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Bogin symposium 2017

Wat brengt ons de implementatie van de FMD?

De EMVO en de NMVO: Hoe staat Europa ervoor?

Johan Verhaeghe
National Policy Liaison

Utrecht – 23 November 2017

agenda

- About Medicines for Europe
- FMD: why, what, who, when…
- FMD: What's the cost?
- Implementation progress
- Collateral damage

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about Medicines for Europe

about Medicines for Europe

Medicines For Europe
VISION


PATIENTS


QUALITY


VALUE


SUSTAINABILITY


PARTNERSHIP

about Medicines for Europe

COMPANIES

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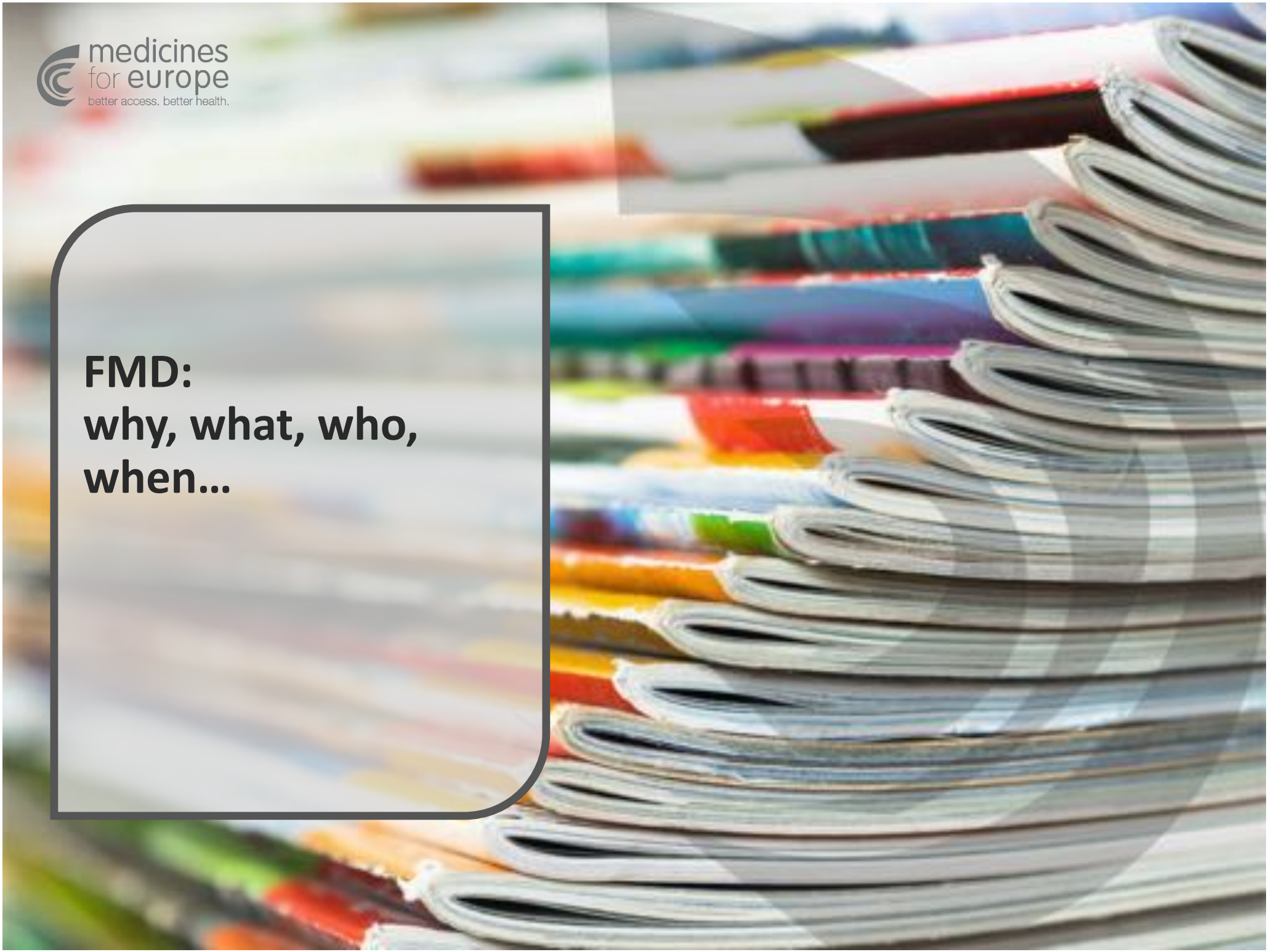
about Medicines for Europe - members

