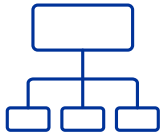
Update of the HMA/EMA Task Force on availability of authorised medicines for human and veterinary use (TF AAM) new structure and composition

TF AAM meeting with industry associations - 12 September 2022

Monica Dias, EMA co-chair
Hugues Malonne, HMA co-chair

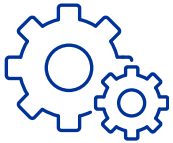
Agenda



New structure and composition

Work programme to 2025

Updated terms of reference



Extension of the mandate for 3 years

Background on the TF AAM

- **Activities on hold** due to COVID-19 business continuity plan
- **Changes in the co-chairs:**
  - Noël Wathion's retirement
  - Kristin Raudsepp's departure from the Estonian Agency

- **New co-chairs appointed**:
  - Monica Dias (EMA co-chair)
  - Hugues Malonne (HMA co-chair)
- **Activities resumed** on 15 December 2021

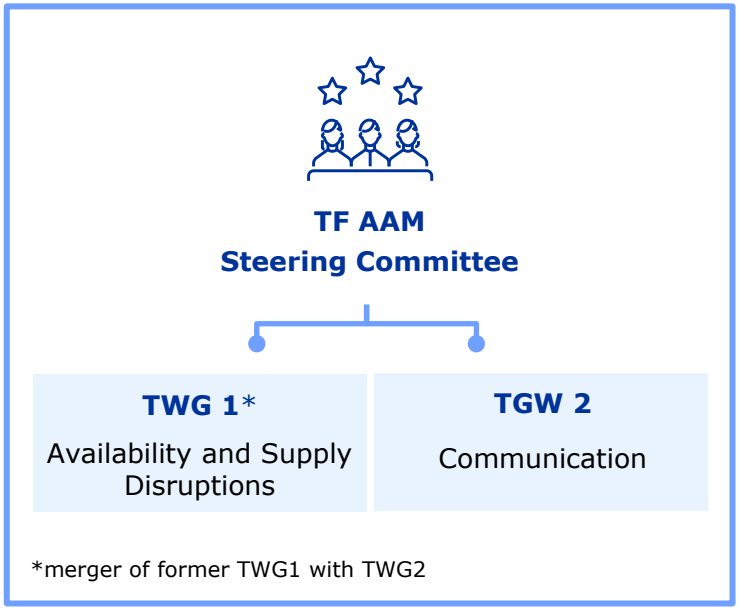
New structure of the TF AAM

New structure consisting of 2 thematic working groups (TWG)

Agreement to have a new structure and composition of the TF AAM to ensure alignment of the activities within the EU Regulatory Network:

- European medicines agencies network strategy (EMANS) to 2025
- Joint action on shortages
- EMA extended mandate

The new structure and composition will **streamline processes, foster synergies and will avoid duplication of work within the network**



New composition of the TF AAM

STEERING COMMITTEE

New composition of the Steering Committee

New members appointed:

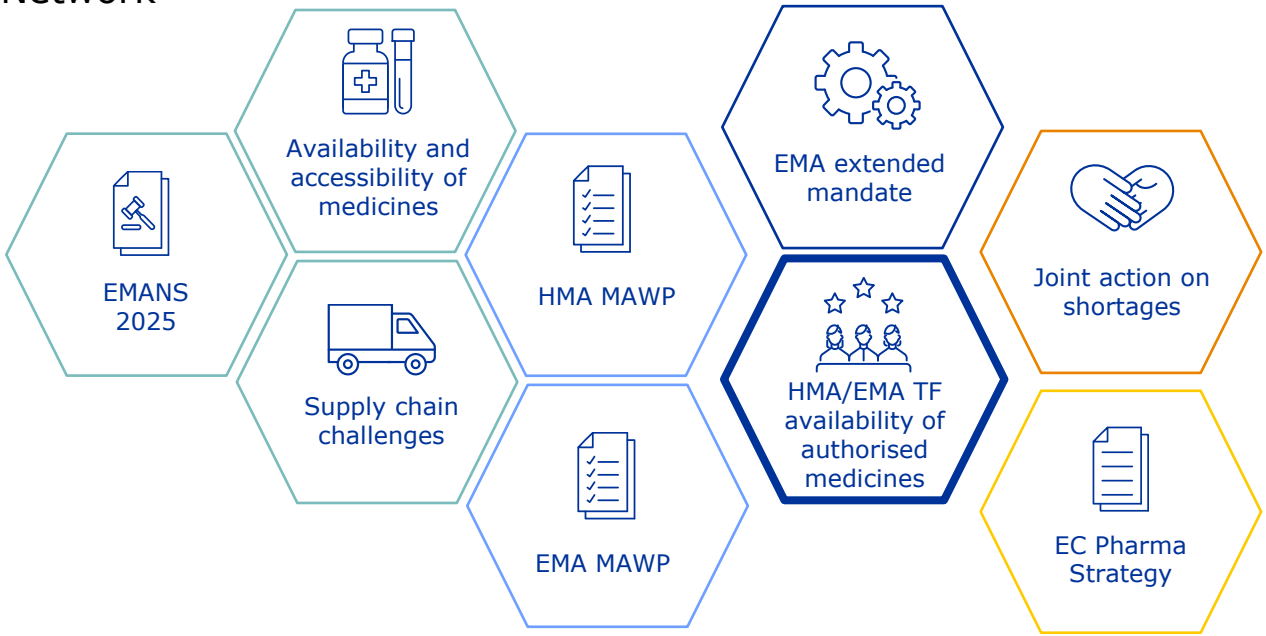
- Lead of theme 1 of the European medicines agencies network strategy
- Lead of Joint action on shortages
- Chairs of the CMDx
- New members appointed from SI, DE-PEI

Steering Committee Members

- Hugues Malonne, HMA co-chair
- Monica Dias, EMA co-chair
- Maria Lamas, ES
- *Jean-Pierre Orand, FR-ANSES*
- Rui Ivo Santos, PT (EMANS lead theme 5: supply chain challenges)
- Lorraine Nolan, IE (EMANS lead theme 1: availability and accessibility)
- Sylvain Giraud, EC
- Momir Radulović, SI
- Maximilian Ehrhardt, DE-PEI
- Domenico Di Giorgio, IT (lead joint action on shortages)
- Kora Doorduyn, chair of the CMDh
- Laetitia Leletty, chair of the CMDv
- Brendan Cuddy, EMA
- Ivo Classen, EMA
- Darren Scully, IE & Maria Alcaraz, EMA (Co-chairs TWG1)
- Yngvil Knudsen, NO & Juan García, EMA (Co-chairs TWG2)

Supply and availability landscape and HMA/EMA TF AAM

Supply and availability **Hub** within the
EU Regulatory Network



Work programme to 2025

Work programme adopted

by the Steering Committee, and subsequently by HMA and the EMA Management Board

Work programme **builds on the objectives** described in theme 1 of the European medicines agencies network strategy to 2025 and **includes actions** from:

- HMA multi annual work programme
- EMA Single programming document
- Ongoing actions from previous work programme
- Actions related to availability of medicines assigned to existing working groups within the European Medicines Regulatory Network (e.g. ePI, biosimilars)

Alignment with Joint Action on shortages and the EC Pharmaceutical Strategy ensures synergies and avoids duplication of work within the network

Work Programme

5 Objectives

12 Actions

25 Indicators (KPIs)

Update of the terms of reference

- Terms of reference of the TF AAM initially drafted in 2016
- Current mandate of the TF AAM ending in December 2022
- Revision necessary in view of the new developments in the area of availability and shortages, the new structure of the TF AAM and the need to extend the mandate for a further 3 years
- Revised terms of reference adopted by the Steering Committee on 29 April 2022 and adopted by HMA via written procedure on 26 May 2022 and by the EMA Management Board on 16 June

Terms of Reference

I. Background
II. Scope
III. Composition/Membership and Secretariat
IV. Working approach
V. Mandate
VI. Revision of the mandate

Any questions?

