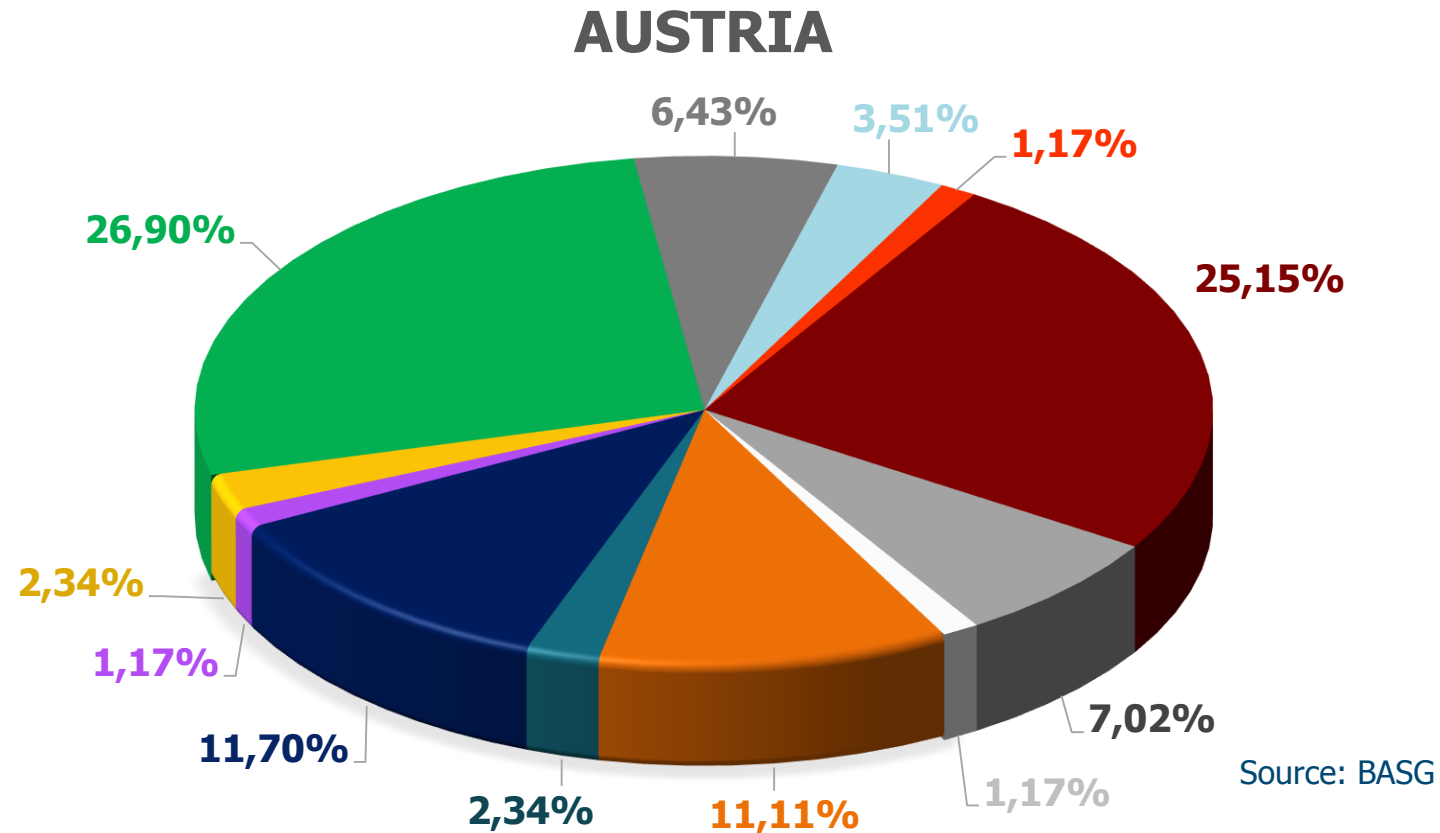


# Causes of supply disruptions – Austria\*

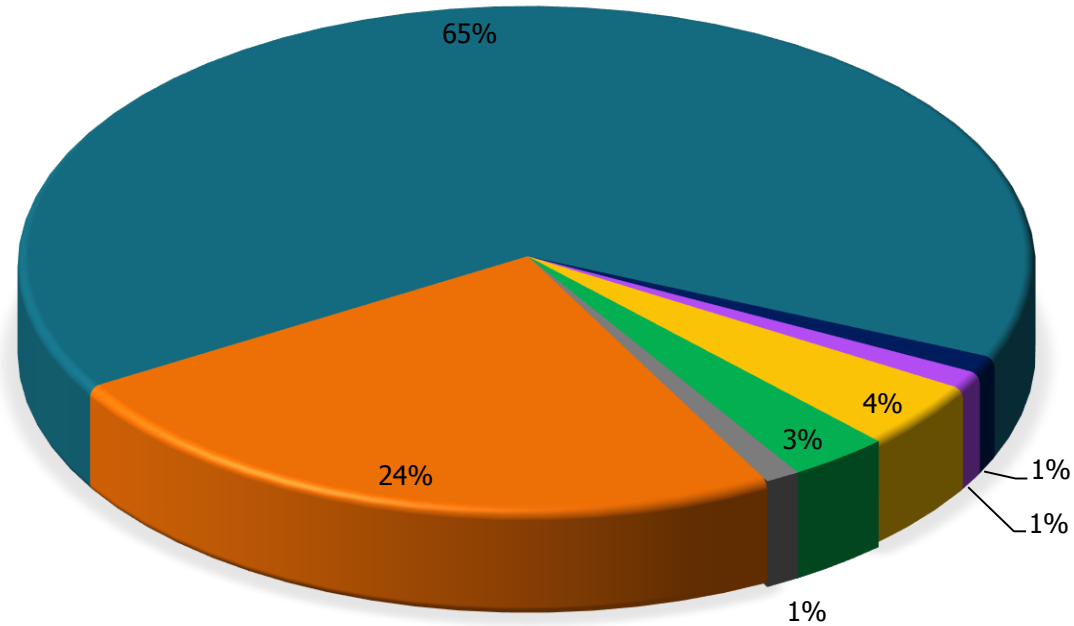


- Quality issues
  Delay in manufacturing or during the release of the finished product
- Capacity constraints at manufacturing site
  Transfer of manufacturing to alternative site
- Shortage or delay of release of the active substance
  Batch recall
  Increased demand
  Regulatory changes
- GMP related issues
  Further supply not planned
