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efpia
European Federation of Pharmaceutical Industries and Associations

Exchange of views with EMA/HMA Supply Group

Second wave risk demand planning for Covid19

Covid-19 Situation

March-June first wave: Initiated industry-Supply group cooperation

Medicines for Europe-EFPIA coordinated ICU Kearney project first wave planning

Supply group: coordination on EU & member state responses to first wave

Second wave: Monitoring localised waves linked to vacation & loosening of restrictions

Future risks:

- **Return to work/school**
- **Flu season combination with Covid-19**
- **External factors: demand in Americas//outbreak in Asia affecting supply chains**

ICU medicines project recap

1st wave demand assessment for ICU medicines (95% accuracy for COVID patient calculation) and total supply

1st wave ind-gov cooperation: dramatic increase in supply (reg flex) & better demand calculation (#of patients & meds consumption)

Country allocation: More Gov. coordination to improve allocation across hospitals/countries

Second wave: how to reinitiate industry-Government cooperation?

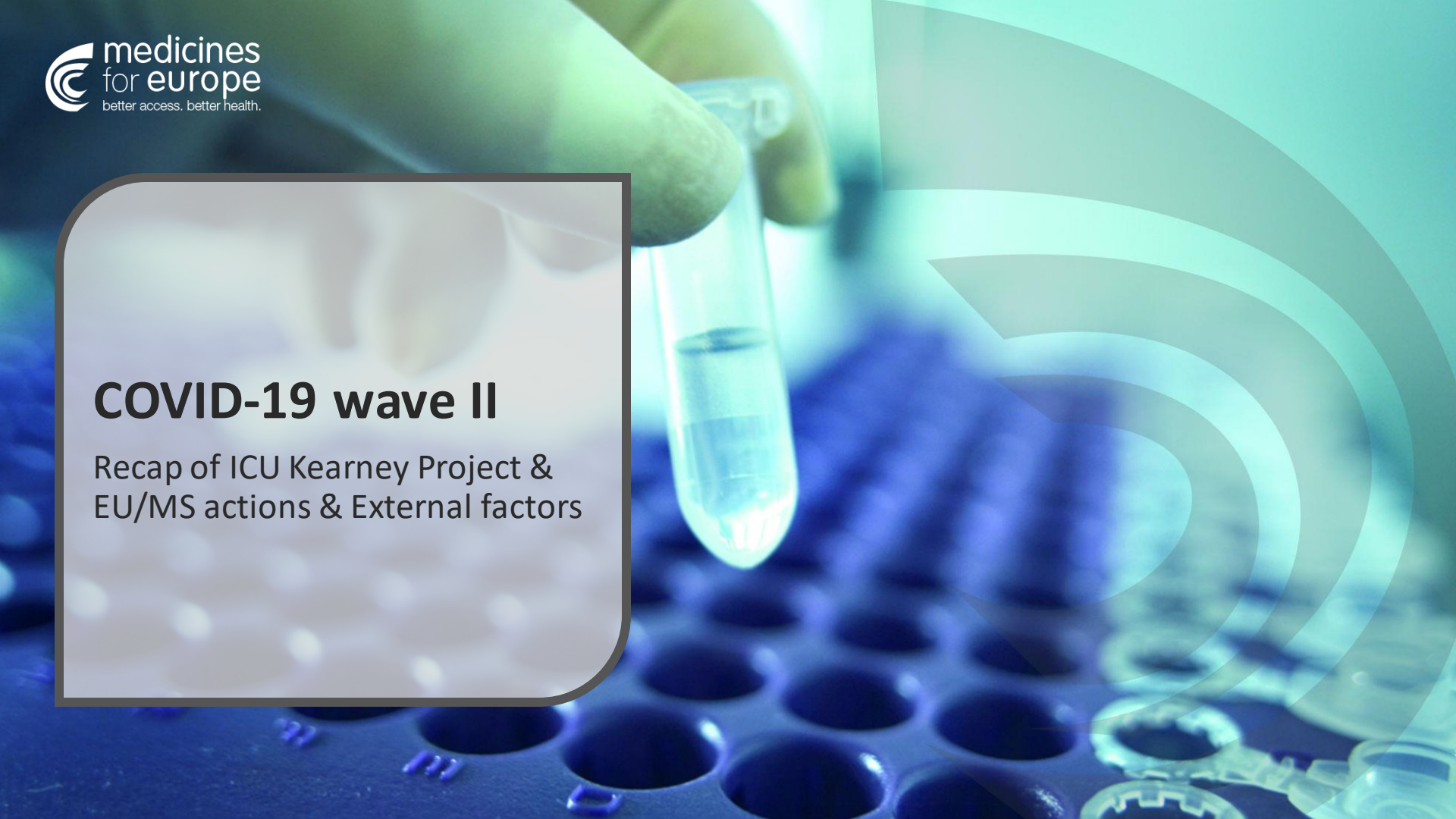
Sharing demand projections for industry planning

ECDC
data projection too short term; collect and aggregate other sources for 2nd wave scenario

EMA-HMA Supply group sharing demand projections: info for industry?

