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**EUROPEAN HEALTHCARE DISTRIBUTION  
ASSOCIATION**

GROUPEMENT INTERNATIONAL DE LA  
RÉPARTITION PHARMACEUTIQUE




**GIRP study - Causes of supply disruptions across Europe**

*April 2020*

# GIRP analysis of root causes of shortages in Europe

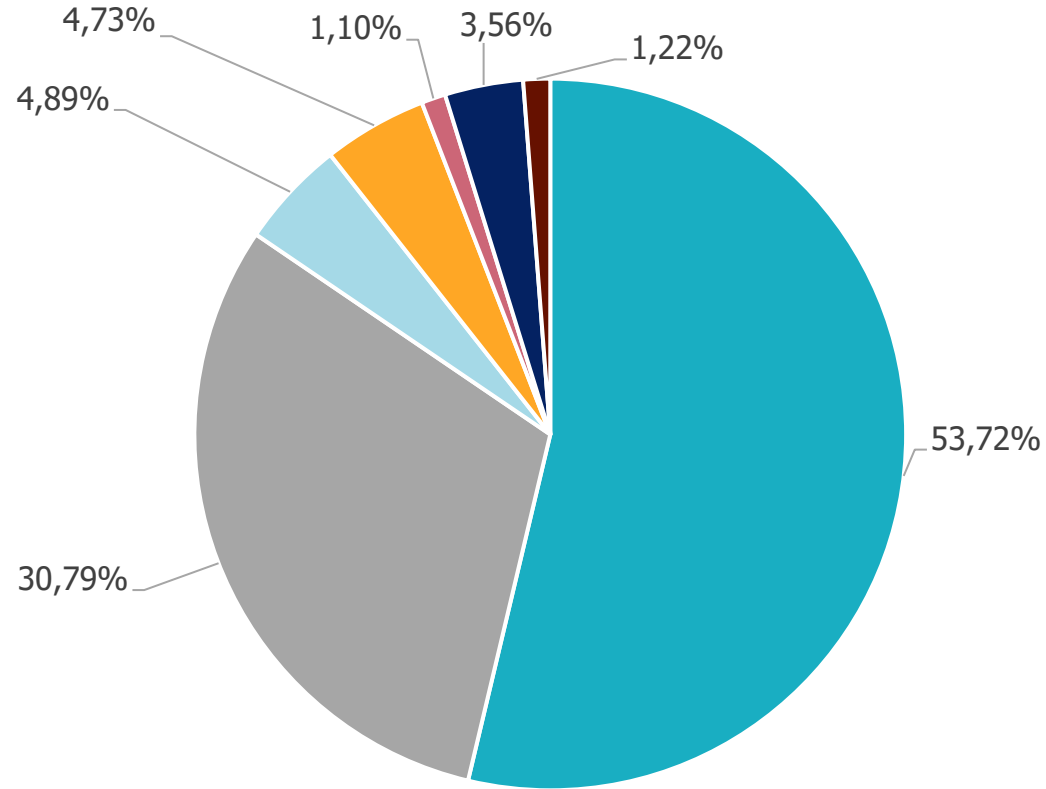
- This slide deck shows the results of the GIRP data analysis of **root causes of shortages** from publicly available sources in European countries
  - First analysis: July 2019, second analysis: April 2020
  - Databases with public information on root causes of shortage: Austria, Belgium, Croatia, Czech Republic, Germany, Hungary, Ireland, Italy, Norway, Romania
  - Note: quality and granularity of data as well as periods of updates of information in databases vary greatly from country to country
- Information in databases usually obtained from MAH (Manufacturing Authorisation Holders) → **no “signals from the market”** (i.e. calculated demand based on no. of prescriptions)
- **Greater harmonisation and transparency across Europe needed**

# Basis for analysis

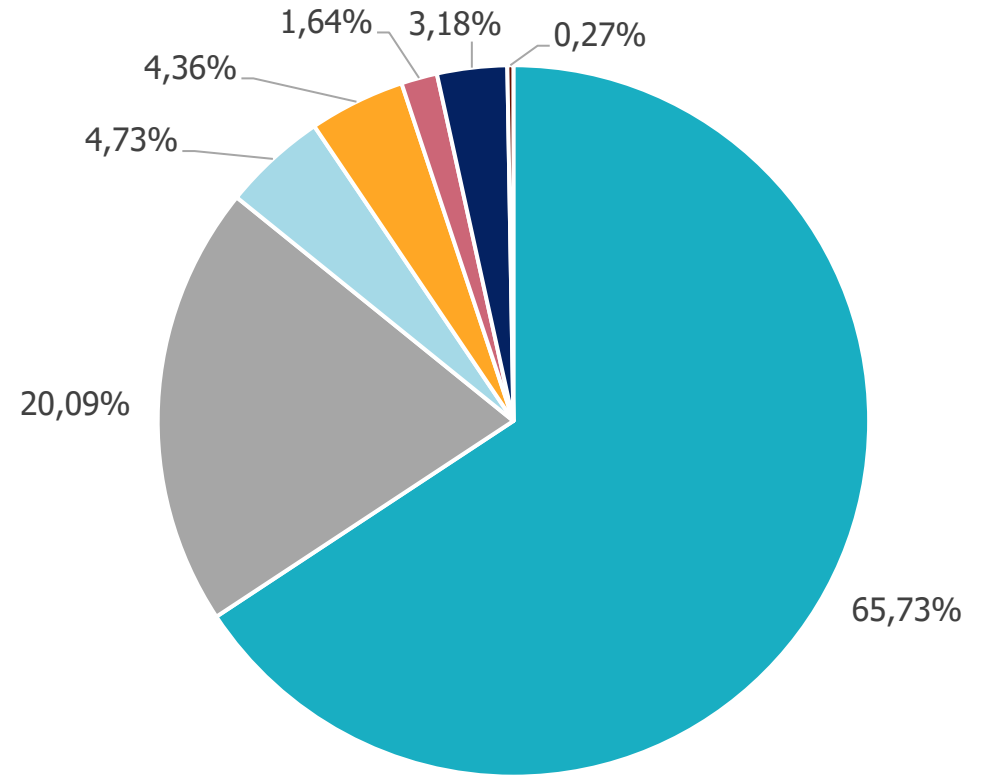
Database with public information on root causes of shortages	Database without public information on root causes of shortages	No public database on shortages
 <p>AT BE CZ IE</p> <p>HR DE HU</p> <p>NO ES RO</p>	 <p>DK EE FI FR</p> <p>LV LI LT</p> <p>PL SK SI</p> <p>SE CH UK</p>	 <p>BG GR LU</p> <p>NL PT</p>

# Causes of supply disruptions – Summary

Driven by an unexpected increase in demand of medicines during the COVID-19 pandemic, manufacturing issues remain the major cause for shortages, directly followed by commercial reasons