  Other reasons
  Cybercrime

\*based on analysis of publicly available data. Database used can be found in the "list of shortages databases EU"

# Causes of supply disruptions – Belgium\*

## BELGIUM



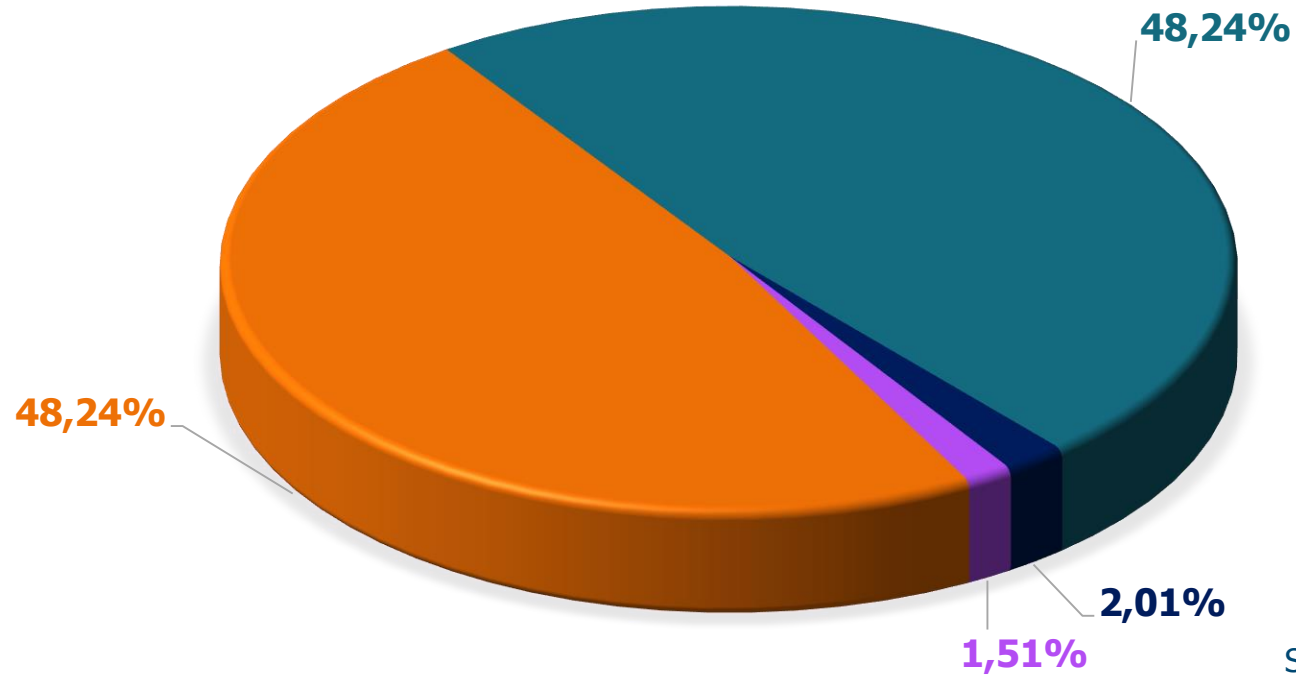
Source: FAGG/AFMPS

- Production problems
- New batch(es) not available yet
- FMD Serialisation
- Packaging problems
- Logistics problems
- Other reasons
- Temporary suspension of commercialisation