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union

NEW COMPOSITION OF THE TF AAM

Thematic Working Groups

Thematic Working Group 1

- Darren Scully, HMA co-chair
- Maria Alcaraz, EMA co-chair
- Martina Unteregger, AT
- Jakub Velík, CZ
- Gabriele Eibenstein, DE-BFARM
- Inke Reimer, DE-BVL
- Juhl Jones Rie Devantier & Lene Margrethe Jacobsen, DK
- Maria Esplugues & Maria Criado, ES
- Ramiro Casimiro, ES-V
- Johanna Linnolahti & Julia Lehtinen, FI
- Carla Maione & Oscar Cruciani, IT
- Kristīne Edolfa-Kalniņa, LV
- Flore Demay, FR-ANSES
- Priscilla Schoondermark, NL
- Andreas Sundgren, NO
- Johan Andersson, SE
- Barbara Razinger, SI
- Janos Kovacs, EMA-V

Thematic Working Group 2

- Yngvil Knudsen, HMA-co-chair
- Juan García, EMA co-chair
- Klára Brunclíková, CZ
- Alina Hoskins, DE-BVL
- Juhl Jones Rie Devantier, DK
- Lene Margrethe Jacobsen, DK
- Diego Pernas, ES
- Katja Lindgren-Äimänen, FI
- Kim Notenboom, NL

Update of activities of the TF AAM

TF AAM meeting with industry associations - 12 September 2022

Maria Alcaraz, EMA
Inga Abed, EMA

TF AAM: Activities to 2025

- TF AAM with mandate extended to 2025
- Two working groups of task force:
  - TWG1- Availability and Supply Disruptions
  - TWG2 – Communication
- Dedicated activities reflected in work programme
- Adopted:
  - Steering Committee on 28 January 2022
  - HMA on 6 May 2022
  - EMA-MB on 16 June 2022
- To be published on EMA/HMA website

THEMATIC WORKING GROUP 1 (TWG1)

Availability and supply disruptions: Main activities (I)

Proposals to change the legislation to improve prevention and management of shortages

- Pharma Strategy
- Draft by TWG1 → adopted by the Steering Committe → HMA consultation
- Proposals sent to the EC on 31st March according to the deadline

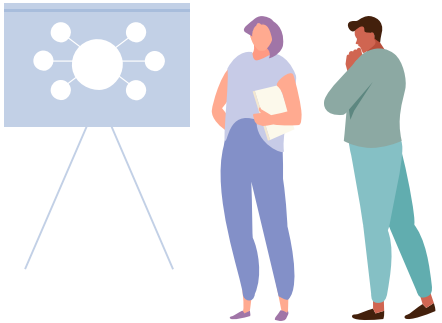
Main activities (II)

Good practice for industry on prevention of shortages of medicinal products for human use

- Dedicated point on agenda

TWG1

Availability and supply disruptions



Main activities (III)

Pilot project on implementing the guidance on detection and notification of shortages of medicinal products for MAHs

- Guidance on detection and notification of shortages of medicinal products for MAHs adopted by stakeholders, consultation with stakeholders and published on 1 July 2019
- Agreement to launch a pilot for the implementation of the guidance
- COVID-19 / activities of the TF AAM on hold
- Survey about availability of shortage reporting template at national level trough the Medicines Shortages SPOC Working Party
- Continue the discussion/engagement under the pharma strategy

THEMATIC WORKING GROUP 1 (TWG1)

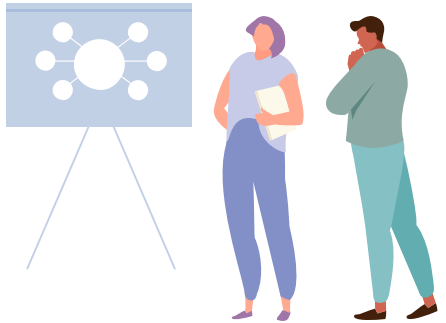
Main activities (IV)

Activities in the field of the **veterinary** sector

Activities to increase **harmonization** within the EEA and with **international** partners

TWG1

Availability and supply disruptions



Main activities (I)

Commitment to transparency

- Publish work plan and composition of taskforce
- Regular updates and publications of outcome
- Review practices to enhance communication on supply problems to EU citizens, their representatives and healthcare professionals

Main activities (II)

Good Practice Guidance for patient and healthcare professional organisations on the prevention of shortages

- Good Practice Guidance stakeholders (patients and healthcare professionals) consultation → adopted by the Steering Committee in May 2022→ published in July 2022
- In collaboration with stakeholders define metrics and monitor implementation of guidance and review practices
- Explore guidance for veterinary sector

TWG2
Communication

THEMATIC WORKING GROUP 2 (TWG2)

Main activities (III)

Communication to the public on medicines' availability issues

- Good Practice Guidance for communication to the public on medicines availability issues published in July 2019
- Monitor and analyse implementation of guidance and update as necessary

THEMATIC WORKING GROUP 2 (TWG2)

Main activities (IV)

Multi-Stakeholder Workshop

March 2023

- Dedicated point agenda

THEMATIC WORKING GROUP 2 (TWG2)

Main activities (V)

Activities in the field of the **veterinary** sector

TWG2
Communication

Task force tracking progress of activities

- Implementation of ePI project
- Electronic formats of veterinary medicinal product information
- Fostering public awareness on approval standards, safety, effectiveness and immunogenicity of biosimilars
- Promotion on use of multi-lingual packs
- Publication of information on marketing status of the EU of centrally authorised medicines

Any questions?

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

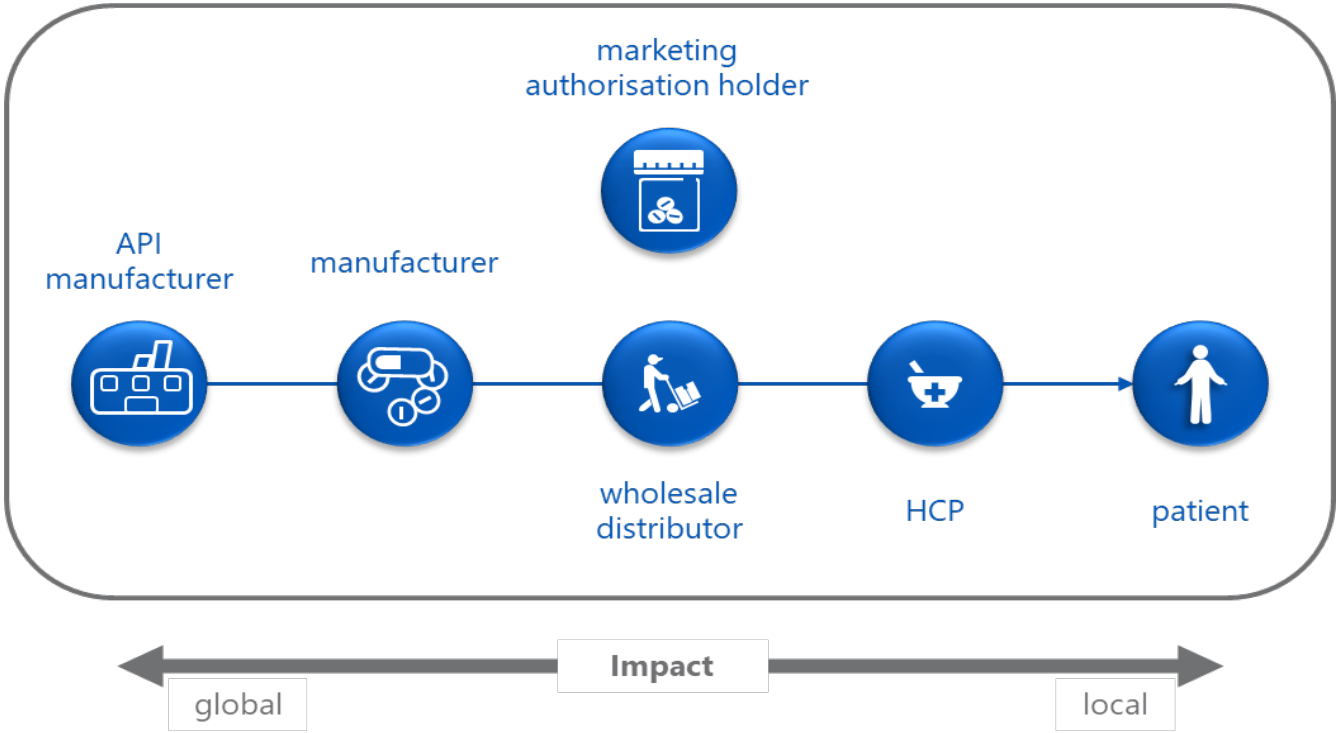
The European Medicines Agency is an agency of the European Union

Good practice guide on prevention and management of shortages of medicines for human use