July 2019



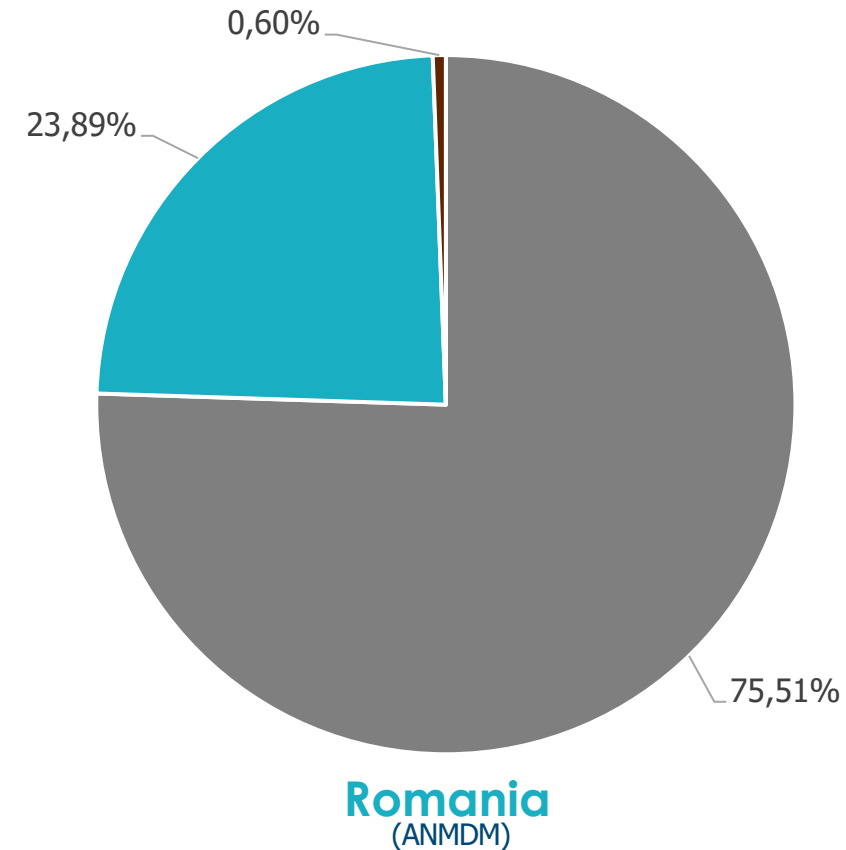
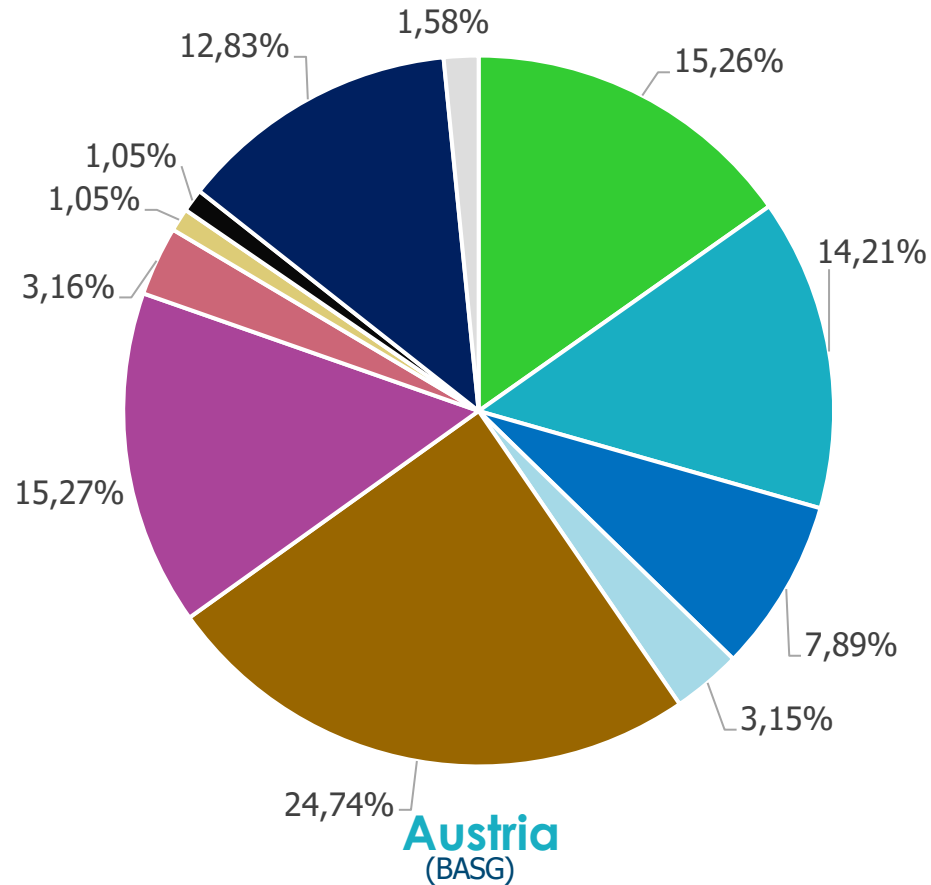
April 2020

- Manufacturing reasons\*
  - Commercial & market-related reasons
  - Other reasons
  - No reason given
  - Regulatory reasons
  - API/starting material reasons
  - Supply chain related reasons
- \*includes manufacturing issues due to unforeseen increases in demand



# Causes of supply disruptions – Granularity of data

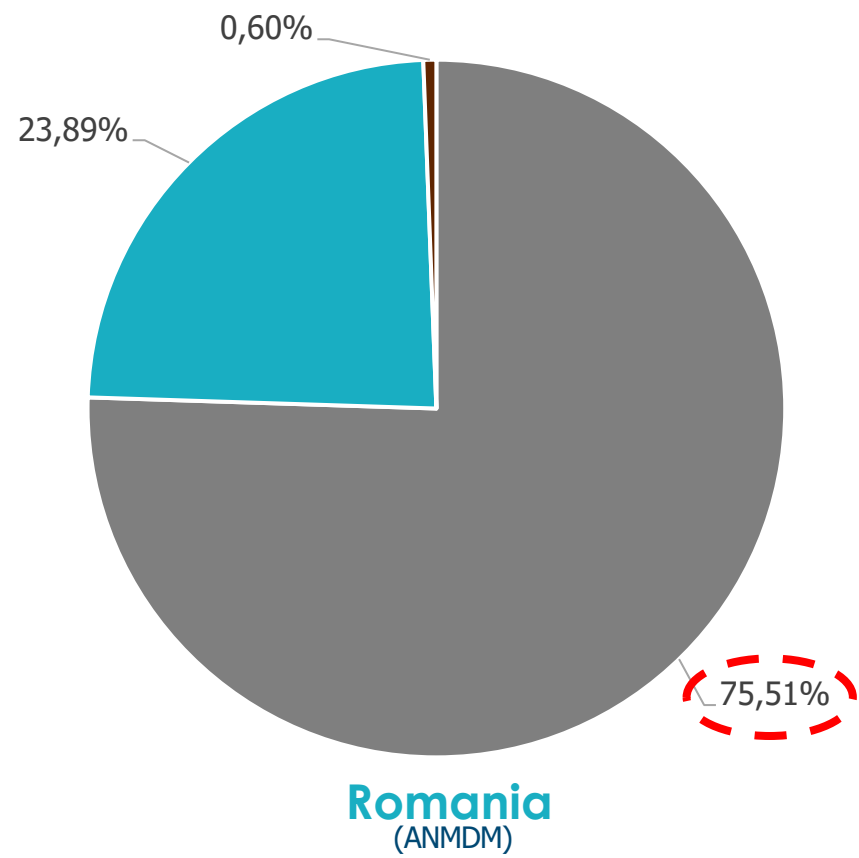
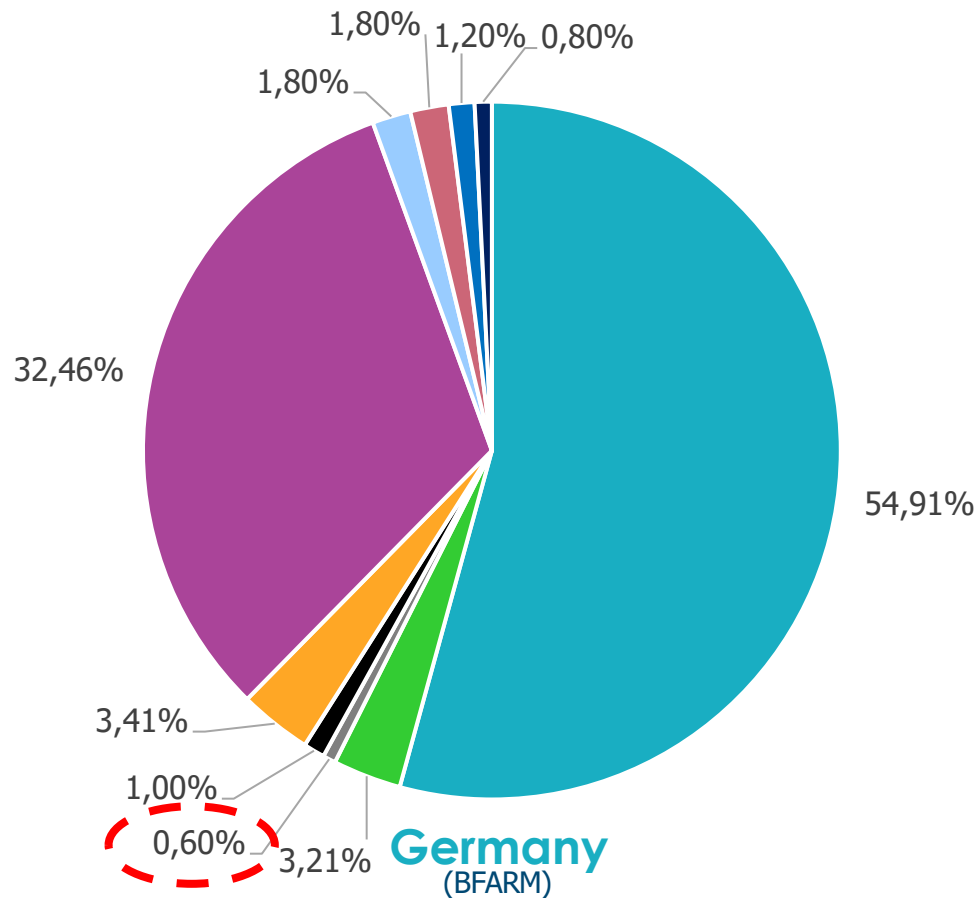
Granularity of data varies greatly across EU and some countries consider withdrawal from market of a product a reason for a shortage, others do not