\*based on analysis of publicly available data. Database used can be found in the "list of shortages databases EU"

# Causes of supply disruptions – Croatia\*

## CROATIA



Source: HALMED

 Production problems  
 Other reasons

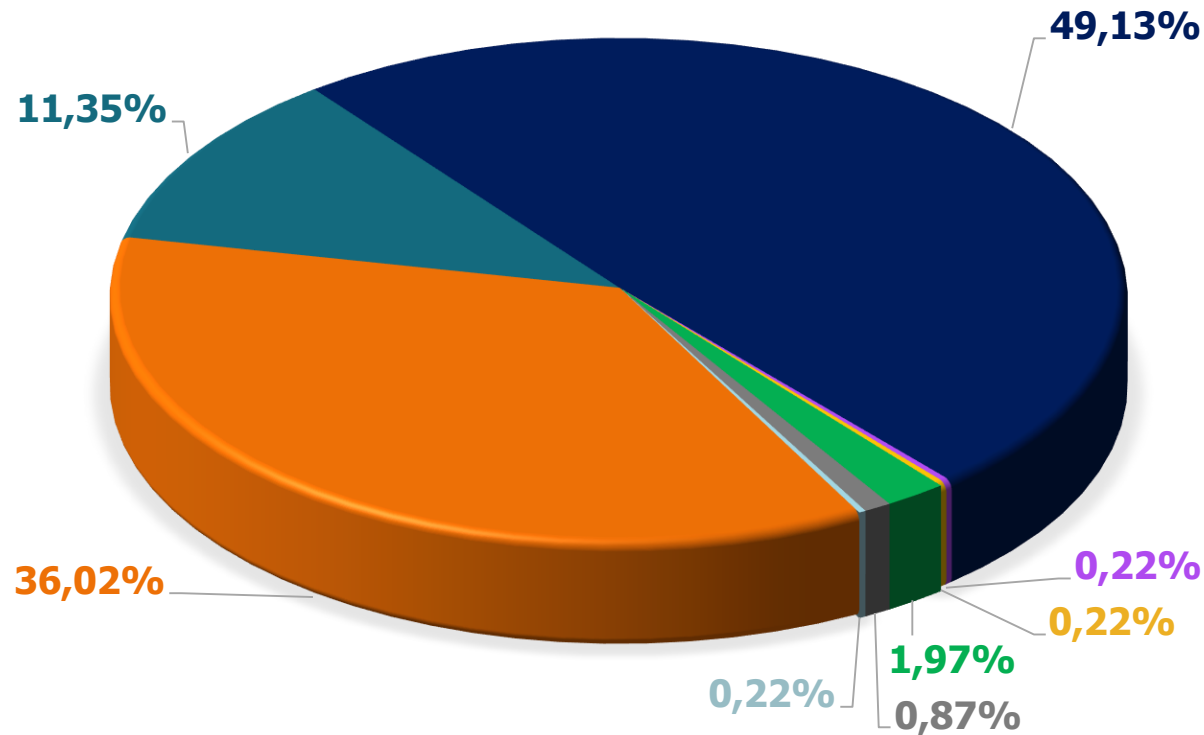
 Discontinued marketing

 Quality issues

\*based on analysis of publicly available data. Database used can be found in the "list of shortages databases EU"