Adapt to new variables: lower hosp. rate; changes to treatment protocols -->impact on ICU med demand?

*This is the view of industry not the view of GIRP (wholesalers)



COVID-19 wave II

Recap of ICU Kearney Project &
EU/MS actions & External factors

A model was developed to estimate the demand of critical medicines for a potential second COVID-19 wave

Demand forecasting model

- Initially developed by **Medicines for Europe** and **Accord Healthcare** for the **first COVID-19 wave**
- Enhanced with additional parameters by **Kearney** for a potential **second COVID-19 wave**

Approach

- **Favoring overestimation of cases** due to the fact that the risk of underestimating is higher than the risk of overestimating
- **Not reflecting the impact** of any behavioral changes, social distancing, or other interventions which could influence case numbers
- **Not addressing** the impact of **tourism** potentially occurring in late summer/ early autumn
- Using **number of reported deaths per country** as base for estimation
- Using **three different parameters** to plan for **future demand scenarios** (# deaths, MV usage, treatment duration)

Source: Medicines for Europe; Accord Healthcare; Kearney

Data sources

- **Actual data** of number of daily deaths as of **May 21st 2020**
- Worldometer Coronavirus reports
- WHO Situation Reports
- Expert opinions
- Secondary research, e.g.
  - Robert-Koch-Institute, Germany
  - International Long-Term Care Policy Network (https://ltccovid.org/)
  - ICNARC – Intensive Care National Audit & Research Centre
  - Various scientific articles (e.g., Grasselli et al., JAMA; Bhatraju et al., NEJM)

Key assumptions

- **Herd immunity will not be achieved** by any country during first COVID-19 wave
- **Individual country responses** to a second COVID-19 wave will be **identical to responses to the first wave**
- The development of the second COVID-19 wave will be **similar to the first wave**
- Only COVID-19 related deaths occurring in ICUs will **cause demand in critical medicines**
- Number of daily deaths will decrease **around 28-days post-lockdown**

Demand forecasting model

Accuracy vs real world data

	Model version: 1 (Data lock point 21 Apr 2020)		
	Model prediction 01 March 2020 17 June 2020	Actual worldometer 01 March 2020 17 June 2020	% difference
Total EU	**170,680**	**174,639**	**-2.3%**
EU-5	**139,769**	**142,239**	**-1.7%**
Spain	26,405	27,136	-2.7%
France	28,707	29,575	-2.9%
UK	45,432	42,153	7.8%
Italy	30,953	34,448	-10.1%
Germany	8,273	8,927	-7.3%

	Model version: 2 (Data lock point 11 May 2020)		
	Model prediction 01 March 2020 17 June 2020	Actual worldometer 01 March 2020 17 June 2020	% difference
Total EU	**163,923**	**174,639**	**-6.1%**
EU-5	**134,205**	**142,239**	**-5.6%**
Spain	28,212	27,136	4.0%
France	28,709	29,575	-2.9%
UK	35,879	42,153	-14.9%
Italy	32,979	34,448	-4.3%
Germany	8,426	8,927	-5.6%

