EAHP Member Teleconference

The Falsified Medicines Directive

eahp
european association of hospital pharmacists

Objectives of the teleconference

1. To provide an update to members of recent EAHP advocacy activity on FMD

2. To provide a forum for information sharing

3. To provide an opportunity for member input ahead of EAHP's February 2016 Board Meeting

4. To otherwise help direct both EAHP and member activity in this policy area

Agenda

1. Update from EAHP
2. The European implementation picture, from EMVO
3. National updates
4. Open discussion, Q&A
5. Summary and next steps

1. Update from EAHP

A brief recap....

Considering issues of FMD implementation, the EAHP General Assembly of June 2016 advised against paying membership subscriptions to the European Medicines Verification Organisation, and instead recommended that a complaint be tabled to the European Ombudsman as to the manner in which Delegated Regulation 2016/161 was developed (e.g. lack of transparency, deficient consultation, inadequate impact assessment).

What happened thereafter?

July 2016 – EAHP submit complaint to Ombudsman

August 2016 – Advised direct correspondence with Commission on points of complaint required

August 2016 – Formal correspondence with Commission

September 2016 – Meeting with Commission

The position today

The European Commission supports EAHP's position that no fees should be demanded as a right of access to European and national medicines verification organisations and is intervening to ensure that.

Article 31

Establishment of the repositories system

1. The repositories system where the information on the safety features shall be contained, pursuant to Article 54a(2)(e) of Directive 2001/83/EC, shall be set up and managed by a non-profit legal entity or non-profit legal entities established in the Union by manufacturers and marketing authorisation holders of medicinal products bearing the safety features.

2. In setting up the repositories system, the legal entity or entities referred to in paragraph 1 shall consult at least wholesalers, persons authorised or entitled to supply medicinal products to the public and relevant national competent authorities.

3. Wholesalers and persons authorised or entitled to supply medicinal products to the public are entitled to participate in the legal entity or entities referred to in paragraph 1, on a voluntary basis, at no cost.

Immediate next steps

18 January 2017 – EAHP meeting with EMVO in bid to secure and agree rights of participation at no cost.

3-5 February 2017 – EAHP Board Meeting to make determination on next steps.

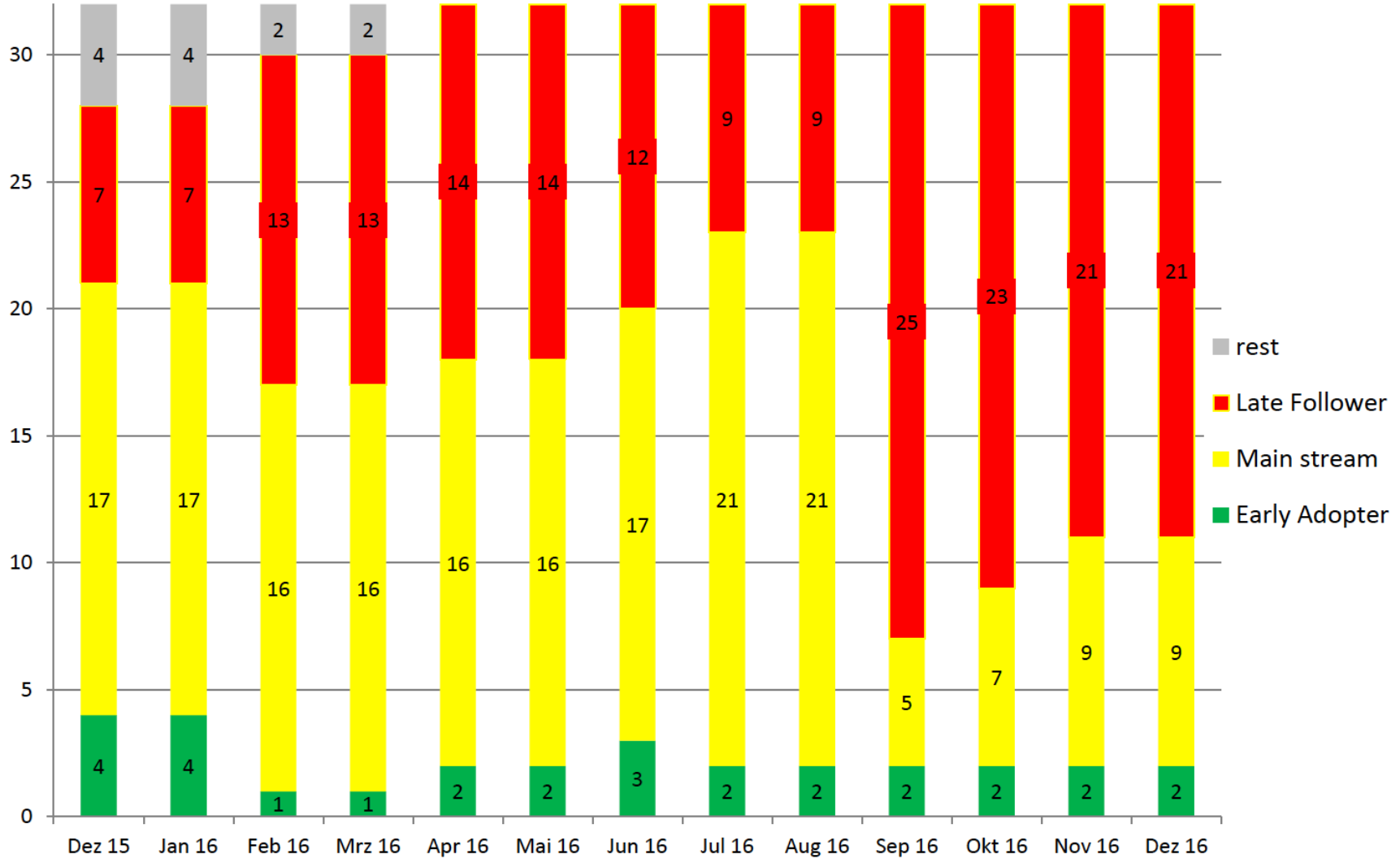
- To continue with complaint?
- Other means by which EAHP can offer support to its members?