# Causes of supply disruptions – Czech Republic\*

## CZECH REPUBLIC

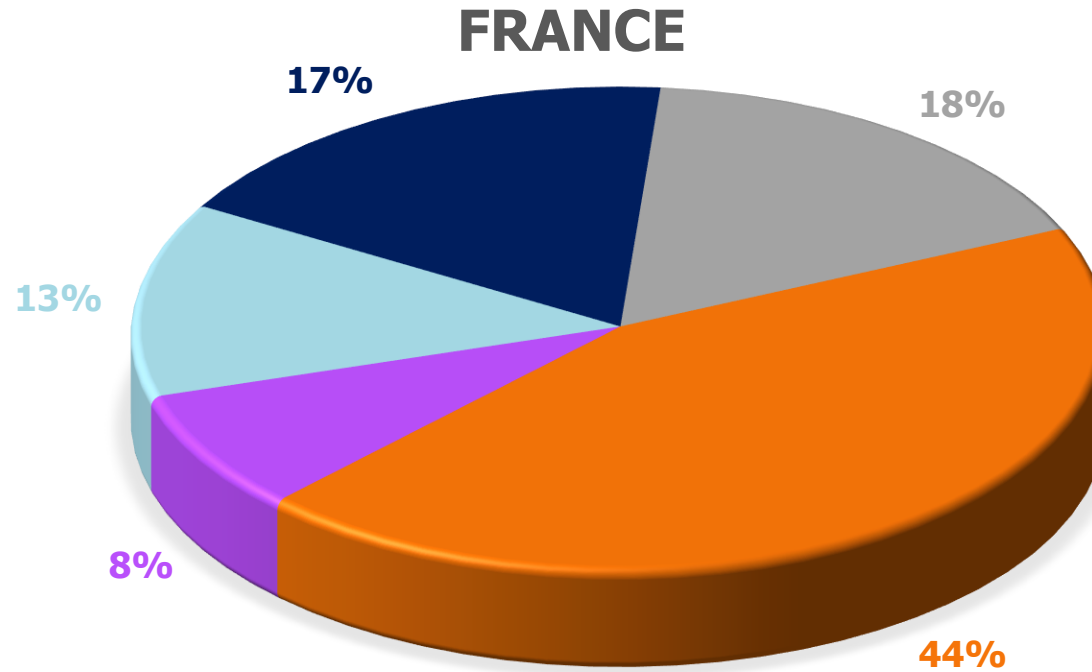


Source: SUKL

- Capacity/distribution issues
- Commercial/marketing reasons
- Manufacturing issues
- Problem with connecting to the EU Hub
- Logistical problems
- Regulatory changes
- Increased demand
- Delays in delivery from the manufacturer

\*based on analysis of publicly available data. Database used can be found in the "list of shortages databases EU"

# Causes of supply disruptions – France\*

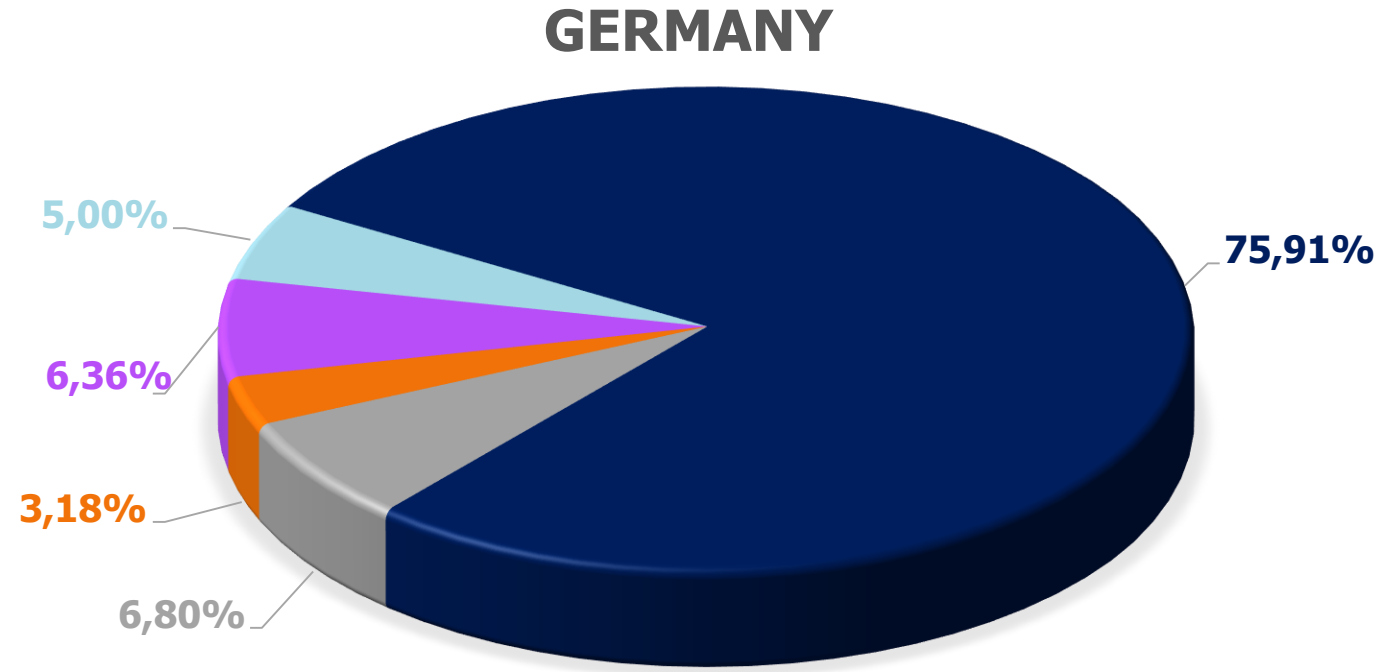


Source: ASNM 2015


- Manufacturing problems
- Problems of supply of raw materials
- Modifications of Marketing Authorisations
- Other reasons
- Quality issues

\*based on publicly available data from official sources.