ASSOCIATIONS

about Medicines for Europe - members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FMD:
why, what, who,
when…

Why?
What?

Falsified Medicines Directive

- EU directives set out results that all EU Member States must achieve (>< Regulation)
- FMD (2011/62/EU): the prevention of the entry into the legal supply chain of falsified medicinal products

Delegated Regulation

- A DR allows Parliament and the Council to delegate to the Commission the power to adopt "non-legislative acts of general application to supplement or amend certain non-essential elements of a legislative act“

How?

Manufacturers have to apply Safety Features (UI+TVF) to the outer packaging of medicines.

Stakeholders have to establish and manage a repositories system with supervision by the NCA.

- Repositories system: (supra)national systems + 1 central EU-hub
  - Allowing systematic verification of the SF + decommissioning of the Unique Identifier at the point of dispense (at the time of supplying it to the public*) + risk-based verification by wholesalers
- The repositories system does not include physical scanning equipment!

*Delegated Regulation, Art 25 (1)

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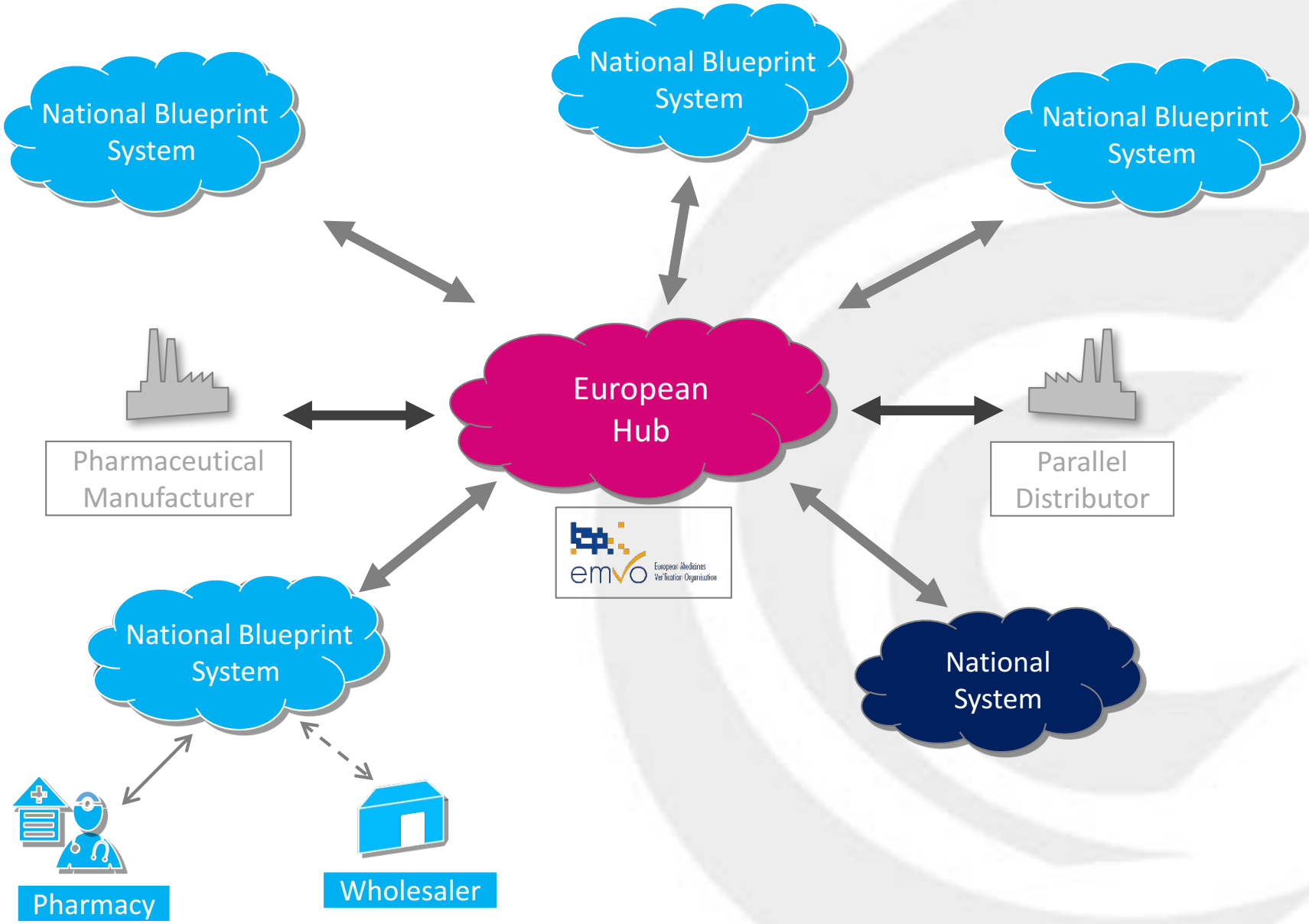
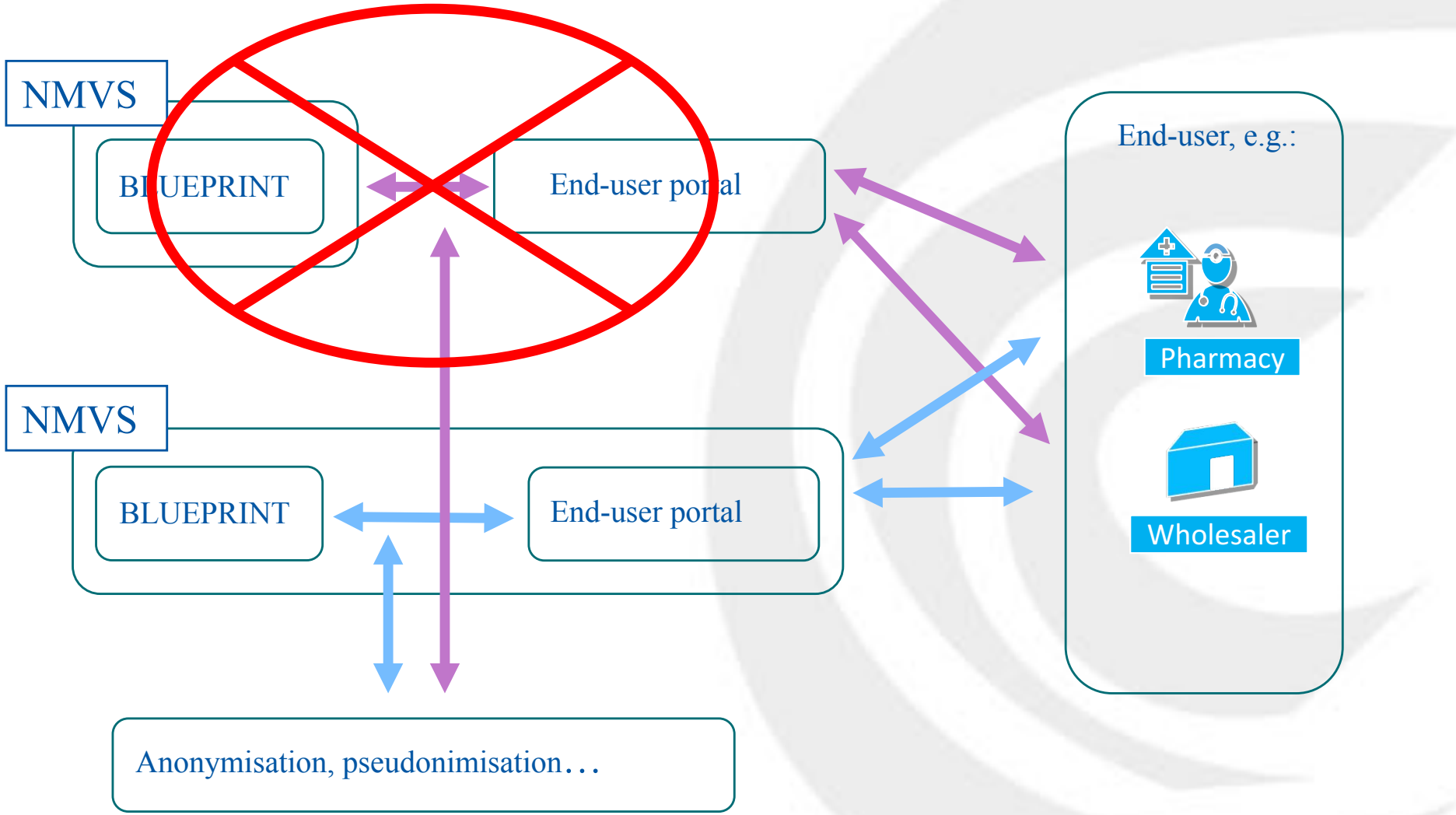
The repositories system