- Quality issues
  Capacity constraints
  Commercial reasons (market withdrawal)
  Delay in manufacturing/releasing product
- Shortage of the API
  Batch recall
  Increased demand
  Regulatory changes
  GMP-issues
- Delay in receiving packaging material
  Other reasons
  Transfer of production to an alternative manufacturer

# Causes of supply disruptions – higher vs lower priced countries

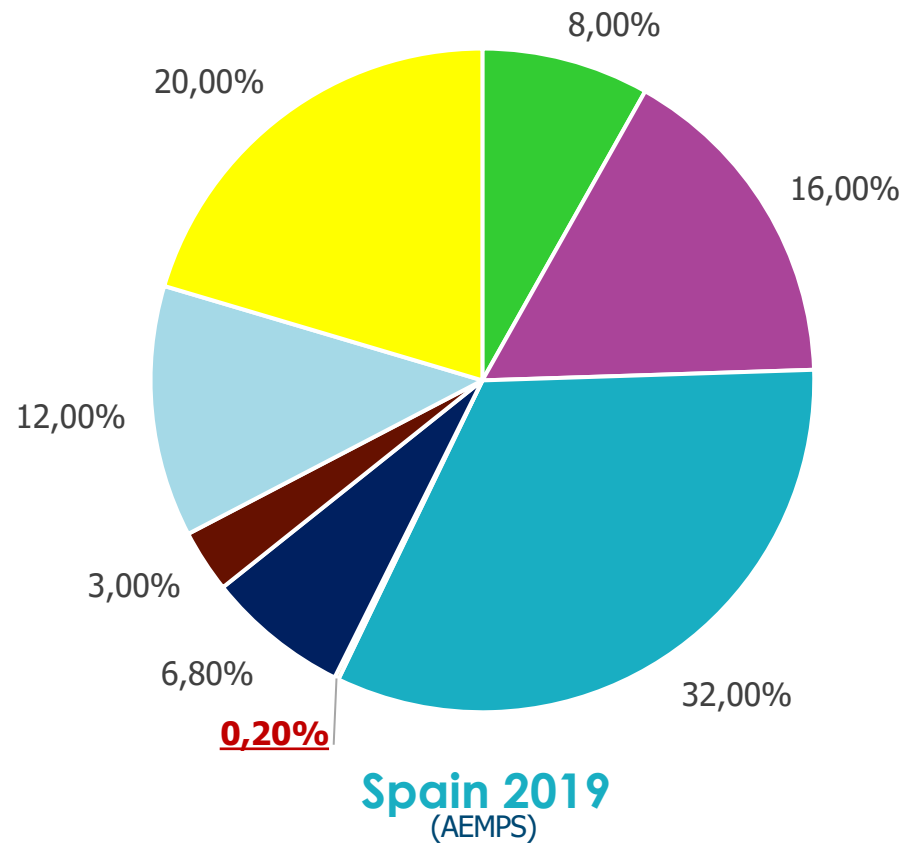
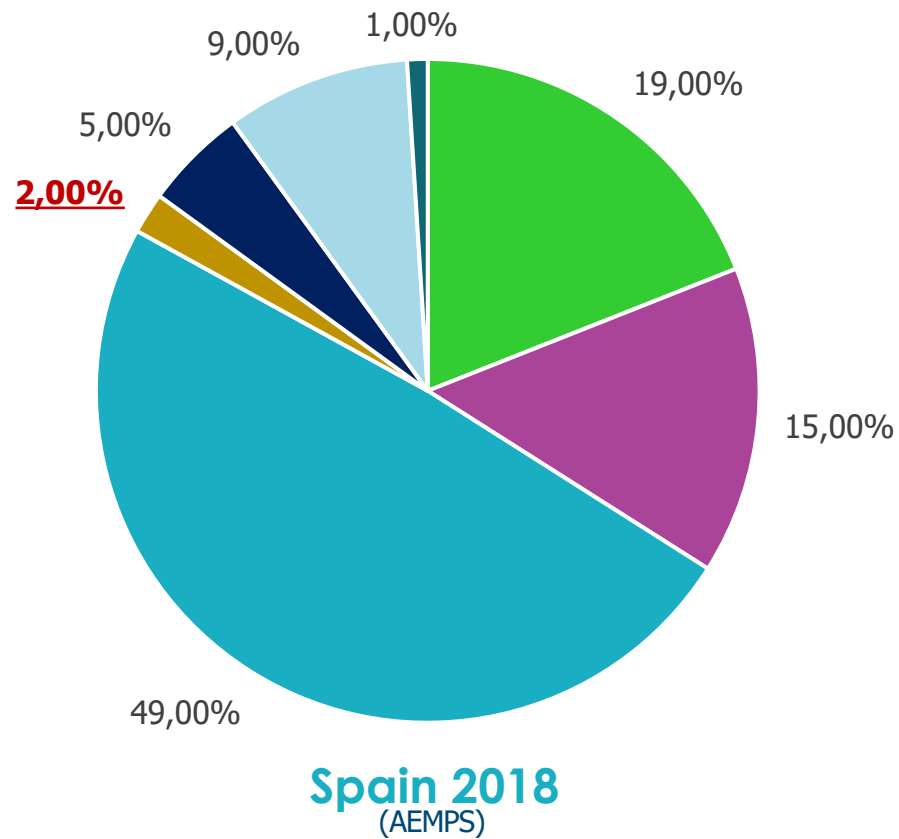
Commercial reasons are a significantly more important factor for shortages in countries in the EU with lower-priced medicines compared to countries