# Causes of supply disruptions – Germany\*

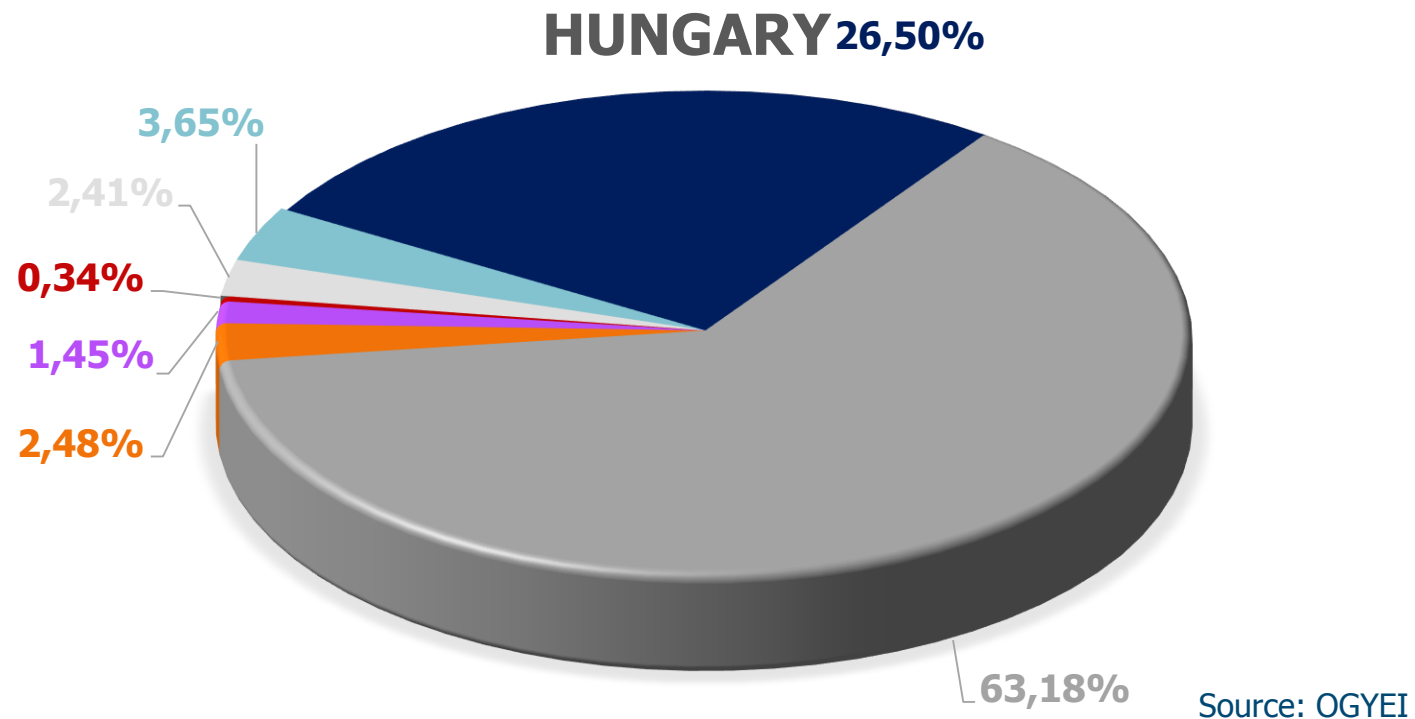


Source: BFARM

-  Manufacturing problems (not further specified)
-  Quality issues
-  Problems of supply of raw materials
-  Increased demand
-  Other reasons

\*based on analysis of publicly available data. Database used can be found in the "list of shortages databases EU"