NMVS design


NMVS
BLUEPRINT
End-user portal
NMVS
BLUEPRINT
End-user portal
Anonymisation, pseudonimisation…
End-user, e.g.:
Pharmacy
Wholesaler

When?

- 8 June 2011: Adoption FMD
- 2 October 2015: Adoption DR by EC
- 9 February 2016: Publication DR in the Official Journal
- Transitional measures
  - 3 year transition phase (till 9 February 2019)
  - Fade-out phase till expiry date of products
  - 6 additional years for Belgium, Italy and Greece

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FMD:
What's the cost?

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Estimated costs

Average company

- Update packaging and production lines:
  € 5 million
- Annual running and maintenance costs:
  € +2 million

Total pharma industry

- Update packaging and production lines:
  € 5 billion
- EMVS:
  - implementation cost: € +90 Mio
  - annual running cost: € +90 Mio

Implementation cost: details from technical workshop at EGA on 22 February 2012


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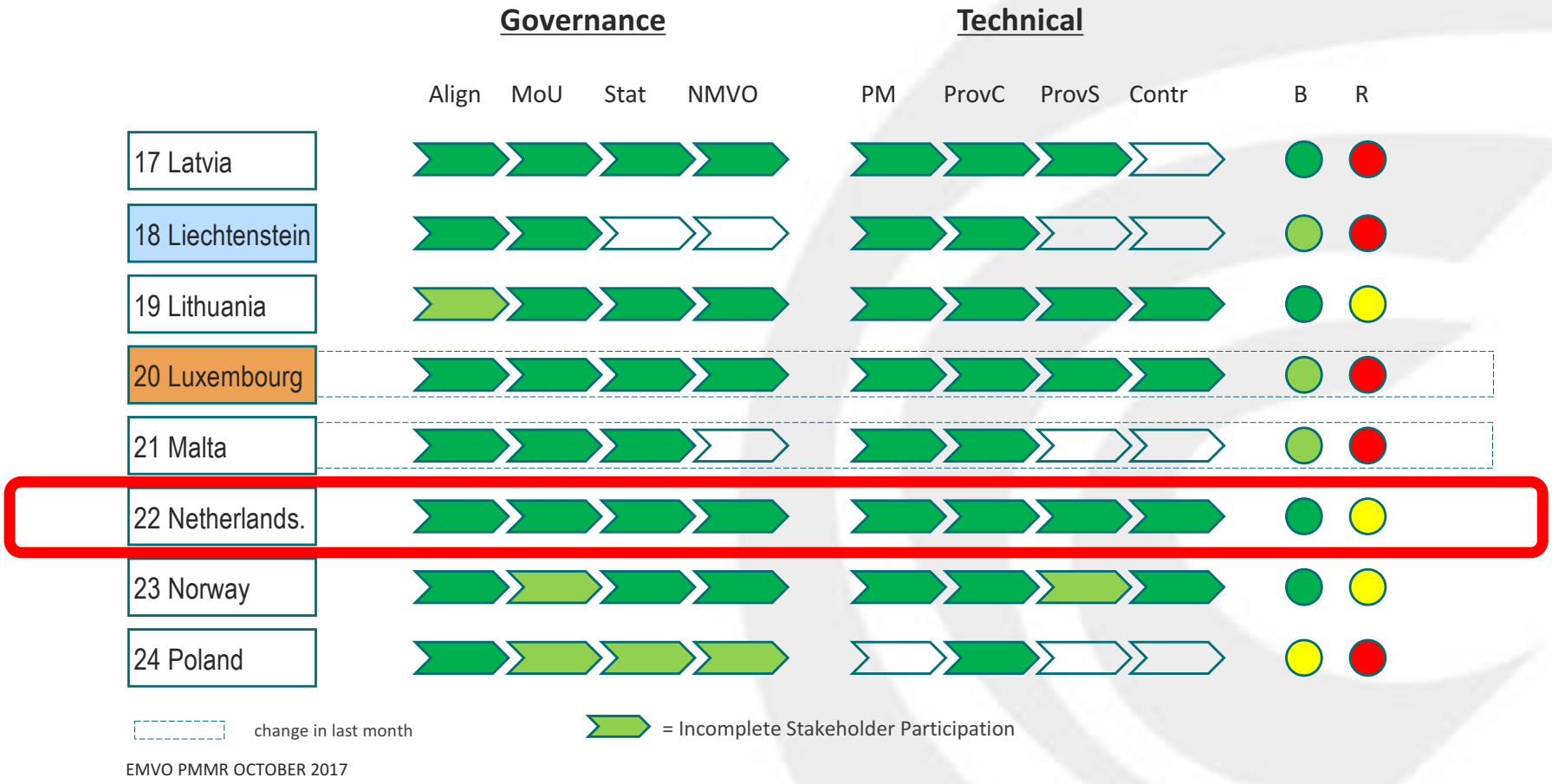
Implementation progress*
*source: EMVOs PMMR October 2017

