

# Upstream convergence and downstream divergence?

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## Upstream: EU-level (policy formulation)

### EU wide medicine authorization

- EMA: centralized procedure
  - Some medicines
- *Uniformity in the market authorization of some medicines*

### 'Development' principle

- Mutual recognition procedure for national authorizations

## Downstream: national-level

### National medicine authorization

- National (decentralized) procedure
  - Most medicines

### National pricing and reimbursement

- Linked with *national health insurance* schemes
  - All medicines
- *Differences in the availability and use of medicines (divergence)*

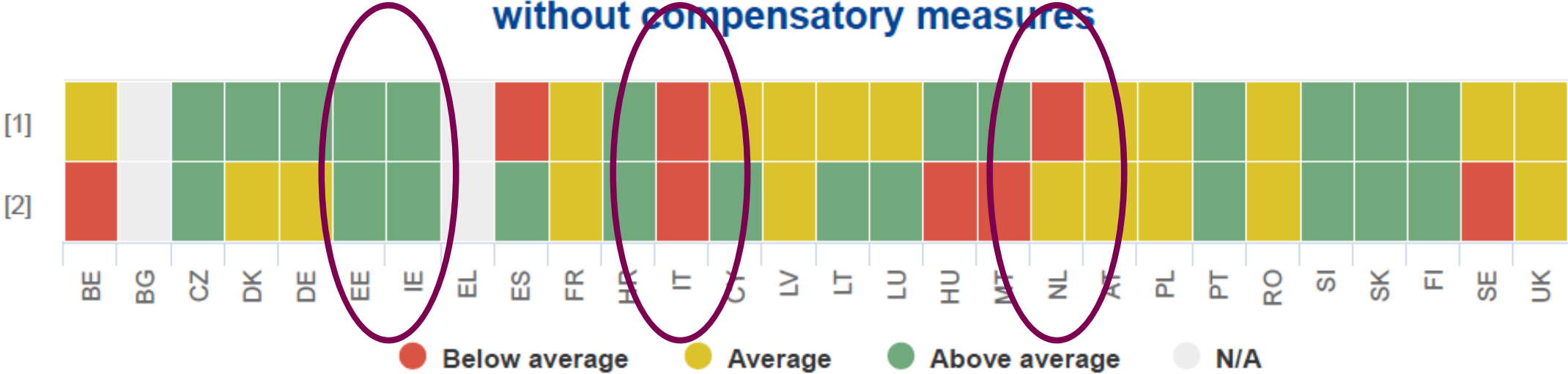
# EU Residence rights policy

| Land | BE  | BG     | CZ    | DK    | DE    | EE    | IE     | EL     | ES     | FR    | HR    | IT  | CY  | LV    | LT     | LU     | HU     | MT  | NL    | AT     | PL     | PT    | RO     | SI    | SK    | FI     | SE     | UK    |
|------|-----|--------|-------|-------|-------|-------|--------|--------|--------|-------|-------|-----|-----|-------|--------|--------|--------|-----|-------|--------|--------|-------|--------|-------|-------|--------|--------|-------|
| (1)  | Red | Red    | Green | Green | Red   | Green | Green  | Red    | Yellow | Green | White | Red | Red | Green | Green  | Yellow | Red    | Red | Green | Yellow | Yellow | Red   | Red    | Red   | Red   | Green  | Green  | Green |
| (2)  | Red | Green  | Red   | Green | Green | Green | Red    | Red    | Yellow | Green | White | Red | Red | Green | Yellow | Yellow | Yellow | Red | Red   | Green  | Green  | Green | Red    | Red   | Green | Green  | Yellow | Red   |
| (3)  | Red | Yellow | Red   | Green | Green | Green | Yellow | Yellow | Yellow | Green | White | Red | Red | Green | Green  | Green  | Red    | Red | Green | Green  | Red    | Green | Yellow | Green | Red   | Green  | Yellow | Red   |
| (4)  | Red | Green  | Green | Green | White | Green | Yellow | Green  | Red    | Red   | White | Red | Red | Green | Green  | Green  | Green  | Red | Green | Green  | Green  | Green | Green  | Green | Green | Yellow | Red    | Red   |

**Assessment criteria:** (1) information about application; (2) preparing application including required documents; (3) lodging application; (4) decision and issuing of documents

# Professional qualifications

**Chart 1: Proportion of positive decisions as a proportion of all decisions: overall & without compensatory measures**



|  |          |                  |          |
|--|----------|------------------|----------|
| <b>[1] Recognition</b>                               | > 96.30% | 89.22 % – 96.30% | < 89.22% |
| <b>[2] Recognition without compensatory measures</b> | > 45.88% | 25.48 % – 45.88% | < 25.48% |

Source: Regulated professions database (validated up to 1 February 2019).

Based on statistics recorded by national authorities. (Over 2015-2017, Greece recorded no data, while Bulgaria’s data was insufficient.)

**Explanations  
about  
differences in  
implementation  
(‘downstream  
divergence’)**

**Capacity and  
capabilities  
(*systemic*)**

- Level of national or ‘local’ expertise
- Resources to national authorities
- Affordability of medication

**Policy concepts  
and cultural  
differences  
(*institutional*)**

- Other ‘national’ policy concepts
- Different ways of working (e.g. assessing risk)

**Preferences  
and incentives  
(*behavioral*)**

- Conflicting interests
- Different incentives

# Proposition about 'downstream divergence'

*To be successful, the implementation of policy requires flexibility in order to adapt this policy to 'local' circumstances*

'Local' circumstances include capacity and capabilities, policy understandings and cultural differences, and interests of local stakeholders

# Ideas about EU policy development (‘politics’)

## Cost of adaptation

- Member states protect national regulation by imposing their rules on new EU policy

## Protecting national regulatory regimes

- EU rules protect national regulatory regimes (e.g., social security)

## Functional spill- over

- Resolving policy problems at the EU level create new problems that need to be resolved

## Failing forward

- ‘Lowest common denominator’ bargains at the EU lead to imperfect solution causing new ‘crises’ requiring reform

## Propositions about 'upstream convergence'

*EU regulatory policy on market authorization may reveal unexpected problems: these will be input for new EU level negotiations leading to imperfect 'lowest common denominator' solutions*

*EU regulatory policy on market authorization protects national health insurance regimes, including pricing and availability of medicines: upstream convergence about the use of medicines therefore remains limited*



# How likely is convergence?

| <b>National implementation:</b><br><b>EU regulatory policy:</b>                                  | <u><b>national incentives:</b></u><br>change towards EU medicine authorization <b>and</b> pricing | <u><b>national incentives:</b></u><br>no change |
|--|---|---|
| <u><b>No</b></u> exemptions and <u><b>no</b></u> discretion and <u><b>strict</b></u> enforcement | Convergence<br>uniformity   | Limited convergence<br>non-uniform policy       |
| Exemptions and/or discretion and/or limited enforcement  | Limited convergence<br>non-uniform policy   | Divergence<br>non-uniform policy                |

Thank you!



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