2. The European implementation picture, from EMVO

European Medicines Verification Organisation

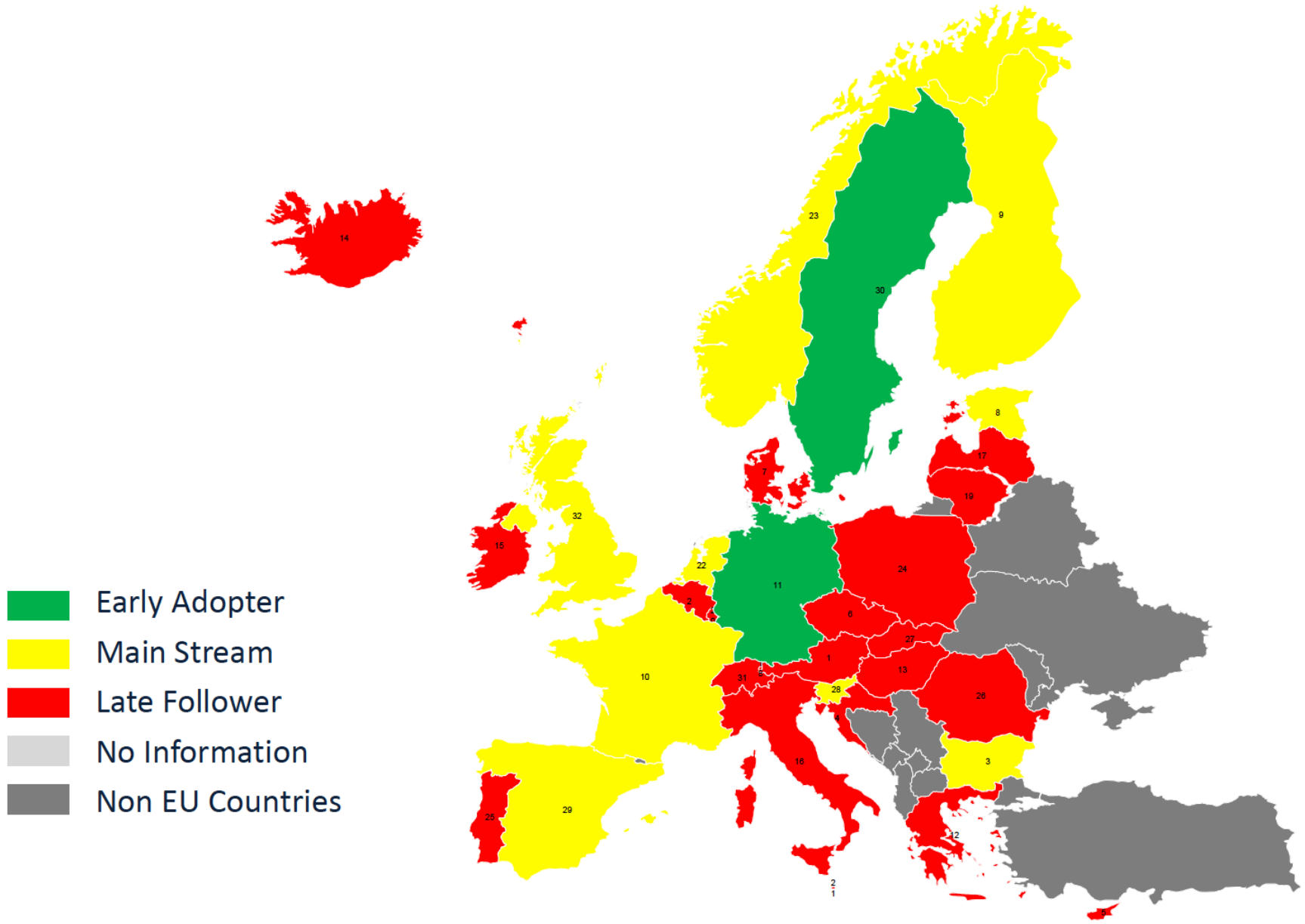
European Medicines Verification Organisation

