regulatory harmonization is essential for flexibility in change management to prevent drug shortages (*i.e.*, production site change for API or drug products).
3. Building confidence and trust within **healthcare providers, patients, and the general public** through messages delivered by authorities and/or industry



## Communication and Transparency

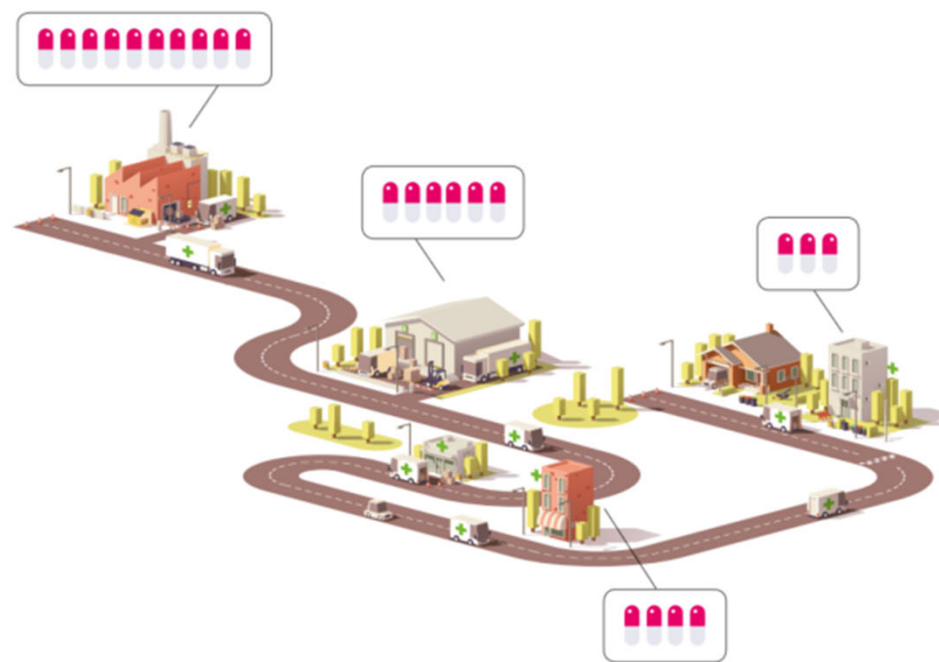
# Transparency: what to share with whom?

1. How can we improve transparency between NCA, regional/global regulatory authorities and industry?
  - Consistent definitions?
  - Alignment on reporting expectations (e.g., impact, timelines, volumes)?
  - Is a full transparency to all stakeholders a benefit?
2. Transparent and timely communication? of certain information is needed by health care providers, patients and the public to minimize the impact of actual supply disruptions
  - The public has a right to useful information important to their healthcare.
  - Focus on aligned industry/associations/regulatory communications that share relevant and useful information to the public should help to counter:
    - misdirecting social media reports
    - unnecessary hoarding
    - patient confusion or decreased confidence in their medicines

## Sequencing Communication for the best Transparency

### Communication Stages for success

1. Industry supply chain
2. Agencies
3. Health professionals
4. Patients
5. General public, e.g., news outlets, social media.



## In Conclusion

### Opportunities for efficient, effective communication and constructive transparency include:

- Harmonization of European regulatory practices
- Improved coordination between NCAs in Europe
- Improved global coordination and regulatory harmonization



## Role of social media and Authorities

### • What is important for transparency and communication?

- Earlier communication with health authorities
- Potential for regulatory harmonization - Consistent definitions/reporting expectations –ISPE is in the process of generating draft standards for consideration
- Communication plan – for agencies then at an appropriate time the public; social media; manage purchasing based on threat rather than on the need (paracetamol example)
- Transparency between NCA or regulatory authorities and industry is important; public transparency can create unintended consequences (e.g., hoarding, not accepting a quality source, questioning quality)
- Confidence and trust in messages delivered by authorities.

### • Role of Social Media

## Communication and Transparency

# Role of media and Health Authorities

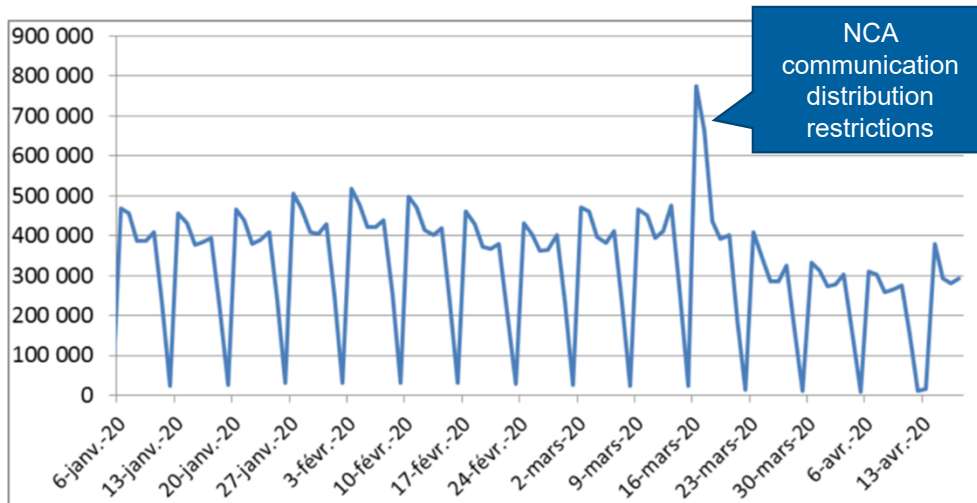


Figure 12 : délivrance de paracétamol: nombre de patients par jour du 1<sup>er</sup> janvier au 15 avril 2020