- Quality issues
  Capacity constraints
  Commercial reasons (market withdrawal)
  Delay in manufacturing/releasing product
- Shortage of the API
  Batch recall
  Increased demand
  Regulatory changes
  GMP-issues
  Pharmacovigilance reasons
- Delay in receiving packaging material
  Other reasons
  Transfer of production to an alternative manufacturer

# Causes of supply disruptions – parallel trade

Spain remains the only country to officially track parallel trade as a reason for shortages and registers a significant decrease over the last years



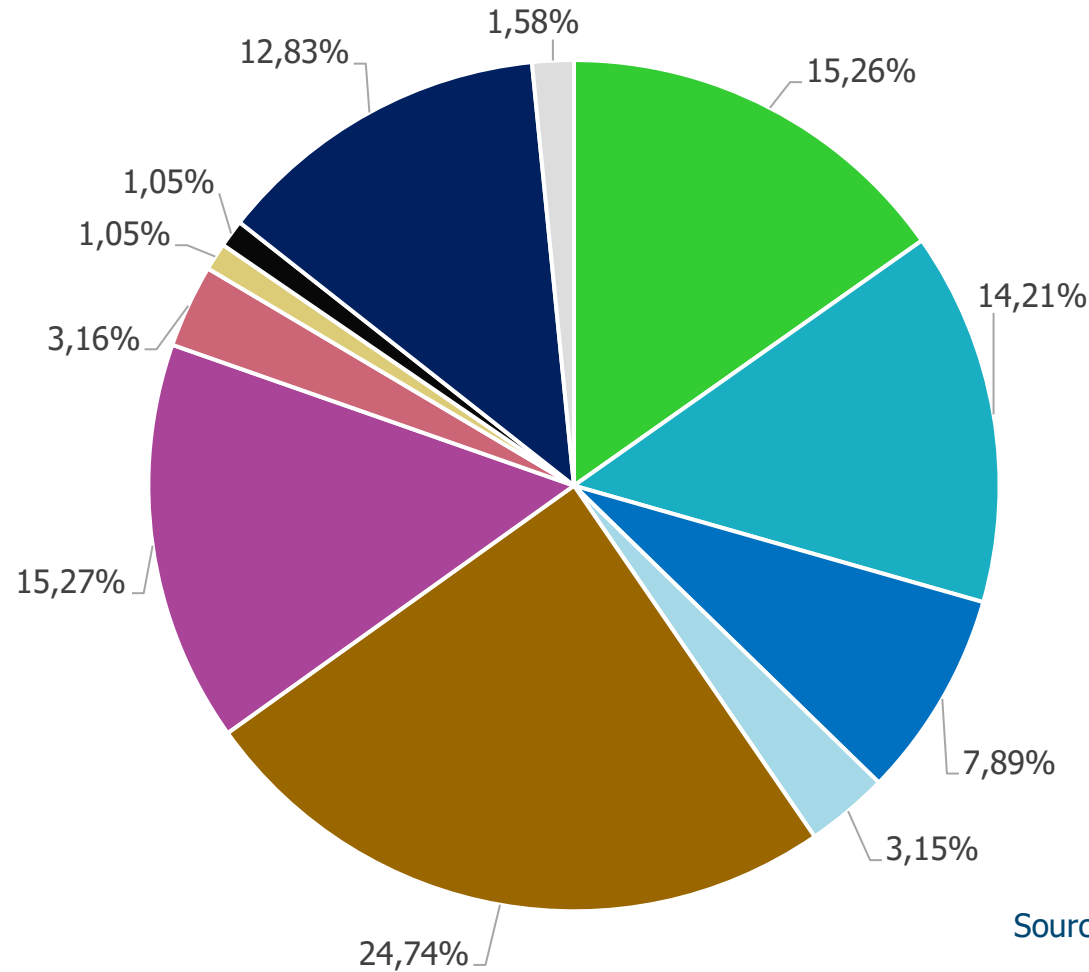
- Increased demand
- Manufacturing problems
- Parallel trade
- Other
- Unknown reason
- Active substance not available
- Production capacity problems
- Quality problems
- Discontinued manufacturing (market withdrawal)

# GIRP analysis of root causes of shortages in Europe

The following slides show the results country by country for the analysis prepared in April 2020



# Causes of supply disruptions – Austria



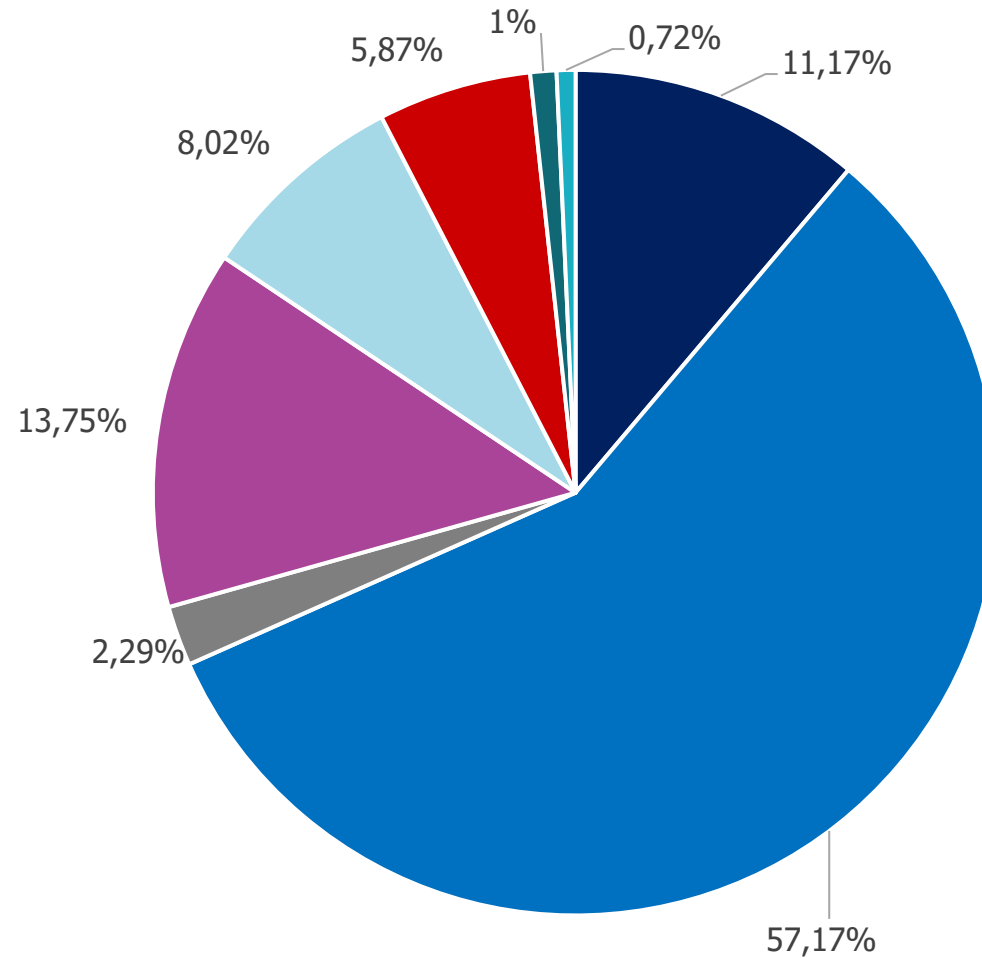
Increased demand  
July 2019: **7.02%**

Increased demand  
April 2020: **15.27%**

Source: BASG

- Quality issues
- Capacity constraints during manufacturing
- Delay in manufacturing or releasing the finished product
- Shortage of the API
- Batch recall
- Increased demand
- Regulatory changes
- GMP-issues
- Delay in receiving packaging material
- Other reasons
- Transfer of production to an alternative manufacturer