Country Readiness

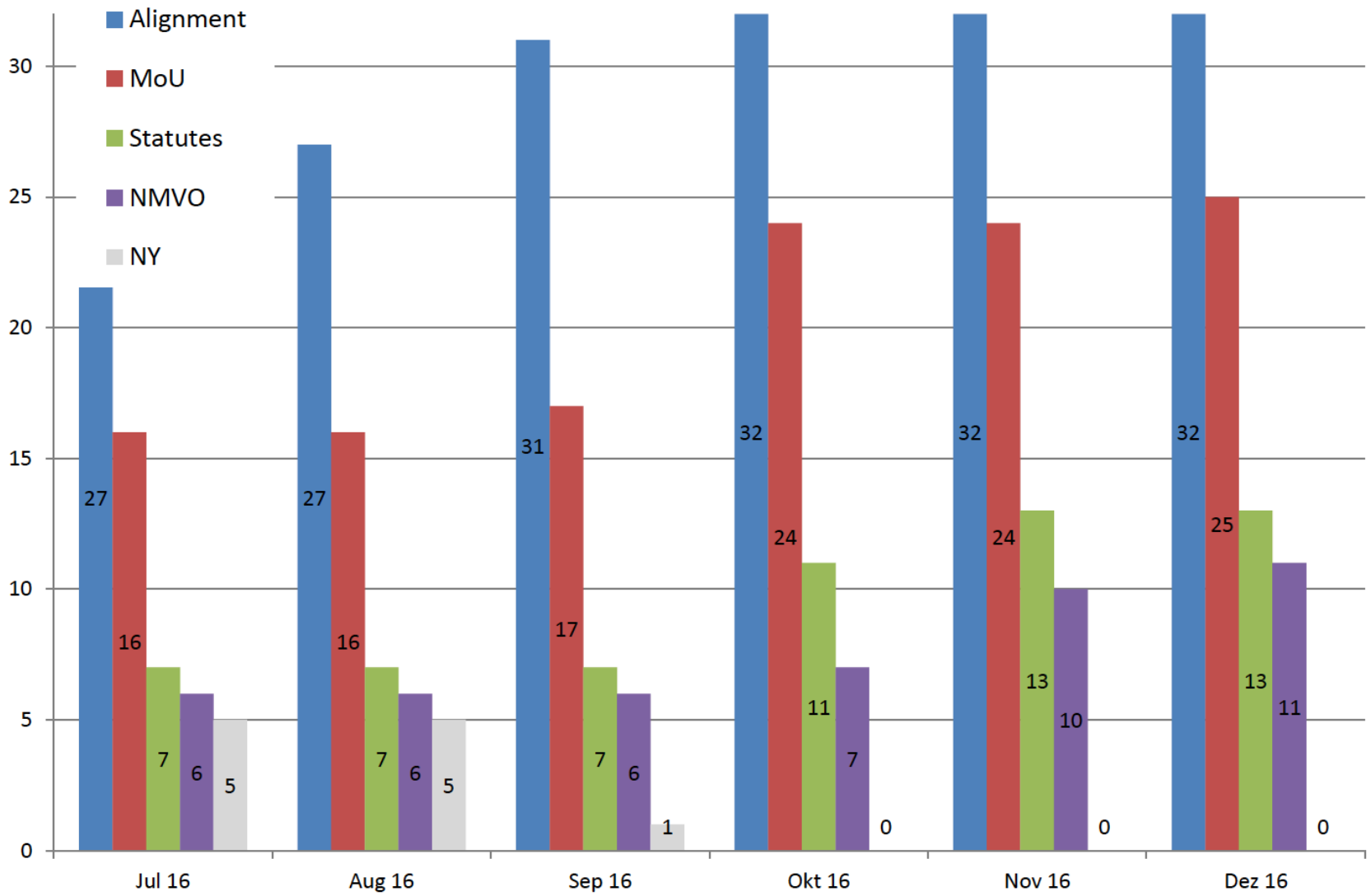


European Medicines Verification Organisation

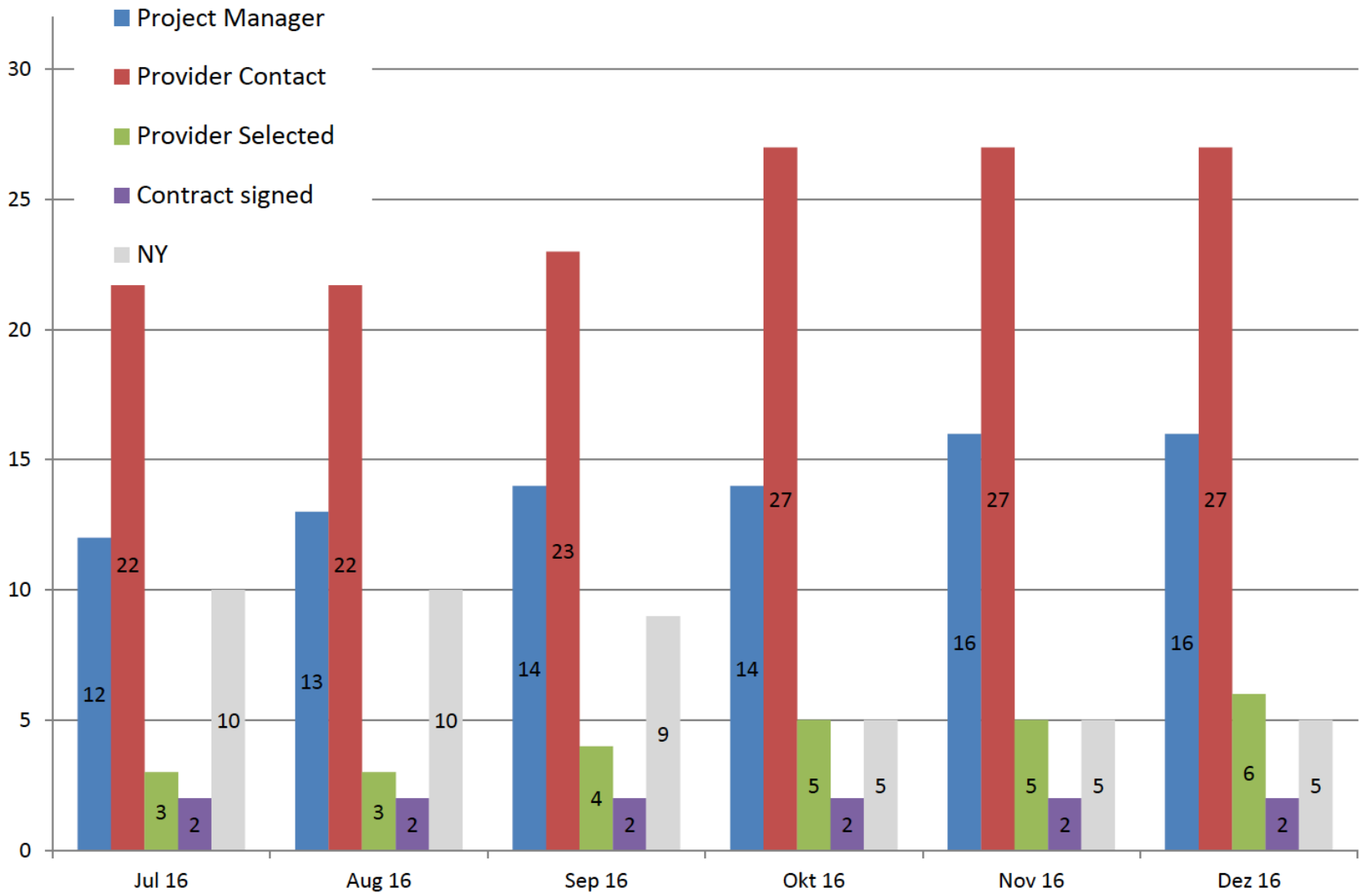
Executive Summary Country Readiness