Status per country 17 - 24



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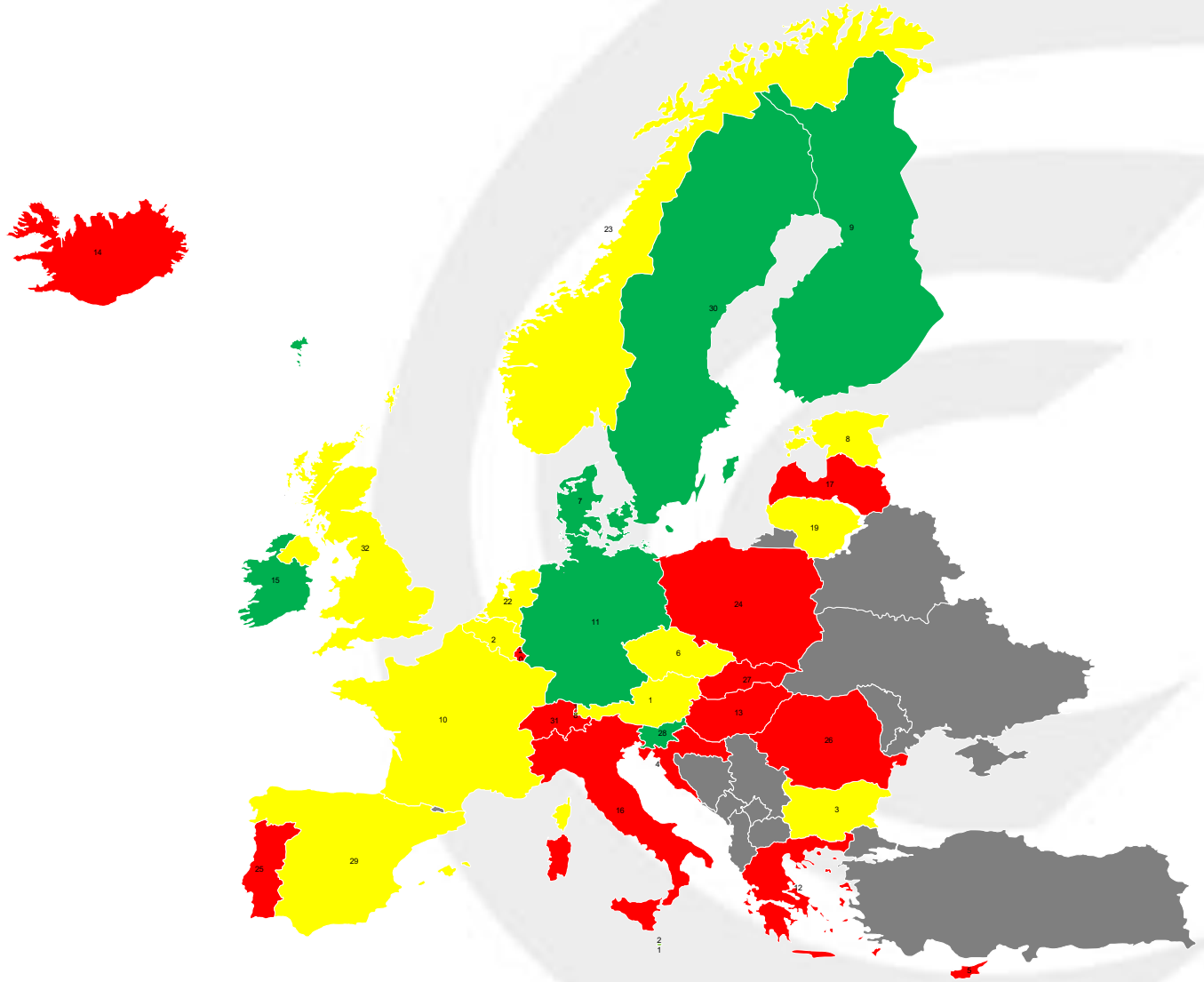
Executive Summary
Country Readiness