# Causes of supply disruptions – Hungary\*



Manufacturing problems

Increased demand

Shipping or storage issues

Market considerations

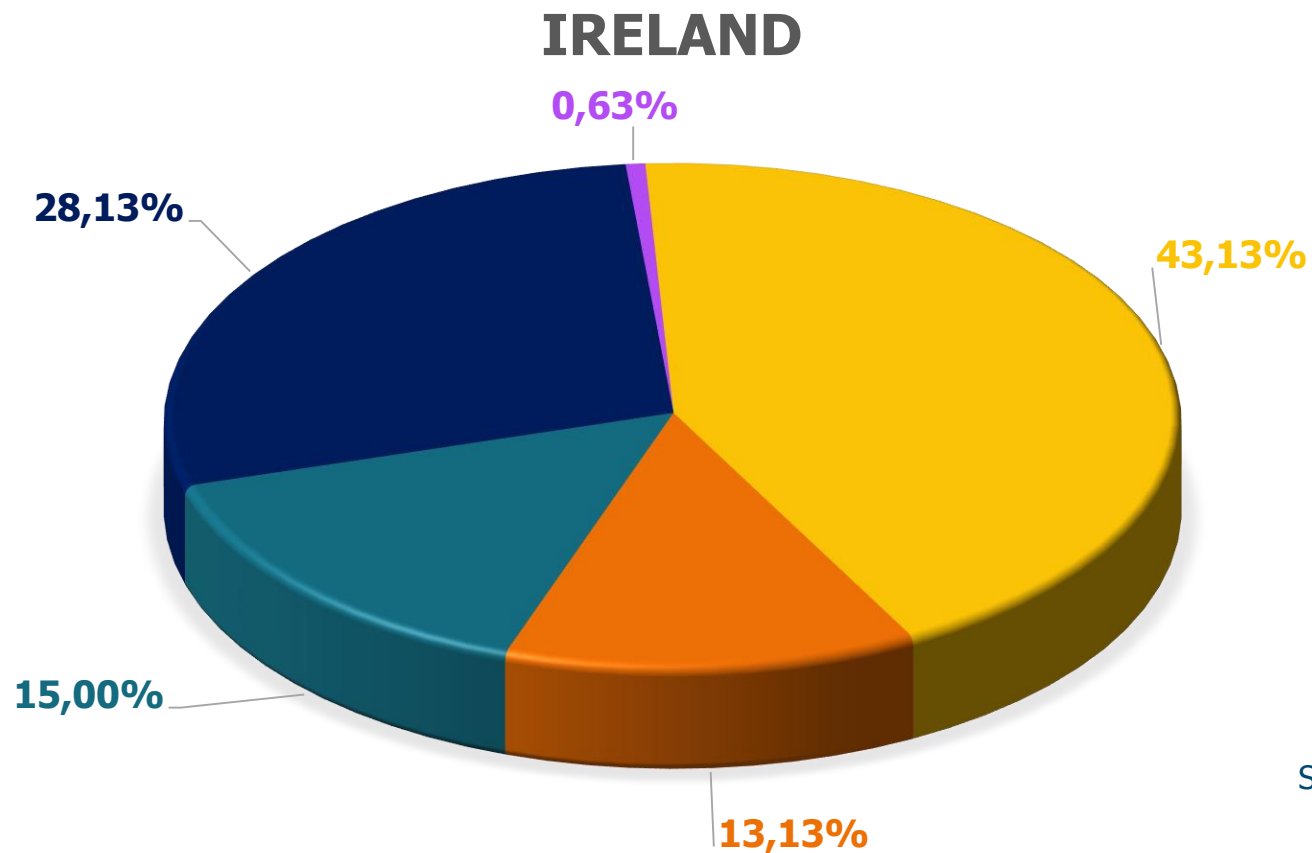
Other reasons

Problems of supply of raw materials

Administrative reasons

\*based on analysis of publicly available data. Database used can be found in the "list of shortages databases EU"

# Causes of supply disruptions – Ireland\*



Source: HPRA

API issue (impurity or unavailability)

(Unexpected) increase in demand

Manufacturing delay

Manufacturing issue

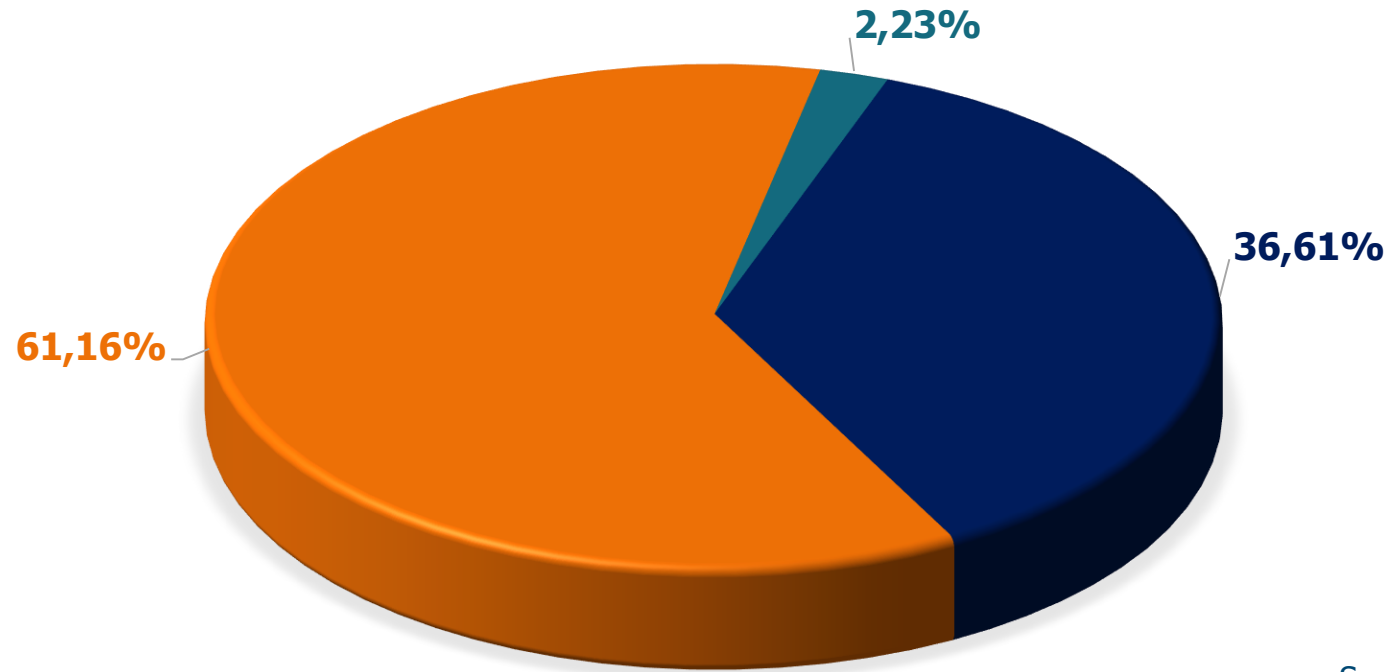
No reason given

\*based on analysis of publicly available data. Database used can be found in the "list of shortages databases EU"