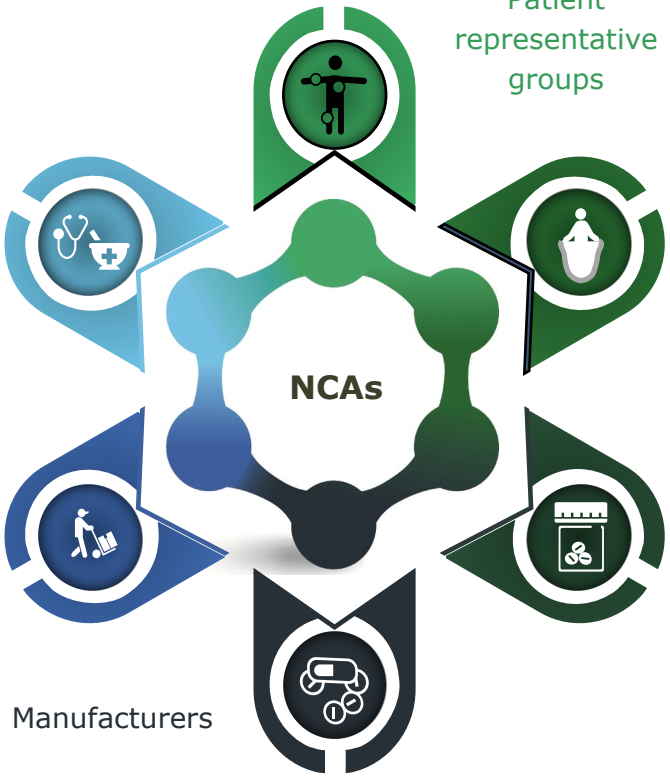
TF AAM meeting with industry associations - 12 September 2022