# Causes of supply disruptions – Belgium



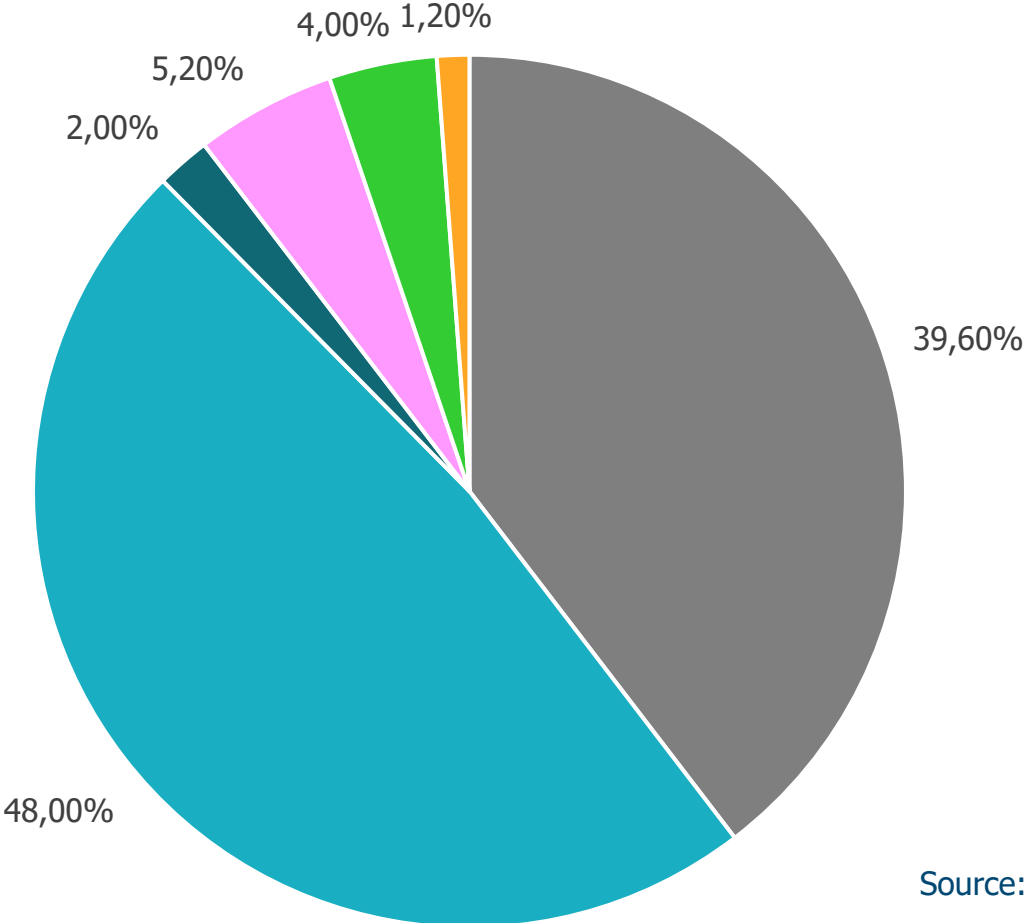
Increased demand  
July 2019: **0%**

Increased demand  
April 2020: **13.75%**

Source: FAGG/AFMPS

- Manufacturing issues
- Other reasons
- Delay in manufacturing or releasing the finished product
- Temporary suspension of the commercialisation
- Increased demand
- Shortage of starting material
- FMD/serialisation issues
- Logistical problems

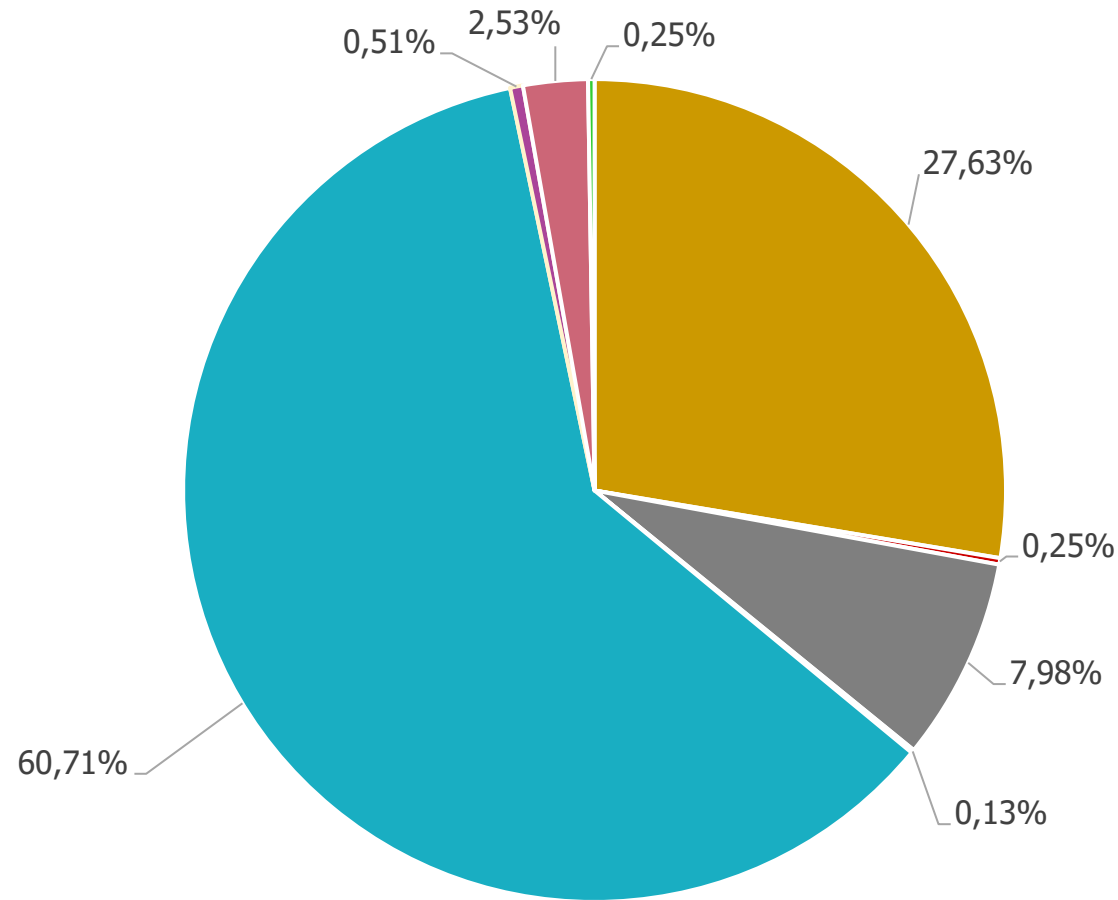
# Causes of supply disruptions – Croatia



Source: HALMED

- Commercial & market-related reasons
- Manufacturing reasons
- Logistical problems
- No demand
- Quality issues
- Supply problems