# Causes of supply disruptions – Italy\*

ITALY



Source: AIFA

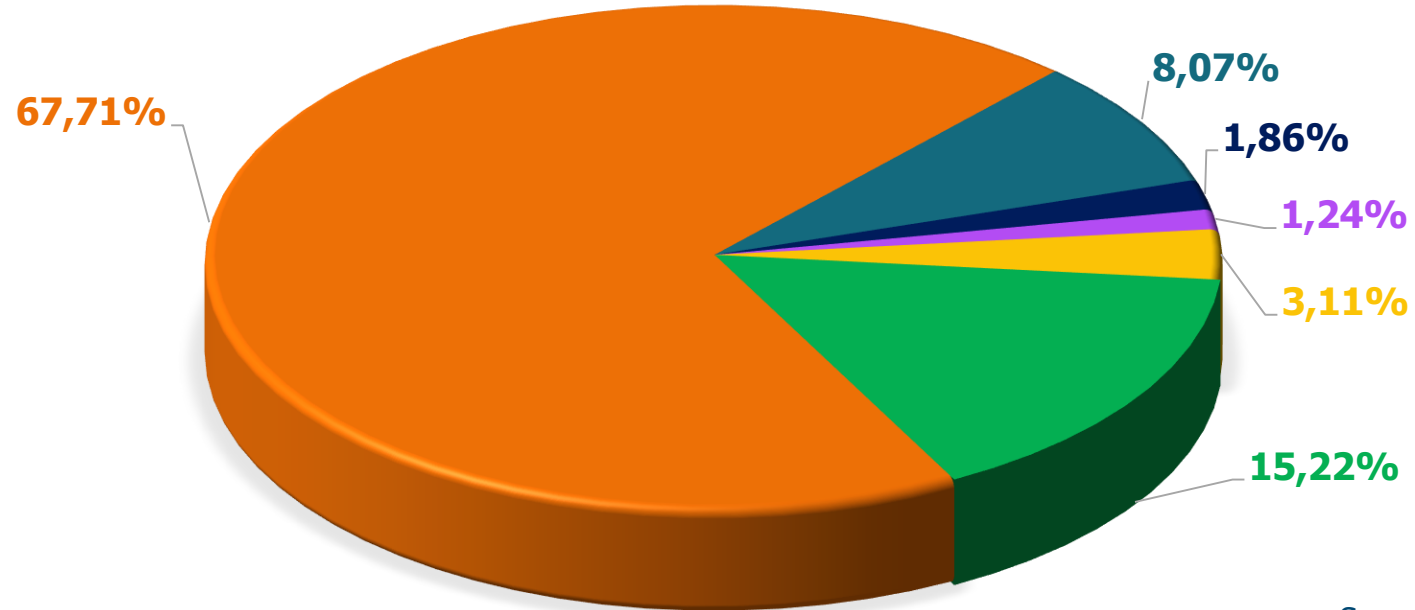
 Production issues

 Commercial/marketing reasons

 Market withdrawal (temporary and permanent)