Darren Scully, IE

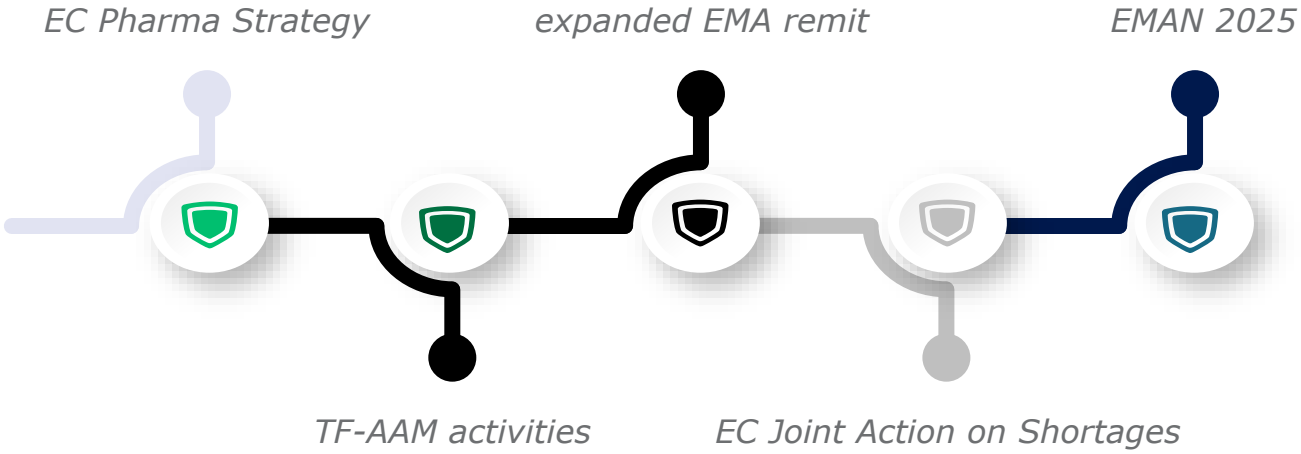
Context – supply chain



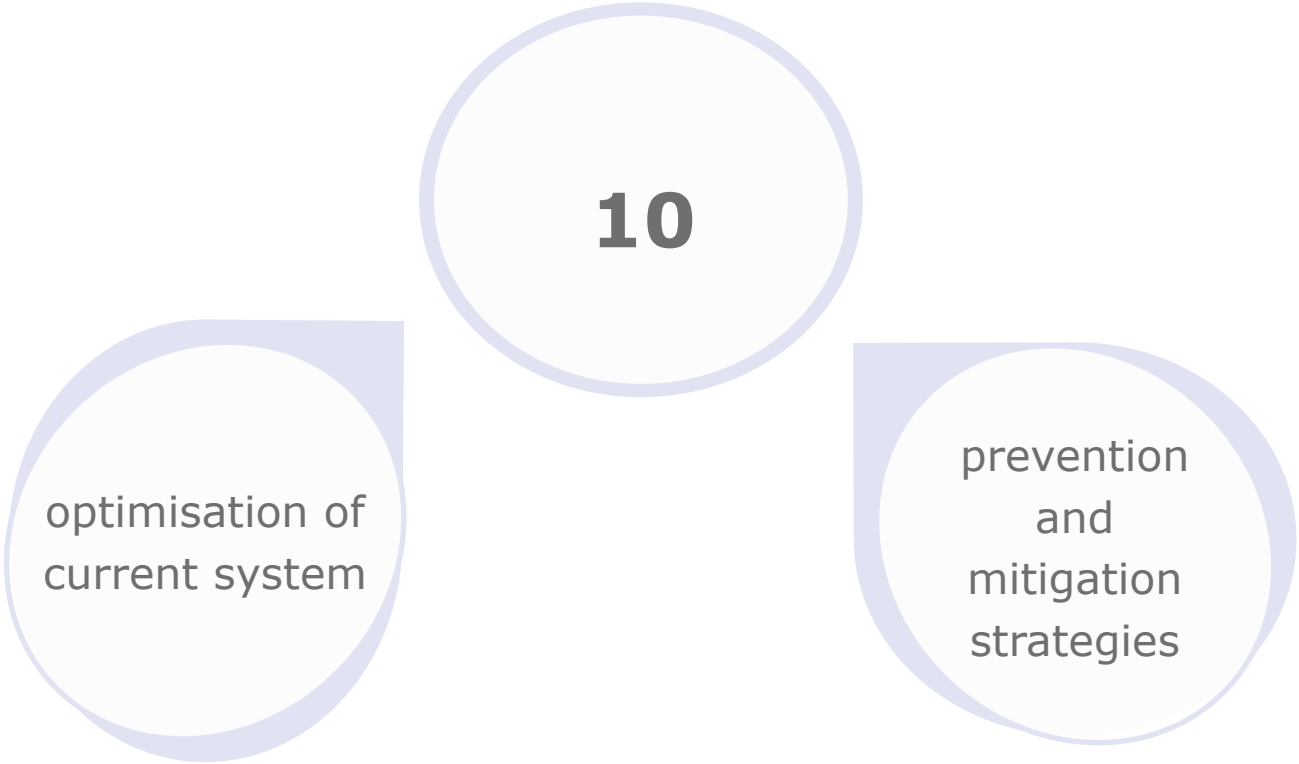
Context – multiple stakeholders



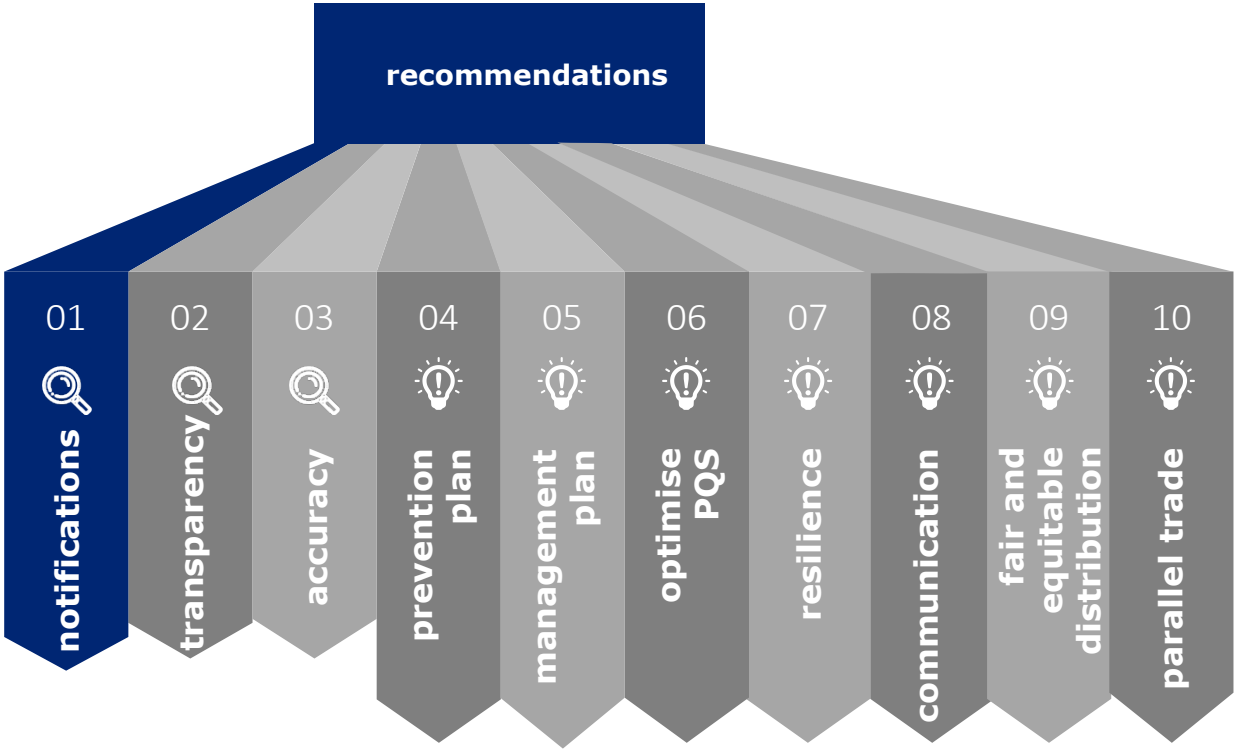
Context – complementary strategies



Shortages – recommendations



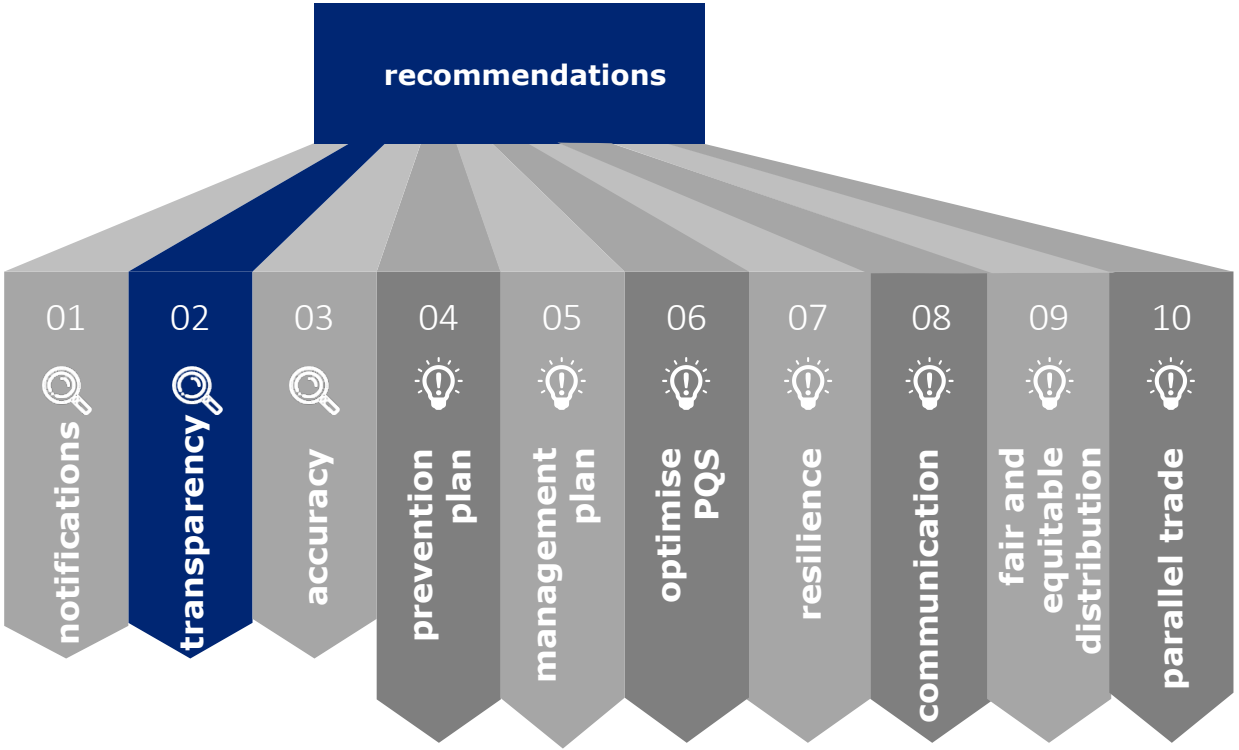
Shortages



earlier notifications

- advantages for all
- return of supply notification

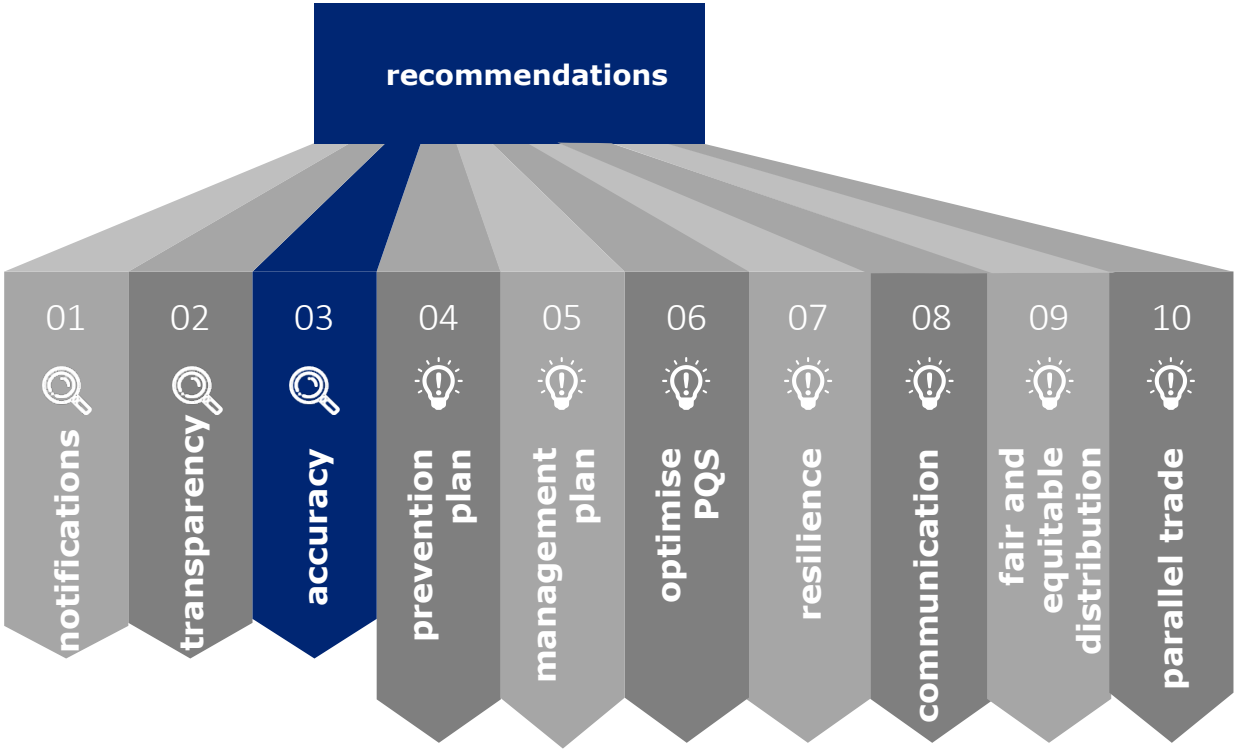
Shortages



increased transparency

- knowledge sharing
- communication
- promote international cooperation and information sharing

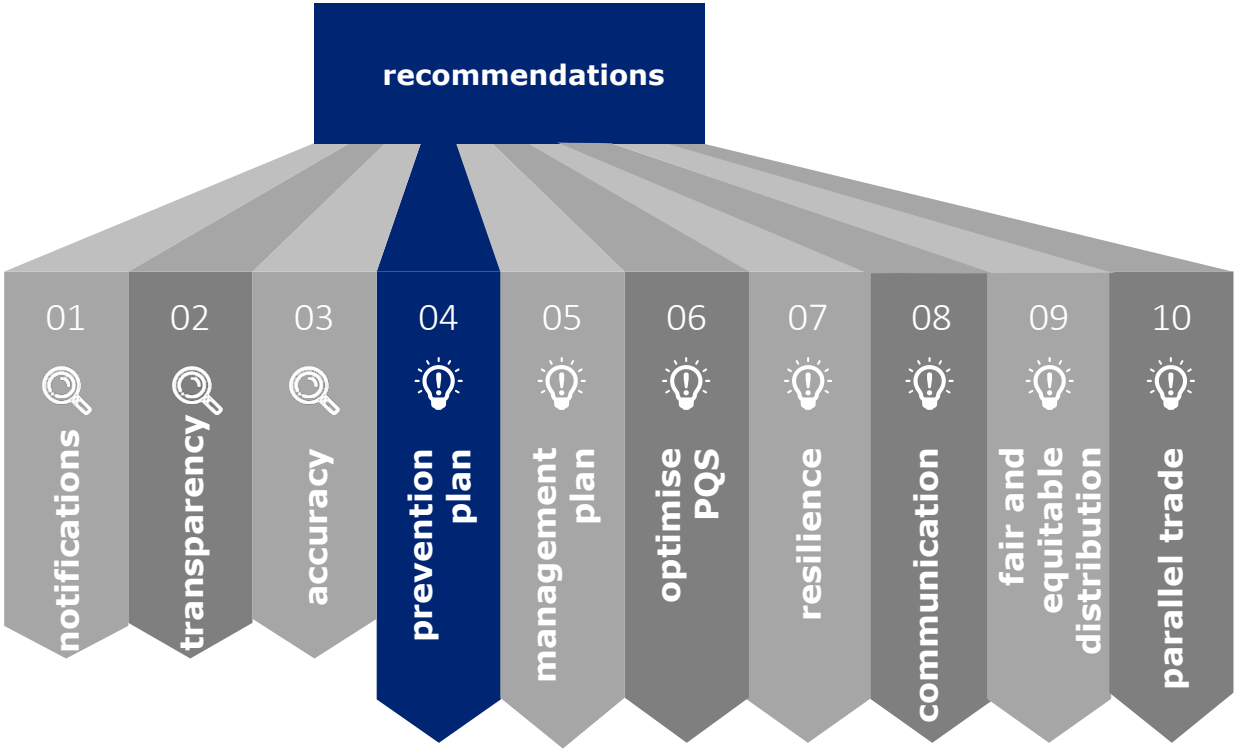
Shortages



increase accuracy

- clarity on cause of shortage (e.g. manufacturing delay)
- how many countries affected?
- accuracy in supply resumption