# Causes of supply disruptions – Czech Republic

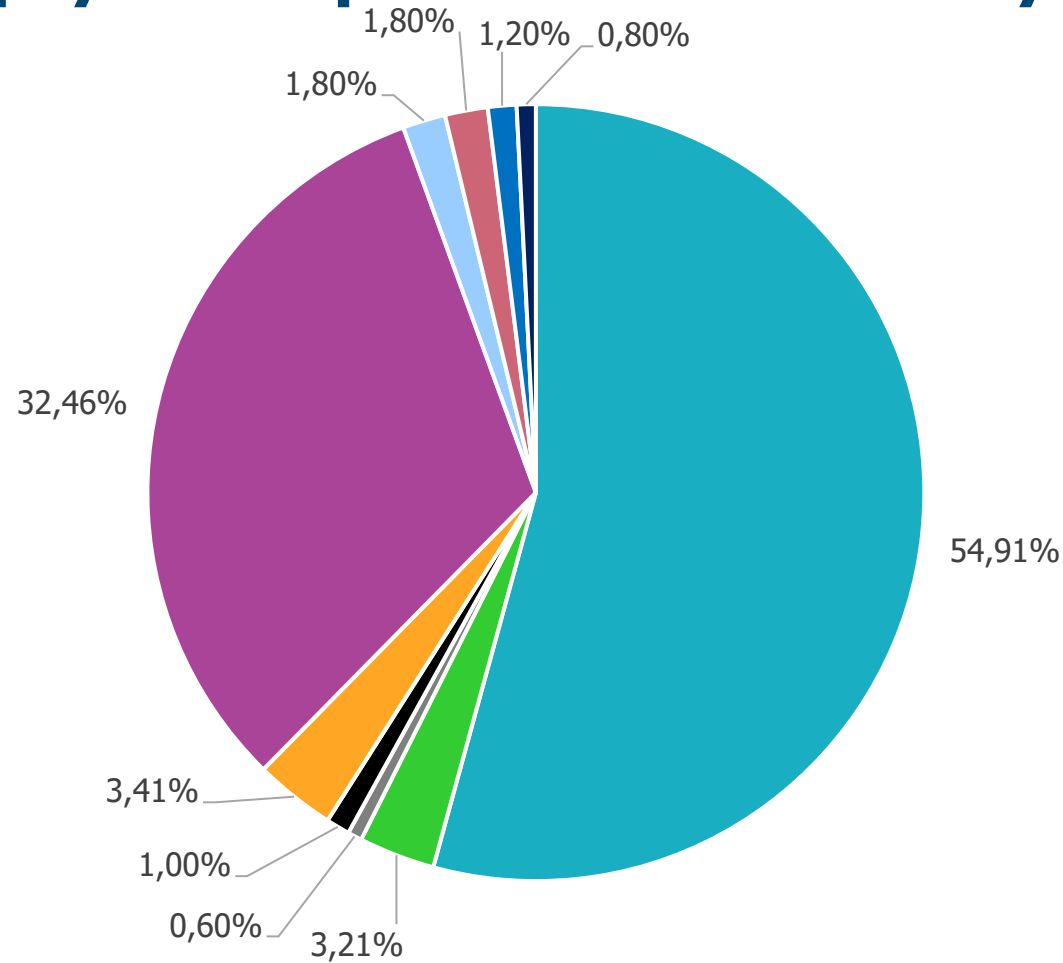


Increased demand  
July 2019: **0.87%**

Increased demand  
April 2020: **0.51%**

- Capacity, distribution reasons
- Serialisation issues
- Commercial, marketing reasons
- Lack of API
- Manufacturing reasons
- Increased demand
- Regulatory reasons
- Quality issues

# Causes of supply disruptions – Germany\*



Increased demand  
July 2019: **6.36%**

Increased demand  
April 2020: **32.46%**

Source: BFARM  
\*Vaccines not included.  
Note: Relates to no. of SKUs in shortage

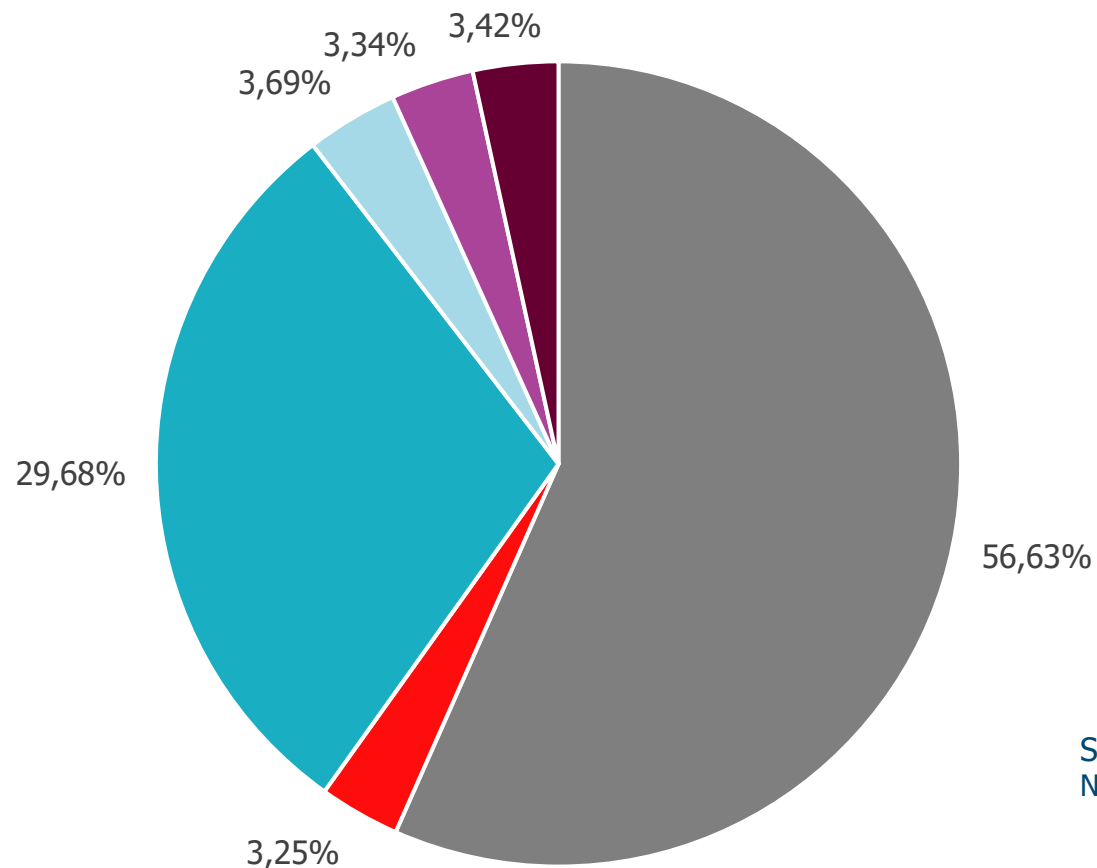
- Manufacturing issues
- Delays in the supply chain
- Regulatory delays/issues
- Quality issues
- Increased demand
- Delays in production
- Commercial reasons
- Packaging issues
- Limited availability of API
- Others



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# Causes of supply disruptions – Hungary



