



Economics and Access, Healthcare Systems and Novel Therapies

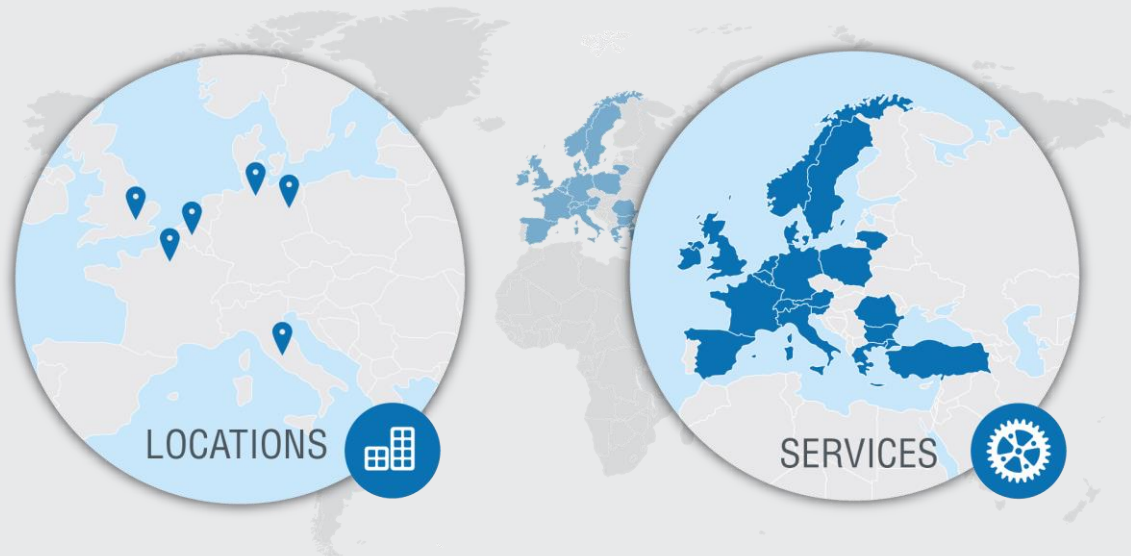
Novel Therapies and European Legislation

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RPP Group: A European Firm



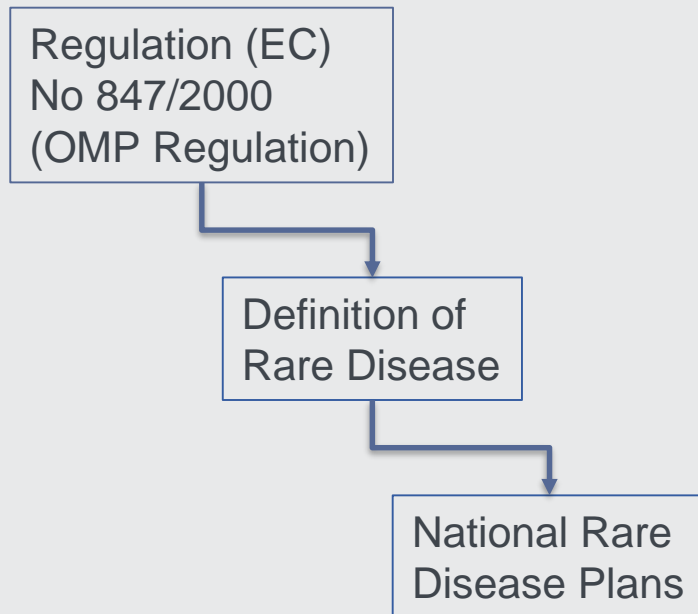
- RPP Group is a consultancy focused on **policy creation and development**, building on our integrated services such as **digital campaigning and visual communications**.
- RPP Healthcare is a member of the RPP Group. Our topical focus and expertise are in **healthcare, well-being, nutrition, R&D, innovation, market access & reimbursement, trade, and internal market policy**.
- RPP Healthcare offers Public Affairs Services in **various European Countries and on EU Level**.

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Why Europe?

- The European Union creates the terminology by which national legislators build provisions on access to medicines
- Example



Novel therapies. Why now?

EU
legislators
are
currently
reviewing
several
crucial
health
provisions

Evaluation of EU Blood and
Tissues and Cells legislation

Update of the ATMPs guidelines
Revision of the ATMPs Regulation?

Health Technology Assessment
proposal for Regulation

OMP/Paediatric Regulation Joint
Assessment

The evolution of the relationship between public health and the internal market, post Lisbon Treaty

- TFEU, art.168, par.1

A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Consequence?

Position patients and medical products on the same page

- The Cross-Border Healthcare Directive (2011) – legal basis – articles 114 (internal market) and 168 (public health)
- The Clinical Trials Regulation (2014) – legal basis - articles 114 (internal market) and 168 (public health)
- Medical Devices Regulation (2017) - legal basis – articles 114 (internal market) and 168 (public health)

Rare bleeding disorders community moving forward