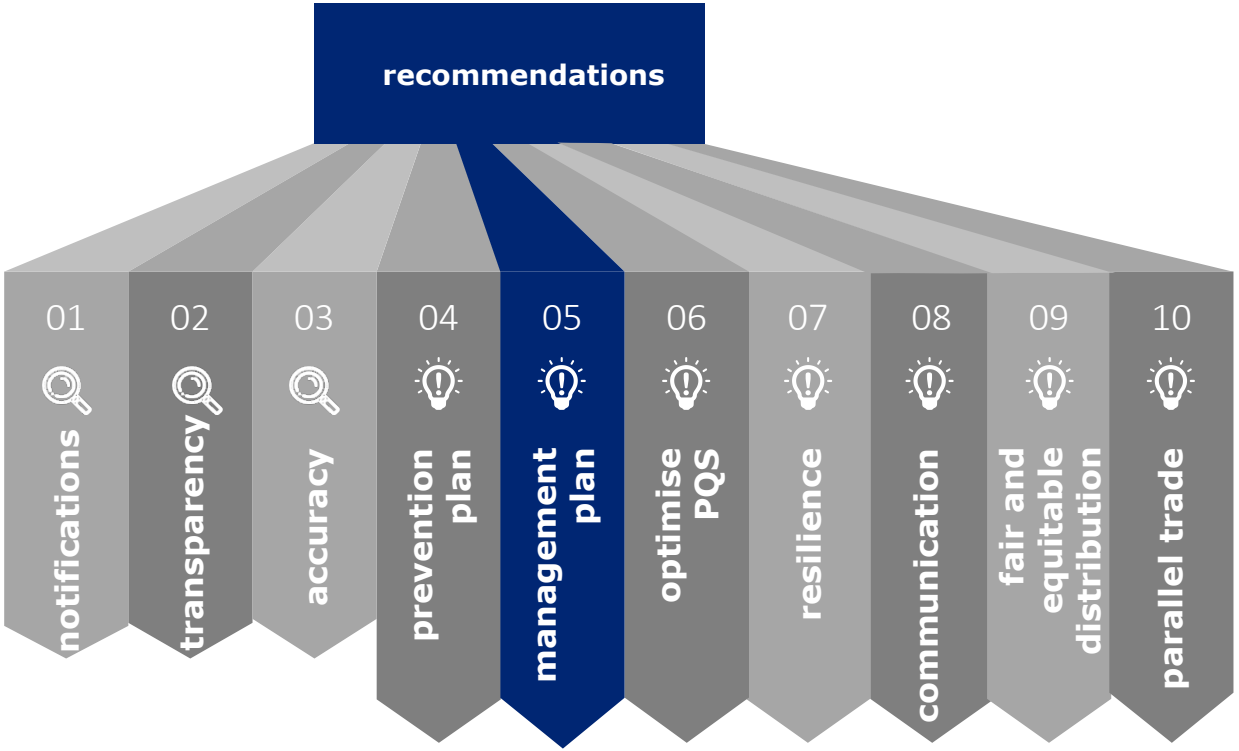
Shortages



shortage prevention plan

- shortage prevention plans implemented by industry
- promote recommendation at EU level

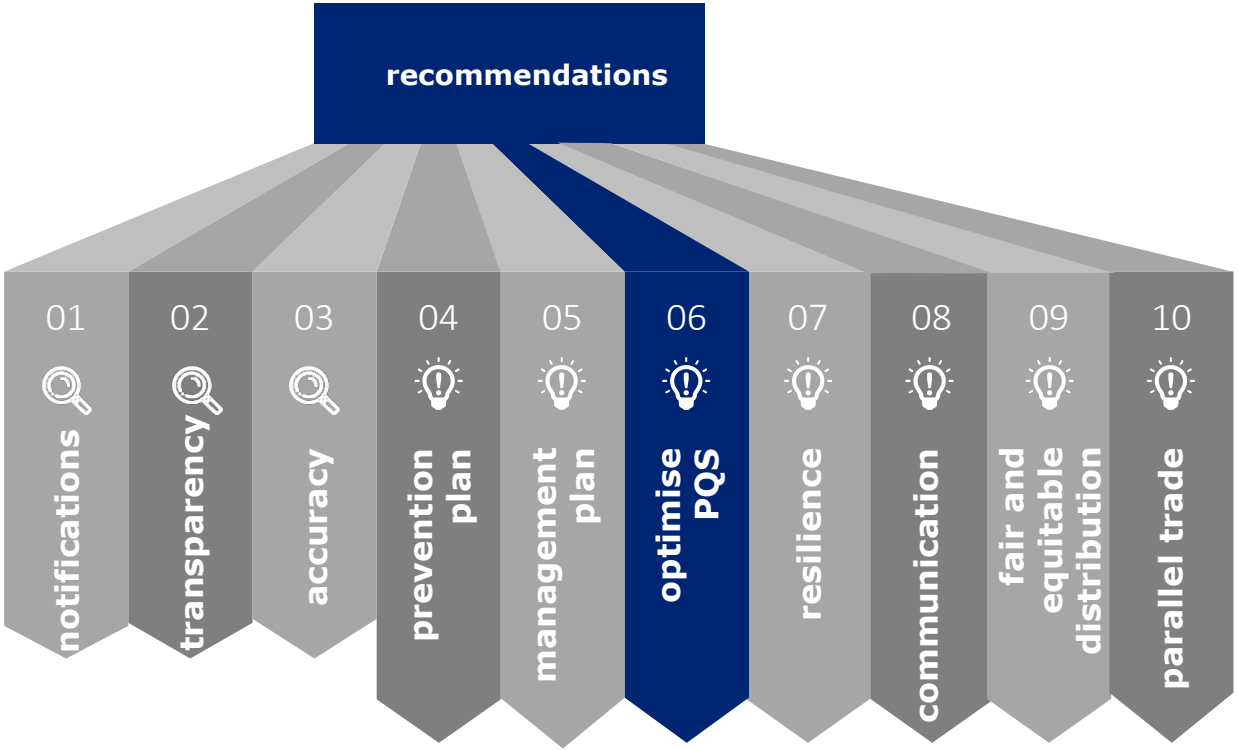
Shortages



shortage management plan

- shortage management plans implemented by industry
- promote recommendation at EU level