# Causes of supply disruptions – Norway\*

## NORWAY



Source: Statens Legemiddelverk

Production issues

Problems of supply of raw material

Supply problems

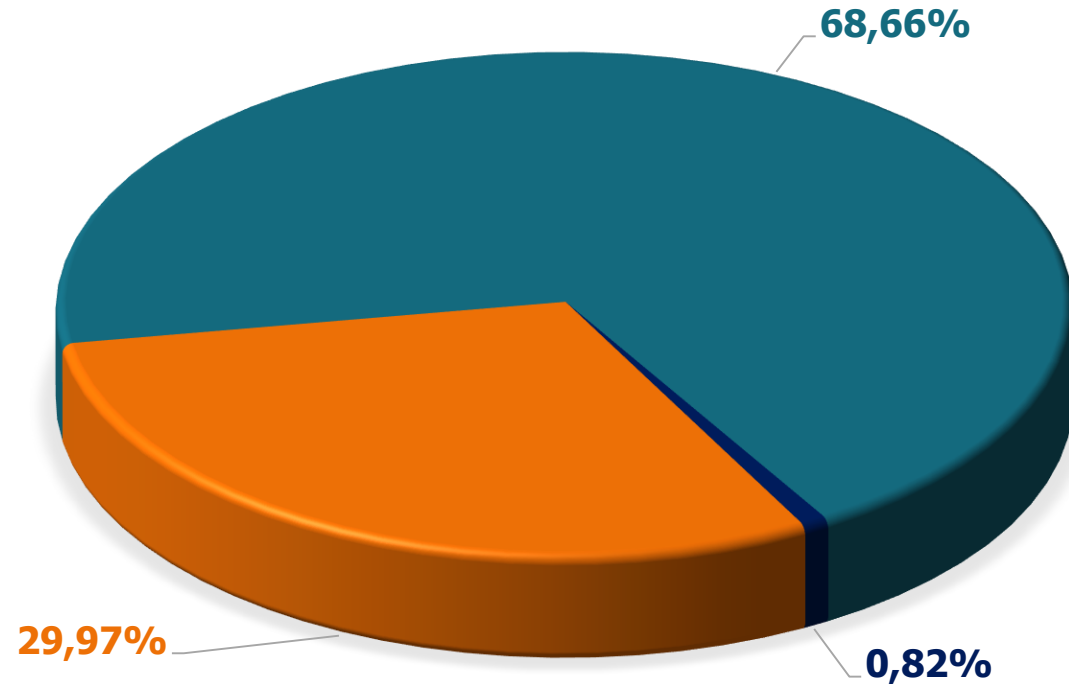
Quality issues

FMD related issues

Increased demand

# Causes of supply disruptions – Romania\*

## ROMANIA



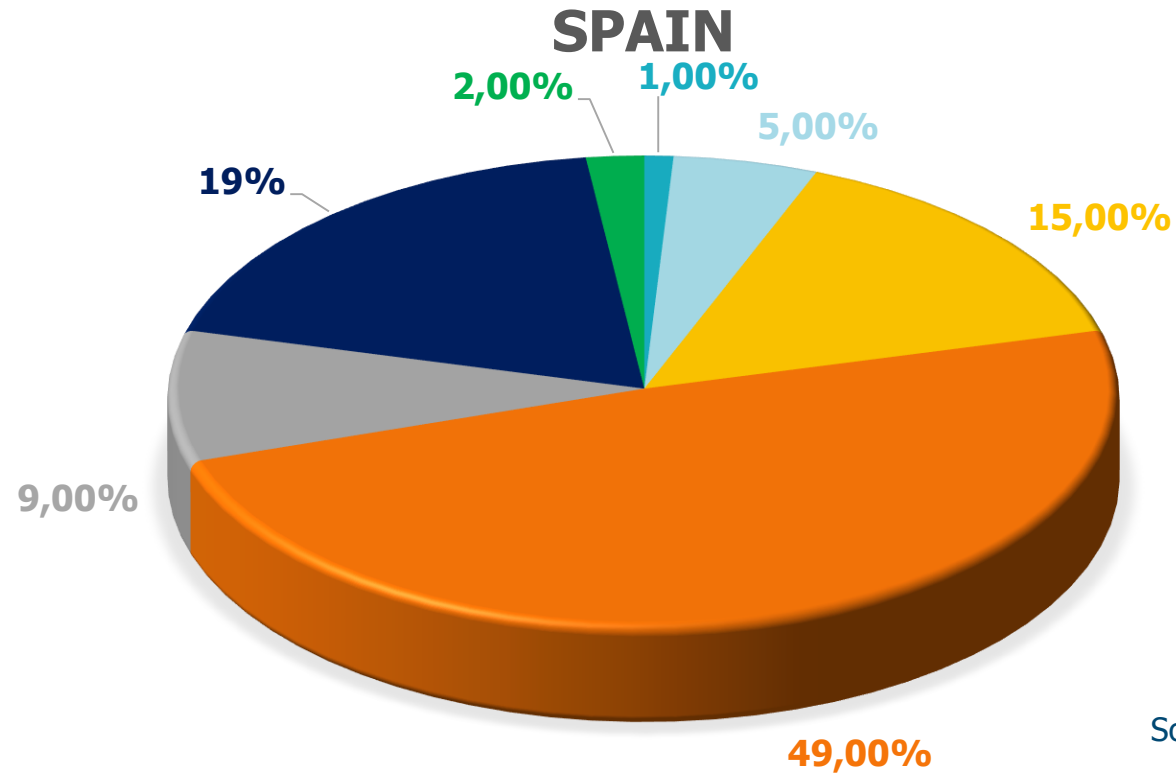
Source: ANMDM

 Production issues

 Commercial/marketing reasons

 Market withdrawal

# Causes of supply disruptions – Spain\*



Source: AEMPS 2018

Manufacturing problems

Parallel Trade

Increased demand

Problems of supply of raw materials

Discontinuous Manufacturing

Quality issues

Other reasons

\*based on analysis of publicly available data from official sources.