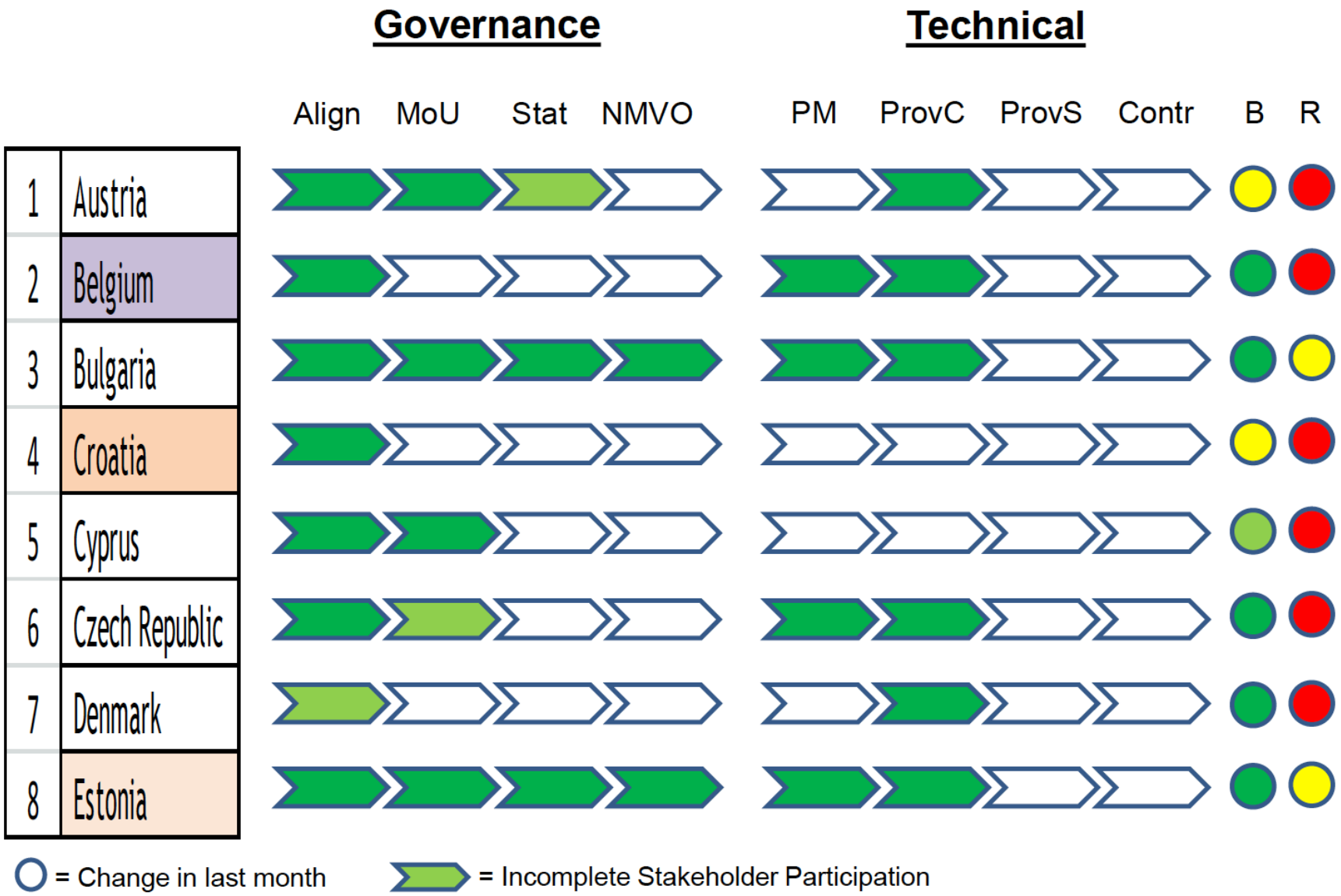
Governance Work Stream



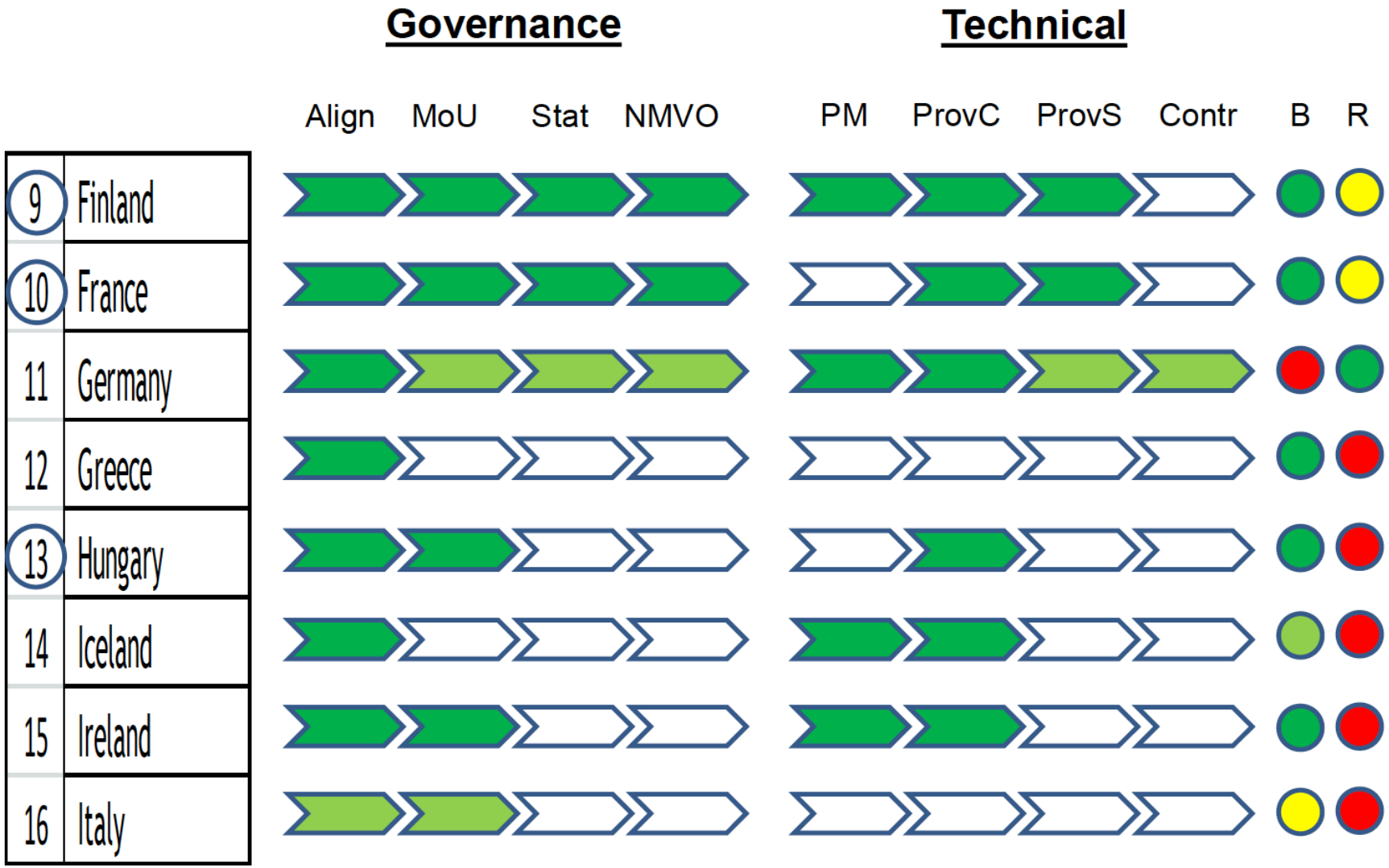
Technical Work Stream



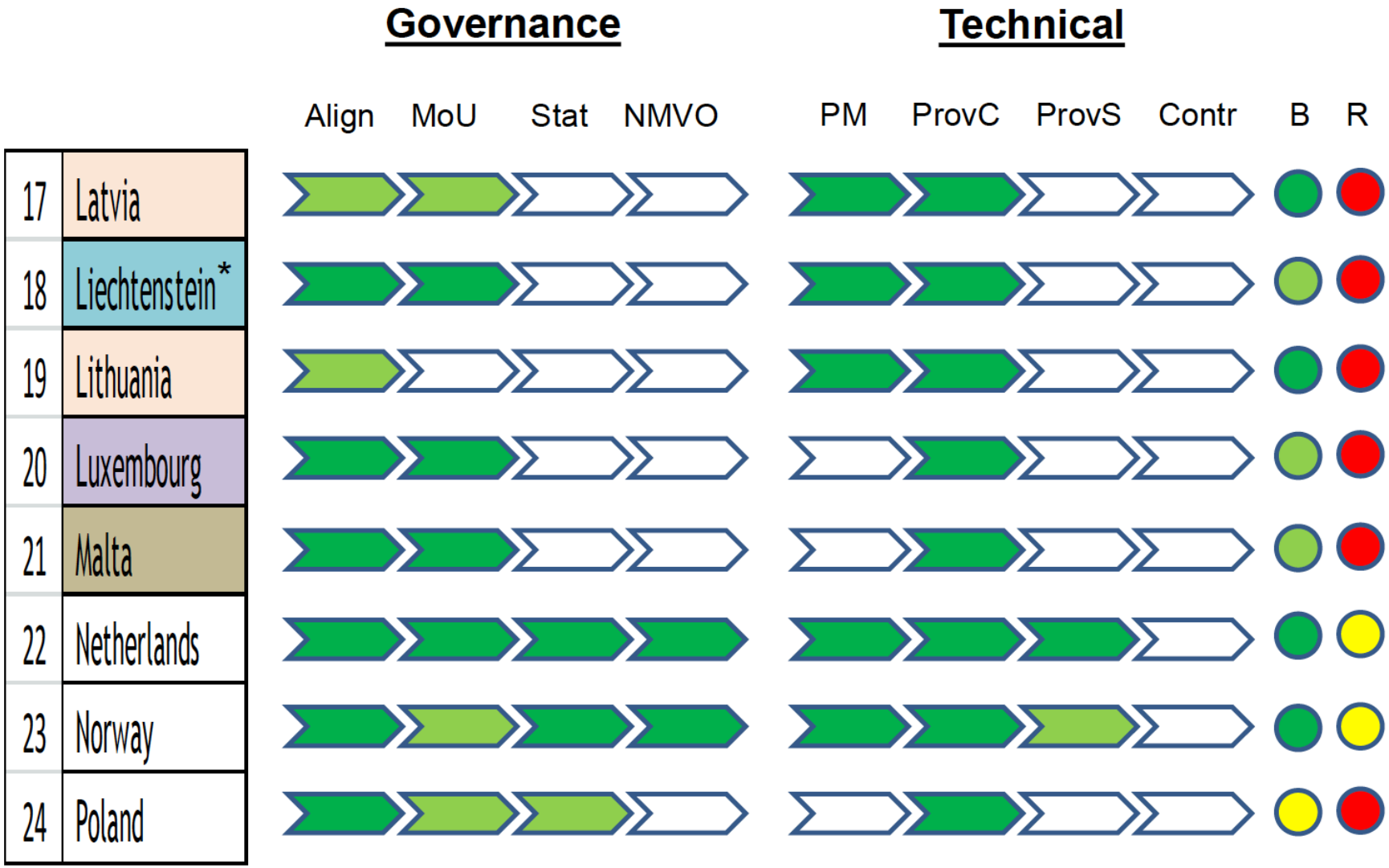
Status per Country 1-8