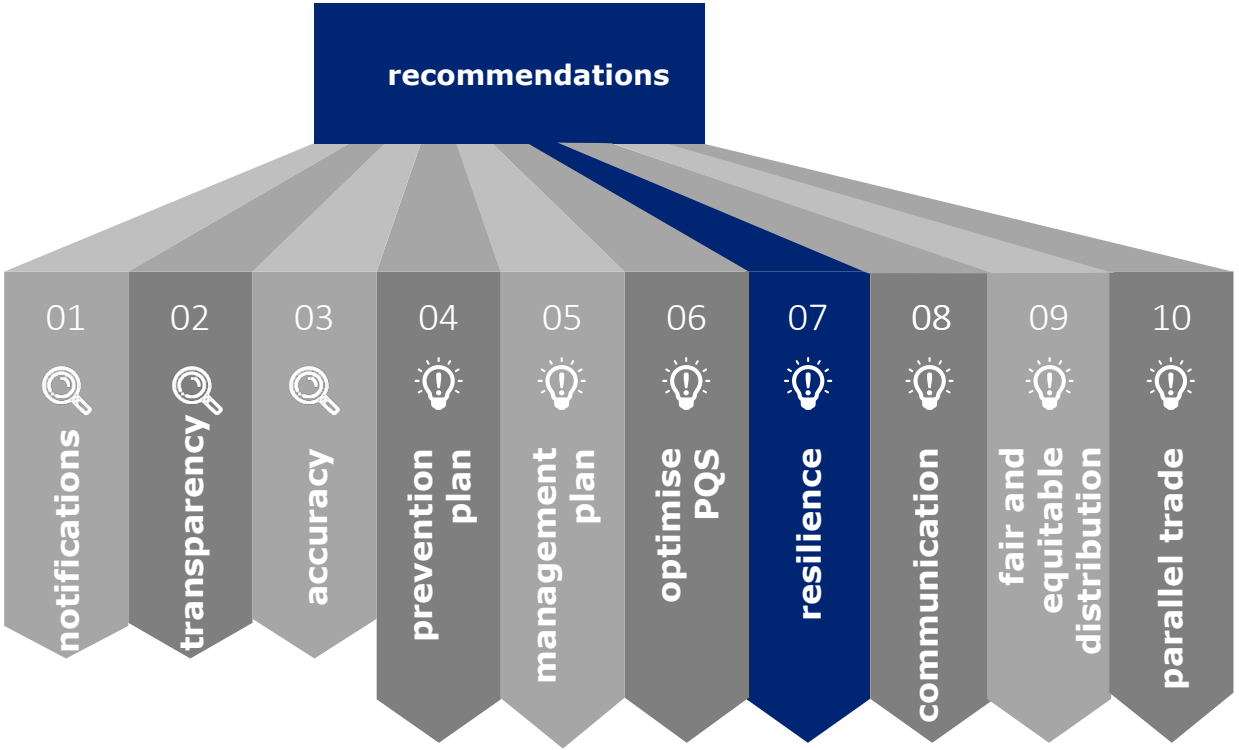
Shortages



optimise PQS

- adapt PQRs to assess supply chain robustness and prevention effectiveness
- continual GxP improvement and post-authorisation change management

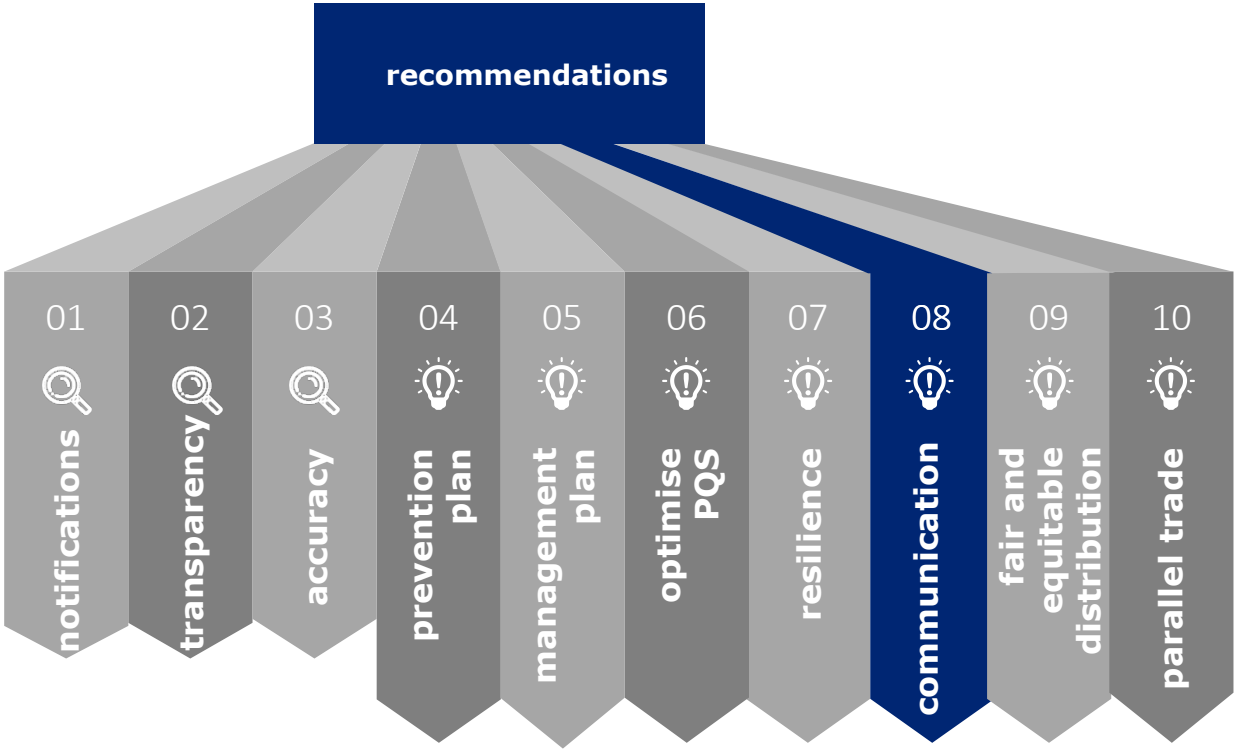
Shortages



increase resilience

- consider and document justification for just-in-time supply model
- contingency stock for MAH and MIA site transfers

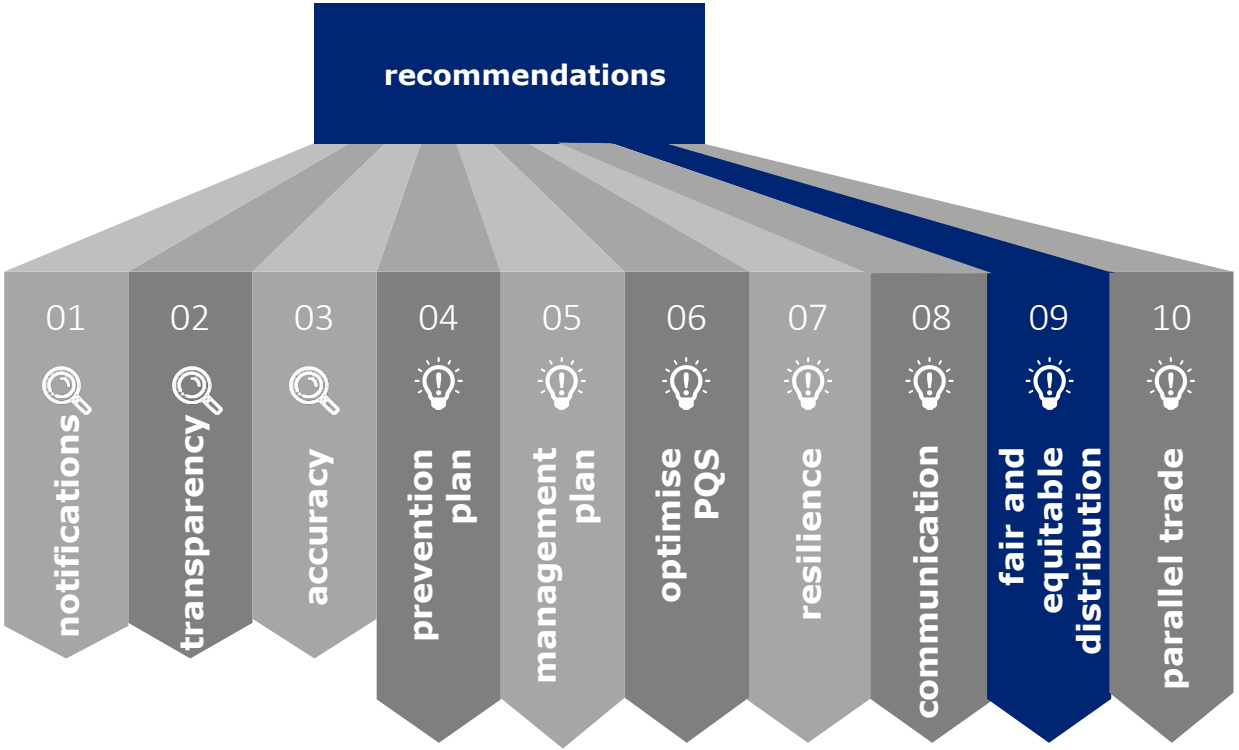
Shortages



improve communication

- identify key processes and supply chain maps for products to establish effective communication between stakeholders
- wholesalers establish 'flag' system to identify and communicate supply disruptions
- health policy implications