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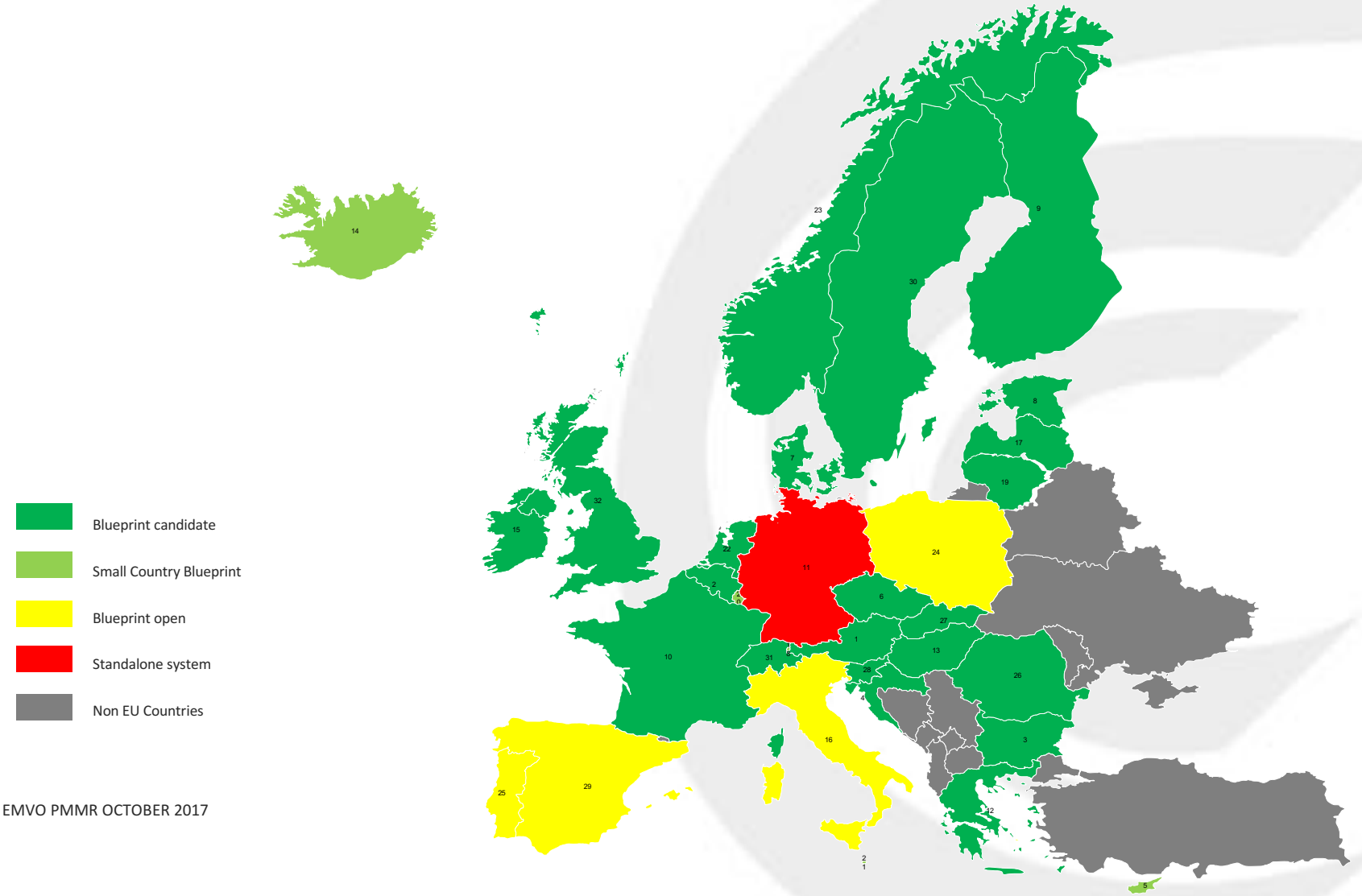
Executive Summary Blueprint Tendency



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EMVO Observations

- Program Progress
  - 26 NMVOs (>75%) founded, 15 contracts signed
  - 22 Countries have chosen their Provider but the contract takes more time than expected
  - Countries choose Blueprint, a few (technical) assessments still ongoing
- To be improved
  - Approx. 50% of Countries are still behind Schedule
  - Stakeholder alignment in MOU and Statutes not complete in a few Countries (e.g. Pharmacies or Wholesalers not integrated in NMVO set up)


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Collateral damage

Safer medicines = less medicines?

- Financial burden industry
  - → Estimated **€ 5 billion** for adoption of production/packaging lines
  - → **Implementation** cost of EMVS: estimated **€ 90 million**
  - → **Annual** running cost of EMVS: estimated **€ 90 million**

- Regulatory Impact - Variations
  - → Workload for industry and NCAs - bottle necks?

- **Reduced** availability → **decreased** access… or not?
  - → Voluntary use of SF
  - → Multi market coding (Pack coding guideline)
  - → Loss of profitability? → withdrawal of products?

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Thank you

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