Increased demand  
July 2019: **1.45%**

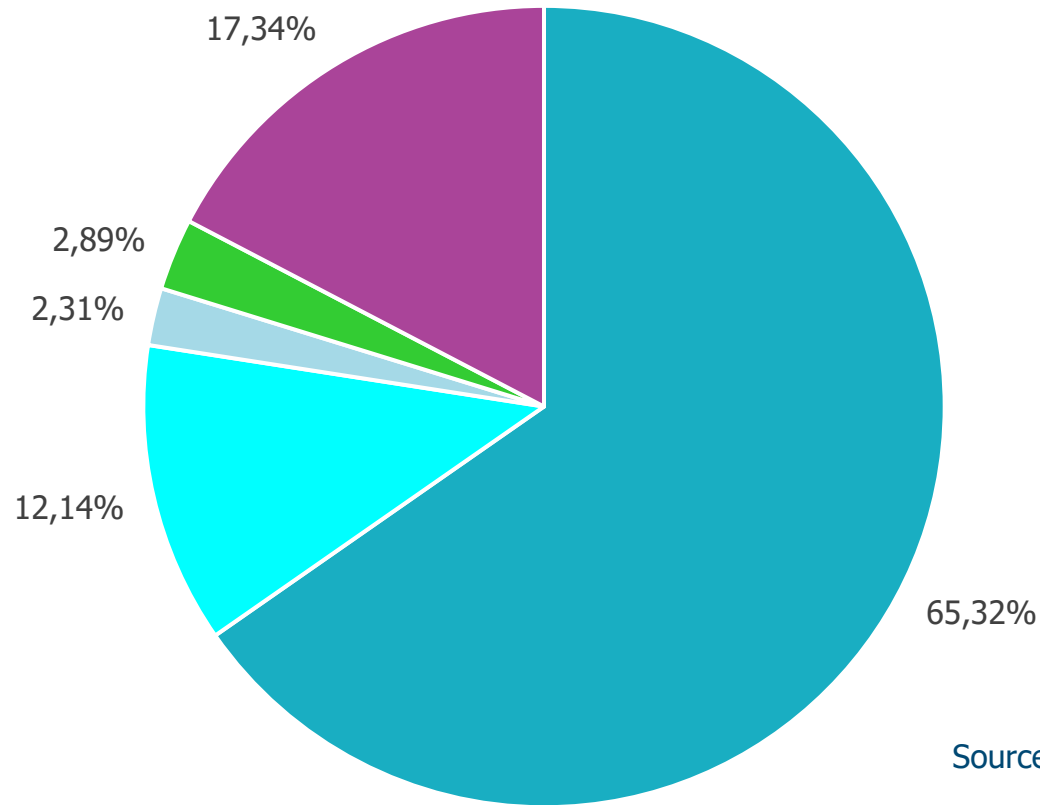
Increased demand  
April 2020: **3.25%**

Source: OGYEI  
Note: Relates to no. of SKUs in shortage

- Market considerations
- Administrative reasons
- Manufacturing issues
- Active substance or other raw material supply problems
- Increased demand
- Transport or storage problems



# Causes of supply disruptions – Ireland



Source: HPRA

Increased demand  
July 2019: **15%**

Increased demand  
April 2020: **17.34%**

Manufacturing delays  
July 2019: **28.13%**

Manufacturing delays  
April 2020: **65.32%**

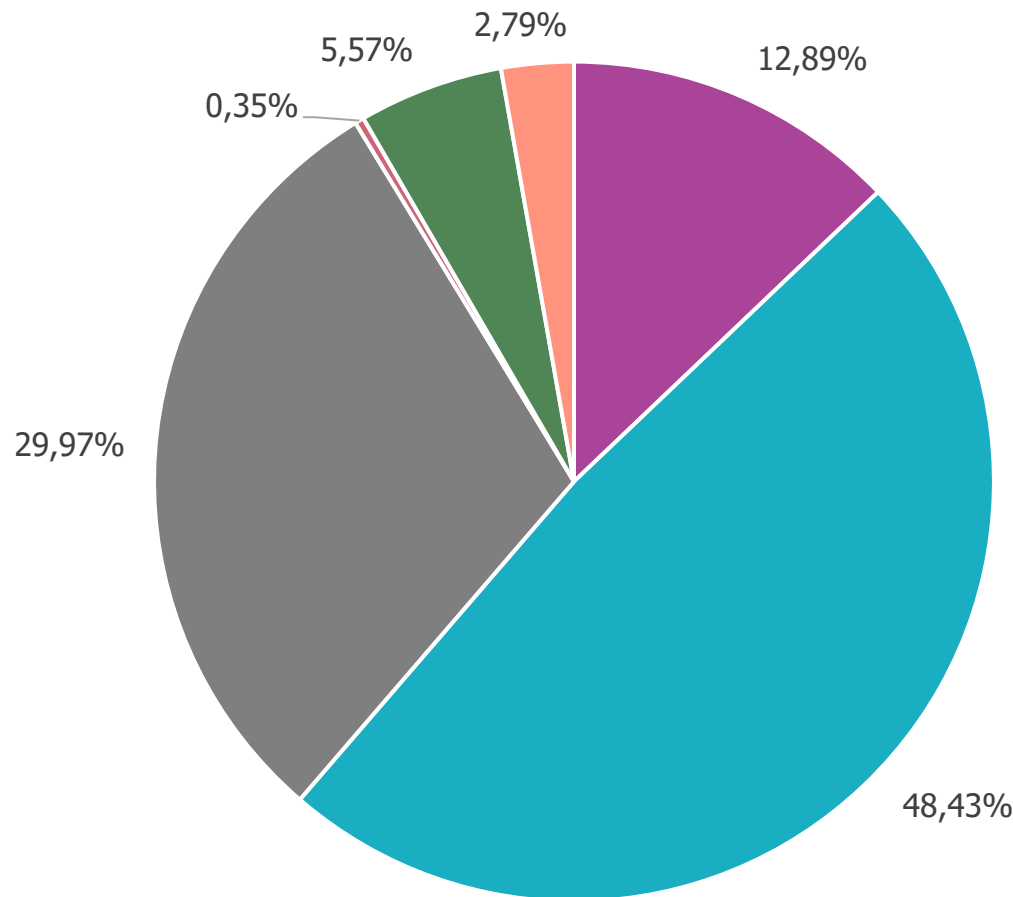
- Manufacturing delays
- Active substance impurity
- API problems (unavailability and delay)
- Quality issues
- Unexpected increase in demand



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# Causes of supply disruptions – Italy



Increased demand  
July 2019: **0%**

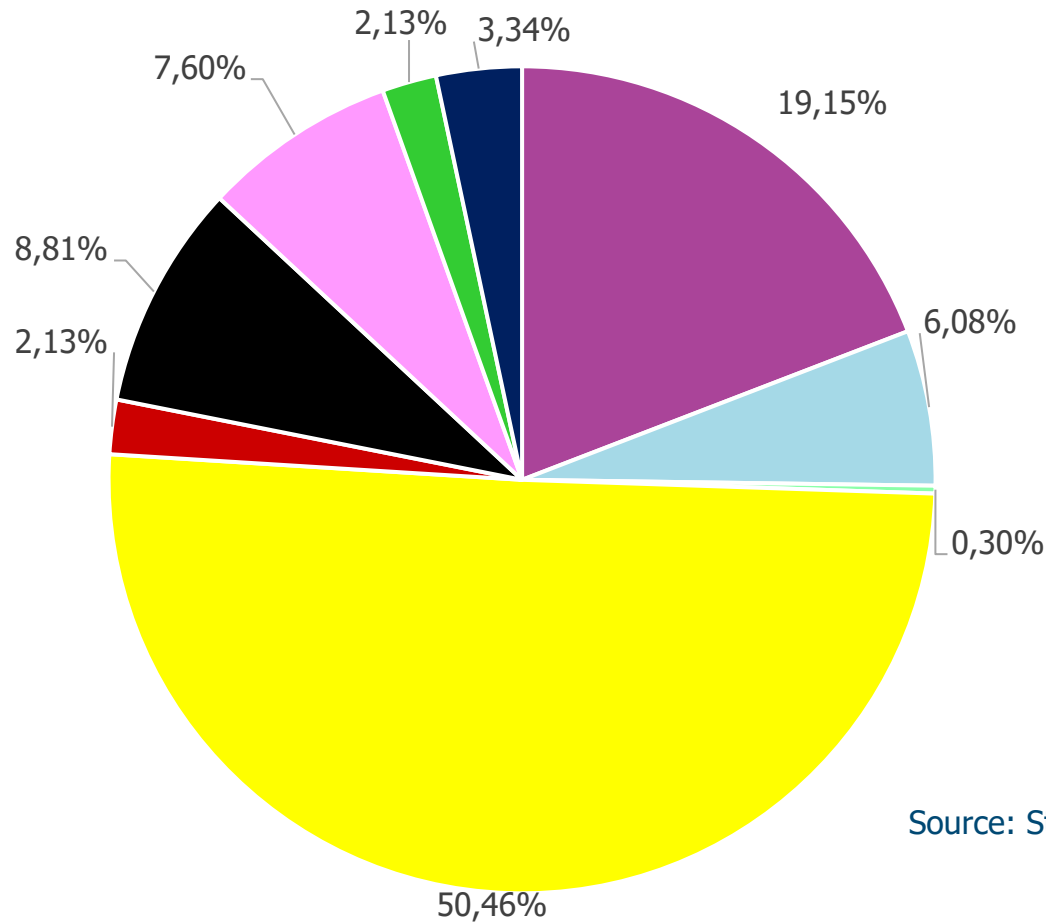
Increased demand  
April 2020: **12.89%**