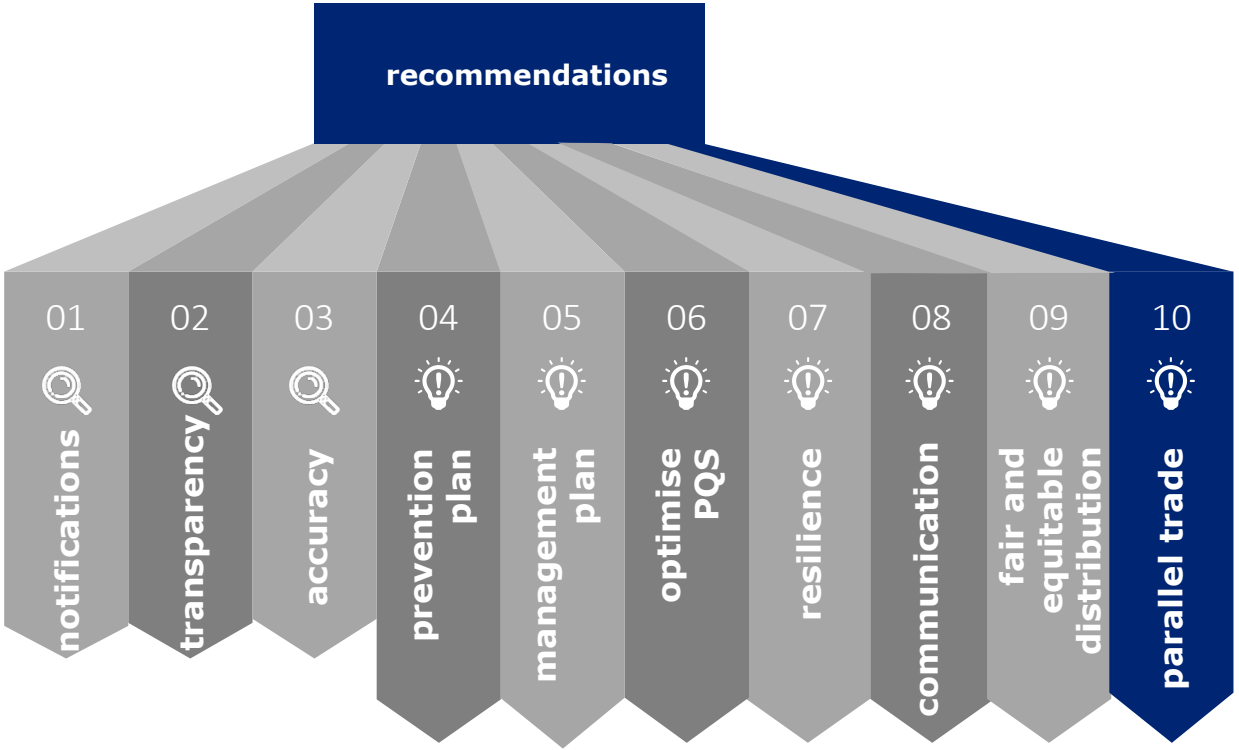
Shortages



fair & equitable distribution

- stockpiling issues
- MAH allocation practices

Shortages



parallel trade

- stakeholders involved in parallel trade to take appropriate steps to reducing the impact of parallel trade on shortages
- includes export

Any questions?

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union

Preliminary comments

- SPP template proposal by 4 industry associations (development started 2019) – AESGP, Medicines for Europe, EUCOPE, EFPIA
- Prior to this meeting, coordination call with other industry organisations on 7 September 2022 to preempt the content only (not to endorse)
- It is acknowledged that SPPs are one out of different aspects of shortage prevention and mitigation.

efpia
European Federation of Pharmaceutical Industries and Associations

Drug Shortage Prevention Plan (SPP)

Industry template proposal






September 2022

Vision

Harmonised **EU template** meeting all NCA's expectations (avoid multiplication of national standards) will reduce the administrative burden and facilitate the life-cycle management of the document

Scope:

- Develop a sustainable harmonised template
    - EU template could be available for national purpose as well
- The need for SPP generation should be commensurate to the identified patient risk
    - Implemented for critical medicines

SPP template foundation:

- Concise and designed for digital use (database format)
- Based on ISPE/PDA template
- Updated regarding Regulation 2022/123
- Availability of SPP only upon regulator request and/or during inspection due to commercially sensitive information included in SPPs

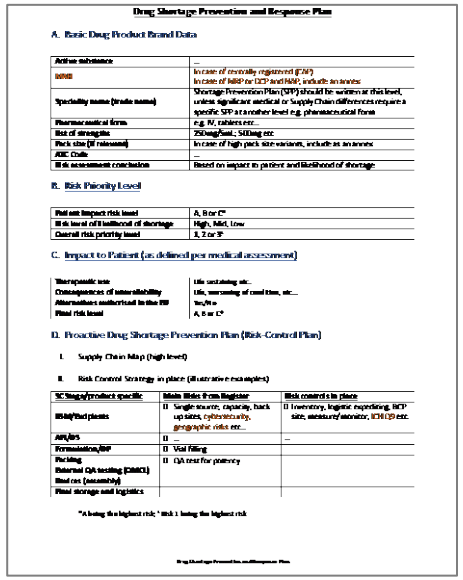
SHORTAGE PREVENTION PLAN TEMPLATE

Vision

Concerns:

- SPPs should not be made available in the public domain (e.g. to avoid for example stockpiling)
- SPPs cannot address all causes of shortages (e.g. due to an unforeseen increase of demand)
- SPPs implemented without a risk-based approach

SPP Template proposal:
(double-click in editable view to open)



Drug Shortage Prevention and Response Plan

A. Basic Drug Product Brand Data

Active substance	...
[illegible]	In case of centrally registered (CAP) In case of MRP or DCP and NAP, include as an annex
Speciality name (trade name)	Shortage Prevention Plan (SPP) should be written at this level, unless significant medical or Supply Chain differences require a specific SPP at another level e.g. pharmaceutical form
Pharmaceutical form	e.g. IV, tablets etc.
List of strengths	25mg/5ml ; 50mg etc
Pack size (if relevant)	In case of high pack size variants, include as an annex
ATC Code	...
Risk assessment conclusion	Based on impact to patient and likelihood of shortage

B. Risk Priority Level

Patient impact risk level	A, B or C*
Risk level of likelihood of shortage	High, Med, Low
Overall risk priority level	1, 2 or 3*

C. Impact to Patient (as defined per medical assessment)

Therapeutic note	Life sustaining etc.
Consequences of unavailability	Life, worsening of condition, etc...
Alternatives authorised in the EU	Yes/No
Final risk level	A, B or C*

D. Proactive Drug Shortage Prevention Plan (Risk-Control Plan)

I. Supply Chain Map (high level)

II. Risk Control Strategy in place (illustrative examples)

SC Stage/product specific	Main Risks from Register	Risk control in place
FDP/Final plants	II Single source, capacity, back up sites, cybersecurity, geographic risks etc...	II Inventory, logistic expediting, BCP site, monitory/automize, ETA/D etc.
API/IPS	II ...	...
Formulation/FDP	II Vial filling	
Packing	II QA test for potency	
External QA testing (OMCL)		
Blend etc (assembly)		
Final storage and logistics		

*A being the highest risk; * risk 1 being the highest risk

Drug Shortage Prevention and Response Plan

A. Basic Drug Product Brand Data

Active substance	…
MAH	In case of centrally registered (CAP) In case of MRP or DCP and NAP, include an annex
Speciality name (trade name)	Shortage Prevention Plan (SPP) should be written at this level, unless significant medical or Supply Chain differences require a specific SPP at another level e.g. pharmaceutical form
Pharmaceutical form	e.g. IV, tablets etc…
List of strengths	250mg/5mL; 500mg etc
Pack size (if relevant)	In case of high pack size variants, include as an annex
ATC Code	…
Risk assessment conclusion	Based on impact to patient and likelihood of shortage

B. Risk Priority Level

Patient Impact risk level	A, B or C*
Risk level of likelihood of shortage	High, Mid, Low
Overall risk priority level	1, 2 or 3[1]

C. Impact to Patient (as defined per medical assessment)

Therapeutic use	Life sustaining etc..
Consequences of unavailability	Life, worsening of condition, etc…
Alternatives authorised in the EU	Yes/No
Final risk level	A, B or C*

D. Proactive Drug Shortage Prevention Plan (Risk-Control Plan)

I. Supply Chain Map (high level)

II. Risk Control Strategy in place (illustrative examples)

SC Stage/product specific	Main Risks from Register	Risk controls in place
RSM/Excipients	• Single source, capacity, back up sites, cybersecurity, geographic risks etc…	• Inventory, logistic expediting, BCP site, measure/monitor, ICH Q9 etc.
API/DS	• …	…
Formulation/DP	• Vial filling	
Packing	• QA test for potency	
External QA testing (OMCL)		
Devices (assembly)		
Final storage and logistics		

*A being the highest risk; [1] Risk 1 being the highest risk

III. Risk Control Details status and in plan (already internally endorsed) (illustrative examples)

Risk controls in place	Time to activate	Cover
Second API source ramp up	• 3 months	• 80% regular demand
Inventory of Bulk tablets	• Immediate	• 3 months
Safety stock	• Immediate	• XX weeks
Sea to Air transport of FP	• 2 weeks	• 4 weeks equivalent
New API site registration	• 24 months	• 20% of regular demand