Source : rapport EPI-PHARE Usage des médicaments de ville en France durant l'épidémie de Covid-19 – point de situation après 5 semaines de confinement

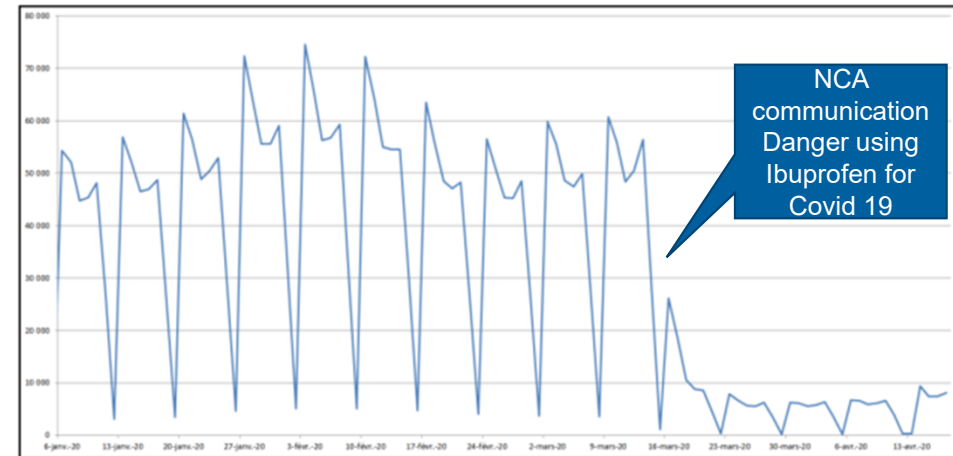
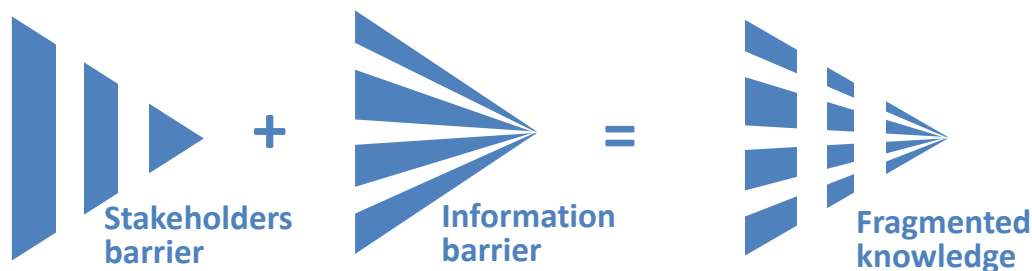


Figure 14 : délivrance d'ibuprofène en nombre de patients par jour durant la période du 1<sup>er</sup> janvier au 19 avril 2020

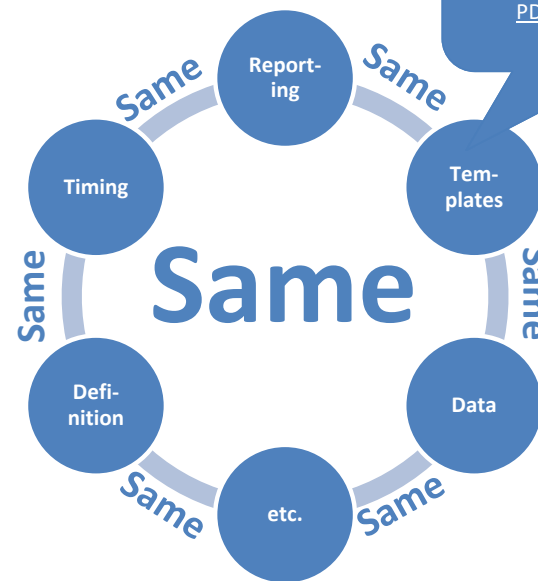
Source : rapport EPI-PHARE Usage des médicaments de ville en France durant l'épidémie de Covid-19 – point de situation après 5 semaines de confinement

- **Setting the scene**
  - Many MAHs are active in multinational markets with different conditions
  - Stakeholders are not used to sharing information about pricing and market opportunities
- **Ideas to be considered for solutions**
  - Build one database environment which allows trustful sharing of confidential data
  - Information in database must be correct, complete, timely and transparent
  - Decision-making must be dynamic and fast reflecting changing environment
  - Database to be hosted/managed by one European authority

## Mind the knowledge gap when collecting data only



- Fragmented data and information from different sources to be collected and analysed
- Communication must be bi-directional (e.g., MAHs ↔ authority)



Risk-based approach for Prevention and management of Drug Shortage  
 PDA Technical Report No. 68  
 open access

- Transparency means to understand the impact in the complex environment
- Diversity in information format impacts supply chain robustness
- Use of standardized data templates supports knowledge and consistent communication
- Synchronized information flow is necessary for analysis and decision-making