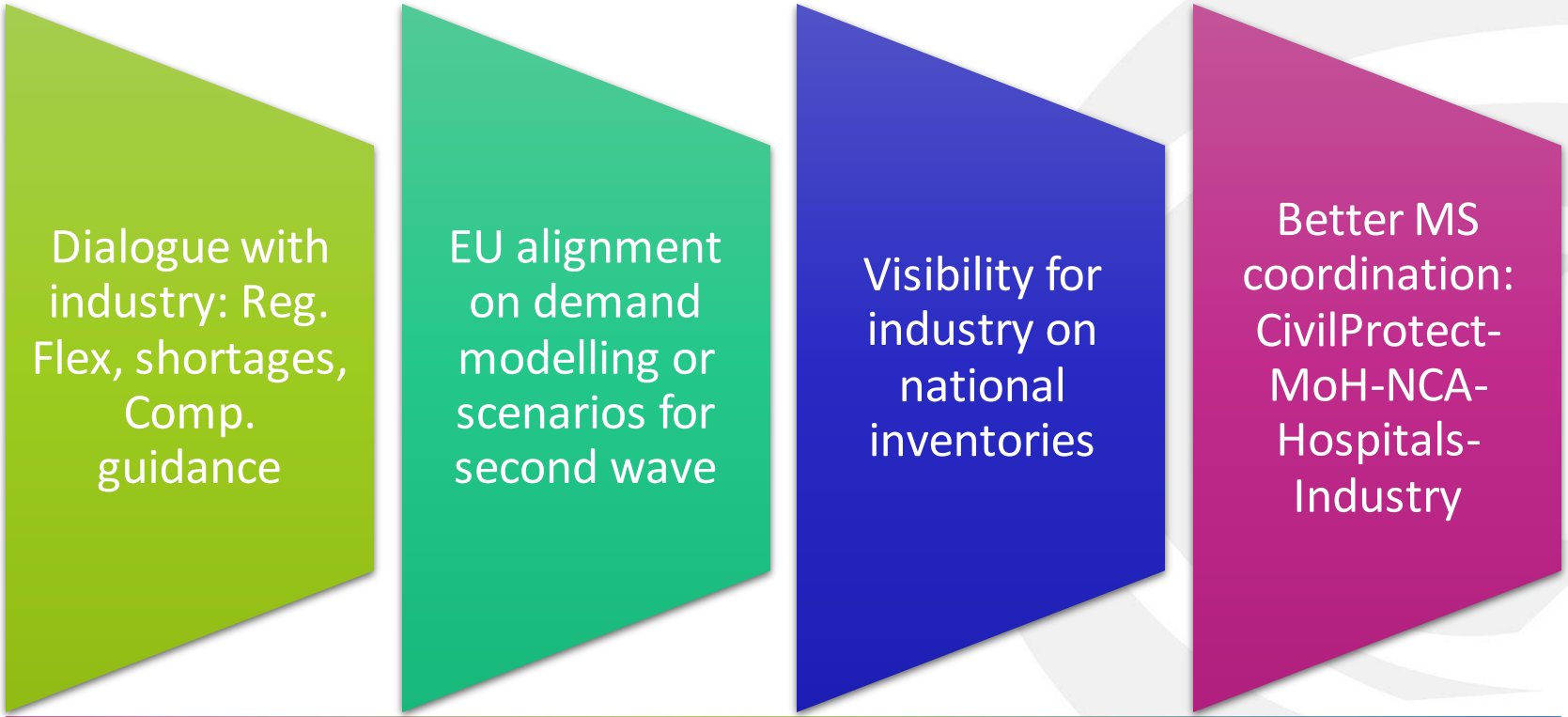
Three different scenarios – best, base and worst case – will indicate medicines demand for a potential second COVID-19 wave

Selected scenario overview for a second COVID-19 wave
Key characteristics

		Best Case	Base Case	Worst Case
Scenario illustration for molecule demand		*Lowest absolute demand (kg)*	*Likely demand (kg)*	*Highest likely demand (kg)*
Model parameters	# of new deaths vs. first wave	- 50%	Same	+ 50%
	% patients on MV	50%	50%	100%
	Treatment duration		Likely	
Total # new ICU patients (October 1st – November 30th 2020)		33’153	66’306	99’459

Source: Kearney

EU & MS Policy action



patients • quality • value • sustainability • partnership

External factors

Second waves in US, Brazil,* Mexico* = demand for medicines

Indian second wave: limited impact on supply chain

India-China military tensions: uncertain impact--> to monitor

Can we improve EU dialogue with key partners?

*LA demand has biggest impact on EU manufacturers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How do we move forward?

Going forward, the industry has three clear asks to the European Commission and the member states

Clear volume commitments

- Each member state should make clear and legally binding volume commitments
- There should be no refund of surplus purchases
- Delivery in instalments should be possible (based on need, contractually determined)

Clear guidelines for storage

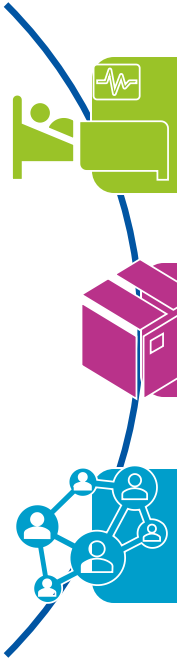
- Medicines Reserve should be warehoused by industry, wholesaler or distributor
- Additional expenses (e.g., for warehouse space) should be covered/ insured
- Unused medicines can be given to hospitals, be donated or moved to other member states in need (in contractually agreed volumes)

Clear allocation policy

- The need-based access of all members states to EC Medicines Reserve should be ensured
- The EC should manage distribution to member states using industry/ wholesaler/ distributor logistics
- National agencies/ governments should manage distribution of stock within countries
- Appropriate regulatory flexibility that was granted in the first wave should be maintained (e.g., for national licensing)

Source: Medicines for Europe; Kearney

Clear asks for predictable results



Accurate **demand forecast** based on expected **patient needs** to prevent speculation and secure necessary manufacturing capacity

Volume commitments are necessary to mobilize stock to where it is really needed → **shared responsibility**

Clarity and coordination at **national** level are important to understand **inventories/stock levels remaining** – preparedness cannot be done in isolation

Thank you