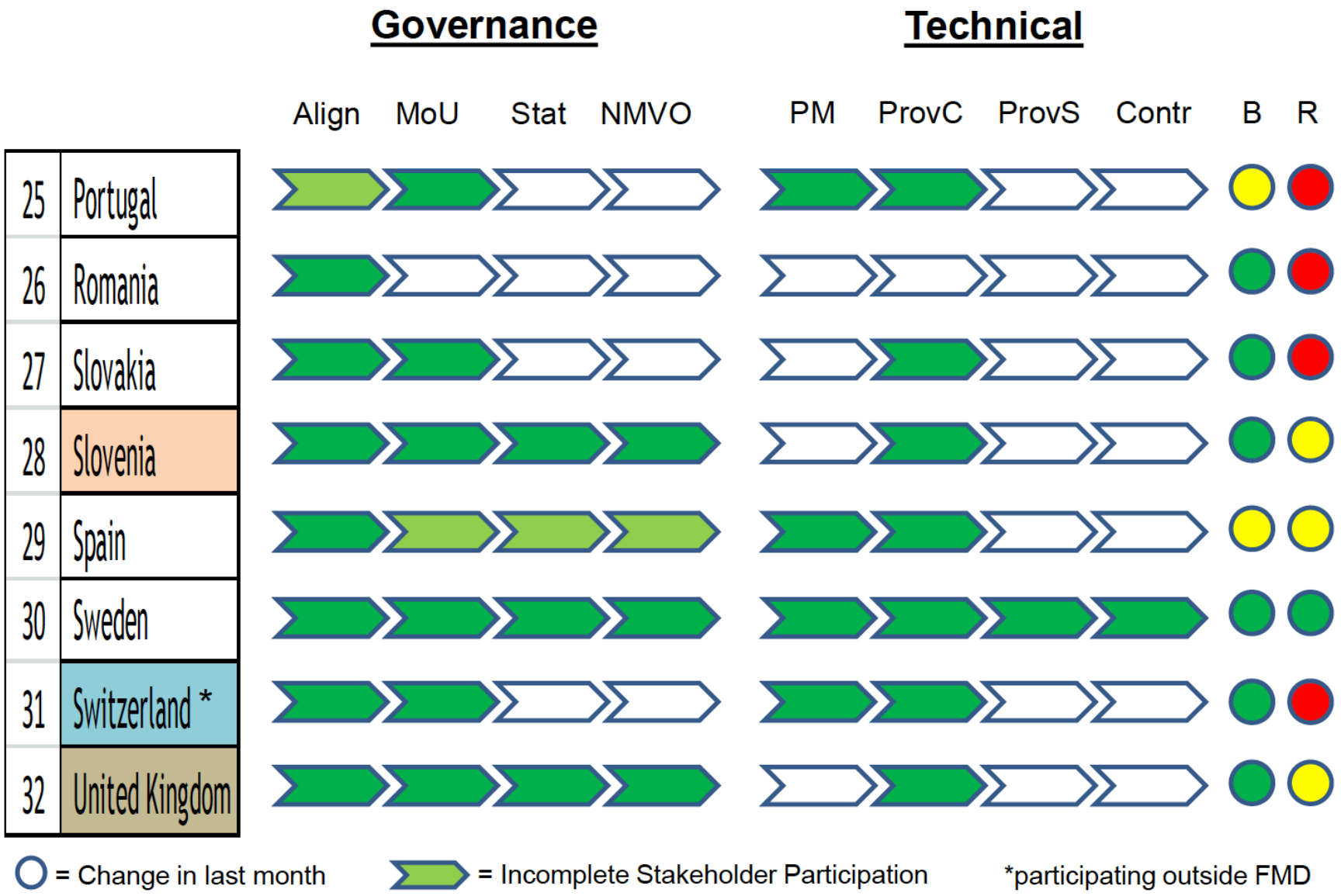
Status per Country 9-16



Status per Country 17-24



Status per Country 25-32



European Medicines Verification Organisation

EMVO Observations

- Program Progress
  - 11 NMVOs founded, 2 Contracts Signed
  - Majority of Countries progress and aim for Provider Contract in Q1 2017

- To be improved
  - 2/3 of Countries are still behind Schedule
  - Still 5 Countries did not start Technical Work Stream
  - Stakeholder alignment in MOU and Statutes not complete in several Countries (e.g. Pharmacies and Wholesalers not integrated in NMVO set up)

3. National updates from participants on the call

1. Malta
2. Czech Republic
3. Estonia
4. Austria
5. Italy
6. Spain
7. Sweden

4. Open discussion, Q&A

5. Summary and next steps