Source: AIFA

- Increased demand
- Manufacturing issues
- Commercial, marketing reasons
- Regulatory reasons
- Quota distribution
- Irregular supply



# Causes of supply disruptions – Norway



Source: Statens Legemiddelverk

Increased demand  
July 2019: **15.22%**

Increased demand  
April 2020: **19.15%**

Manufacturing  
delays July 2019:  
**67.71%**

Manufacturing  
delays April 2020:  
**50.46%**

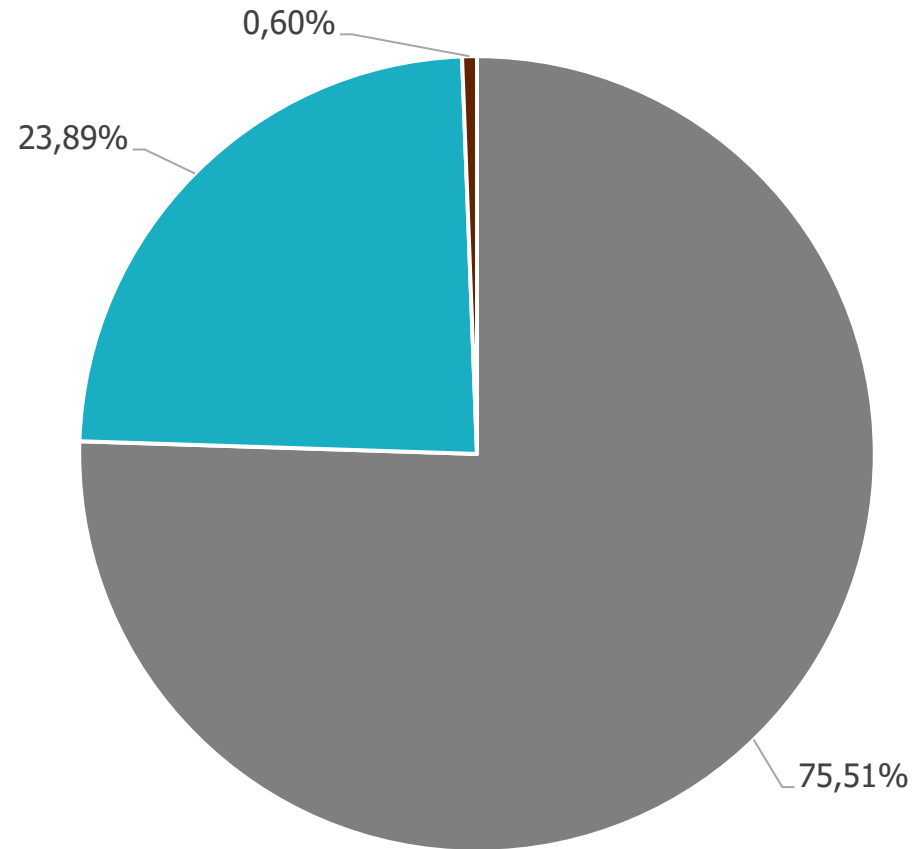
- Increased demand
- API/starting material problems
- Export ban in exporting country
- Production and capacity problems/delays
- Serialisation problems
- Challenges with packing quality and packaging capacity
- Low profitability/low sales
- Quality issues
- Other reasons



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# Causes of supply disruptions – Romania APRIL 2020



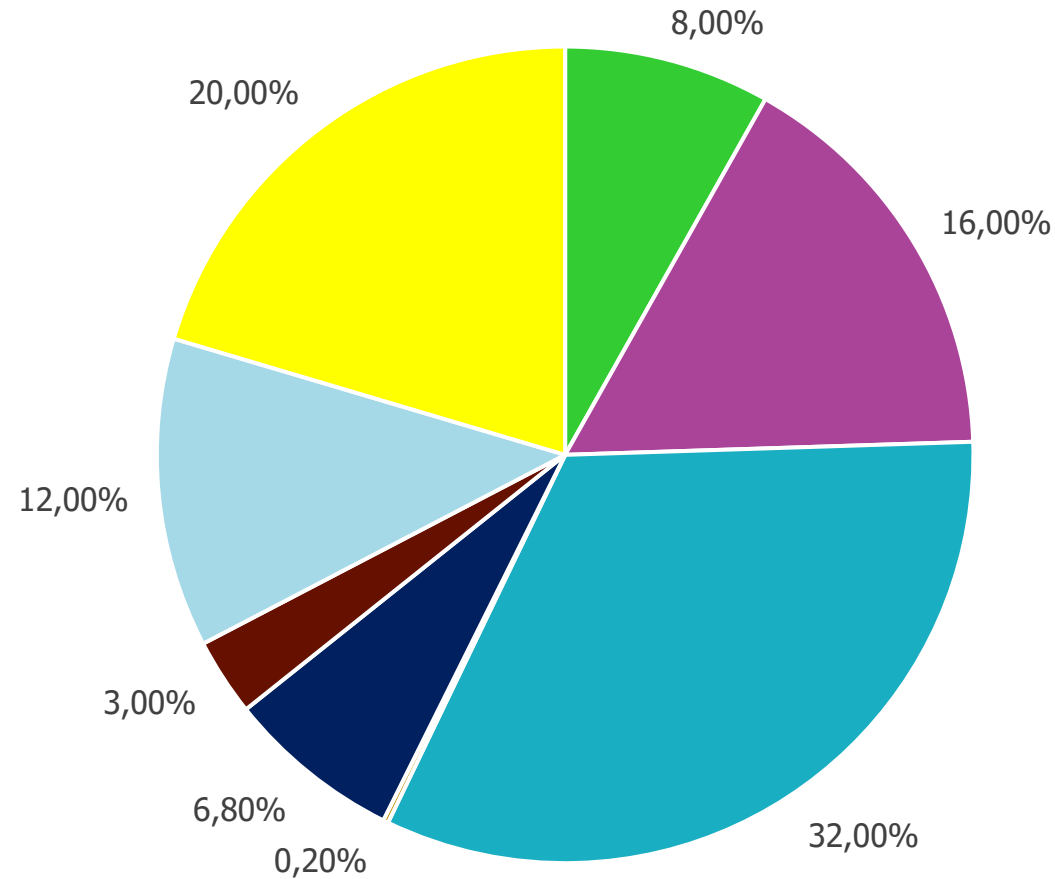
Source: ANMDM

Commercial & market-related reasons

Manufacturing reasons

Pharmacovigilance reasons

# Causes of supply disruptions – Spain\*



Source: AEMPS 2019

\*shortages registered in the second semester of 2019

- Increased demand
- Manufacturing problems
- Parallel trade
- Other
- Unknown reason
- Active substance not available
- Production capacity problems
- Quality problems