E. Reactive Drug Shortage Response Plan

I. Process for Detection and Notification of Shortages

Initiative	Available	Notes
Shortage alerting process	Yes/No	
Shortage metrics	Yes/No	Efficiency, trend, KPIs….
Formalised Shortage management process	Yes/No	Roles and Responsibilities, escalation, coordination Global and National…
Issue Management Team process	Yes/No	
SOP on shortage management and communication	Yes/No	Add reference
Communication process to Health Authorities	Yes/No	

Screenshot 4/6

II. Short Term Mitigating Initiatives (at an EU level)

Initiative	**Time to activate**	**Cover**	**Notes**
Sales order allocation and prioritisation	• 1 day	• 1 week	
Importation from abroad	• 2 weeks	• TBD	
Other Brands available within own company	…	…	
Other presentations available	• XXXX	• XXXX	
Revise supply allocation plan			
Distribution prioritisation for expediting (site to country)			
Other: (e.g. limit production to one pack size/strength)			

EU registered facilities under the Company's control capable of manufacturing the product

EU registered Plant name (API, Bulk, Packaging, Release site) address, etc…	**Time to activate**	**Cover (in % of EU regular demand)**
Site A	• 2 months	• 20% regular demand
Site B	…	…

F. Risk Reviews and Updates

Version	Reason	Key changes	Date
1	First version	NA	12/04/2019
2	Yearly review process	• Update of risk controls • Updated SOP reference	01/04/2020
3	Off-cycle review • New product indication • Shutdown of a facility • New market approval	…	01/12/2020

Recommend a yearly periodic review of the document.

G. Approvals Required

Name	Title and Function	Signature	Date
…	Person Responsible	…	…
…	QA Decision Maker	…	…
…	Senior Management Function	…	…

APPENDIX – commercially sensitive information

Likelihood of Shortage

Based on a risk register available in the Company.

SC Stage	Main Risks from Register	Risk level
RSM/Excipients	• Single source, capacity, back up sites, etc	High, Mid, Low
API/DS	• …	
Formulation/DP		
Packing		
Final storage and logistics		
Overall likelihood		High, Mid, Low

Industry topics for further meetings

- Continued dialogue with industry on governance developments, and how the different EMA forums will interplay, e.g. EMA-HMA, ISG
- Possibility to address other Shortage Prevention topics, e.g. regulatory flexibility, shortage notification, electronic product information (ePI), EU packs…

efpia

European Federation of Pharmaceutical Industries and Associations

THANK YOU

Drug Shortage Prevention and Response Plan

A. Basic Drug Product Brand Data

Active substance	…
MAH	In case of centrally registered (CAP) In case of MRP or DCP and NAP, include an annex
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Therapeutic use	Life sustaining etc..
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II. Risk Control Strategy in place (illustrative examples)

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API/DS	• …	…
Formulation/DP	• Vial filling	
Packing	• QA test for potency	
External QA testing (OMCL)		
Devices (assembly)		
Final storage and logistics		

*A being the highest risk; [1] Risk 1 being the highest risk

III. Risk Control Details status and in plan (already internally endorsed) (illustrative examples)

Risk controls in place	**Time to activate**	**Cover**
Second API source ramp up	• 3 months	• 80% regular demand
Inventory of Bulk tablets	• Immediate	• 3 months
Safety stock	• Immediate	• XX weeks
Sea to Air transport of FP	• 2 weeks	• 4 weeks equivalent
New API site registration	• 24 months	• 20% of regular demand

E. Reactive Drug Shortage Response Plan

I. Process for Detection and Notification of Shortages

Initiative	**Available**	**Notes**
Shortage alerting process	Yes/No	
Shortage metrics	Yes/No	Efficiency, trend, KPIs….
Formalised Shortage management process	Yes/No	Roles and Responsibilities, escalation, coordination Global and National…
Issue Management Team process	Yes/No	
SOP on shortage management and communication	Yes/No	Add reference
Communication process to Health Authorities	Yes/No	

II. Short Term Mitigating Initiatives (at an EU level)

Initiative	**Time to activate**	**Cover**	**Notes**
Sales order allocation and prioritisation	• 1 day	• 1 week	
Importation from abroad	• 2 weeks	• TBD	
Other Brands available within own company	…	…	
Other presentations available	• XXXX	• XXXX	
Revise supply allocation plan			
Distribution prioritisation for expediting (site to country)			
Other: (e.g. limit production to one pack size/strength)			

EU registered facilities under the Company's control capable of manufacturing the product

EU registered Plant name (API, Bulk, Packaging, Release site) address, etc…	**Time to activate**	**Cover (in % of EU regular demand)**
Site A	• 2 months	• 20% regular demand
Site B	…	…

F. Risk Reviews and Updates

Version	Reason	Key changes	Date
1	First version	NA	12/04/2019
2	Yearly review process	• Update of risk controls • Updated SOP reference	01/04/2020
3	Off-cycle review • New product indication • Shutdown of a facility • New market approval	…	01/12/2020

Recommend a yearly periodic review of the document.

G. Approvals Required

Name	Title and Function	Signature	Date
…	Person Responsible	…	…
…	QA Decision Maker	…	…
…	Senior Management Function	…	…

APPENDIX – commercially sensitive information

Likelihood of Shortage

Based on a risk register available in the Company.

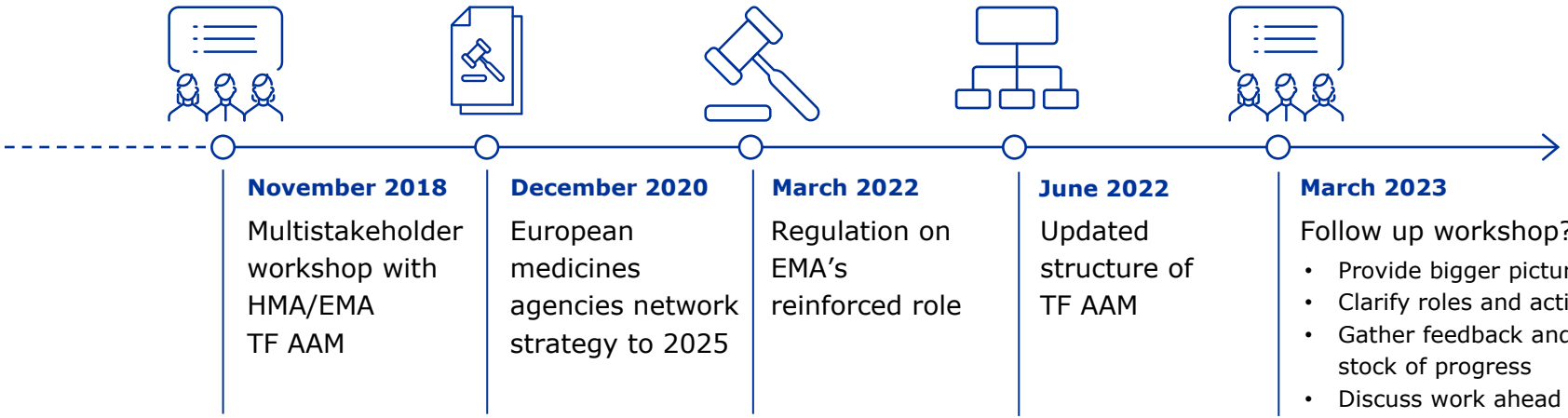
SC Stage	Main Risks from Register	Risk level
RSM/Excipients	• Single source, capacity, back up sites, etc	High, Mid, Low
API/DS	• …	
Formulation/DP		
Packing		
Final storage and logistics		
Overall likelihood		High, Mid, Low

Multi-stakeholder Workshop in Q1 2023

TF AAM meeting with industry associations - 12 September 2022

Juan García, EMA

Why a multi-stakeholder workshop in 2023?



November 2018

Multistakeholder workshop with HMA/EMA TF AAM

December 2020

European medicines agencies network strategy to 2025

March 2022

Regulation on EMA's reinforced role

June 2022

Updated structure of TF AAM

March 2023

Follow up workshop?

- Provide bigger picture
- Clarify roles and activities
- Gather feedback and take stock of progress
- Discuss work ahead

COVID-19 Pandemic/ crisis preparedness and management

Pharmaceutical Strategy

Joint Action on Shortages

Proposal for a multistakeholder workshop

Date

- 2 or 3 March 2023
- One day will be used for the multistakeholder workshop on shortages, the other day will be for PCWP/HCPWP joint meeting

Format

- Full day F2F meeting (with hybrid option)
- Recorded and broadcast?

Audience

- Representatives of patients, consumers and healthcare professional organisations, pharmaceutical industry associations and regulators

Call for action

Potential topics for discussion:

- Provide bigger picture
- Clarify roles and activities
- Gather feedback and take stock of progress
  (i.e. Best Practice Guide for industry on prevention/management of shortages of medicinal products)
- Discuss work ahead

What topics would industry like to discuss?

Any questions?

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union