



# What are the requirements for compounding in Europe?

Joyce M Hoek  
Diāna Neza  
Marie L De Bruin  
[j.m.hoek@uu.nl](mailto:j.m.hoek@uu.nl)

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## Comparative analysis of national legislation across 12 member states

### INTRODUCTION

- Magistral and officinal pharmacy preparation are important for addressing patient's needs: e.g., tailored medications, access to unavailable medicines, shortages

- Exempt from the EU pharmaceutical legislation (Directive 2001/83/EC, Art. 3)

→ Rules differ per member state

### GOAL

- Create comparative overview of compounding legislation across EU member states

- Identify and compare requirements

### METHODOLOGY

- 12 countries, different EU regions








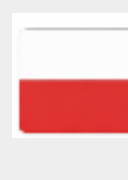




- Identify relevant national primary legislation (laws, acts and decrees, no policy notes, pharmacopeia etc.)

- Systematically screen legislation for mention of compounding

- Identify & compare specific compounding requirements

### RESULTS

Does national legislation define the following compounding requirements?

	DK	LV	FI	FR	DE	NL	CZ	PL	SK	PT	ES	IT
												
Does legislation define <b>magistral formula</b> ?	✓	✓	p	✓	✓	X	✓	✓	✓	✓	✓	✓
Does legislation define <b>officinal formula</b> ?	X	✓	X	✓	✓	p	✓	✓	✓	✓	✓	✓
Does the pharmacy require an <b>additional licence or authorisation</b> to compound?	p	✓	✓	X	?	?	✓	X	p	?	?	?
Can a pharmacist compound a drug if a suitable, licenced <b>alternative is available</b> ?	p	?	?	p	?	?	?	?	?	?	?	?
Is <b>outsourcing</b> between the compounding and dispensing pharmacy permitted?	p	p	p	p	p	?	p	?	p	p	p	p
Are there restrictions on the <b>scale</b> of compounding? E.g. number of packages/drug	?	?	✓	?	✓	✓	?	?	?	?	?	?
Are there specific rules for compounding in <b>exceptional circumstances</b> ? E.g. shortages	✓	?	?	✓	✓	?	?	?	?	?	?	?

Legend: ✓ = yes; X = no; p = partially; ? = unknown

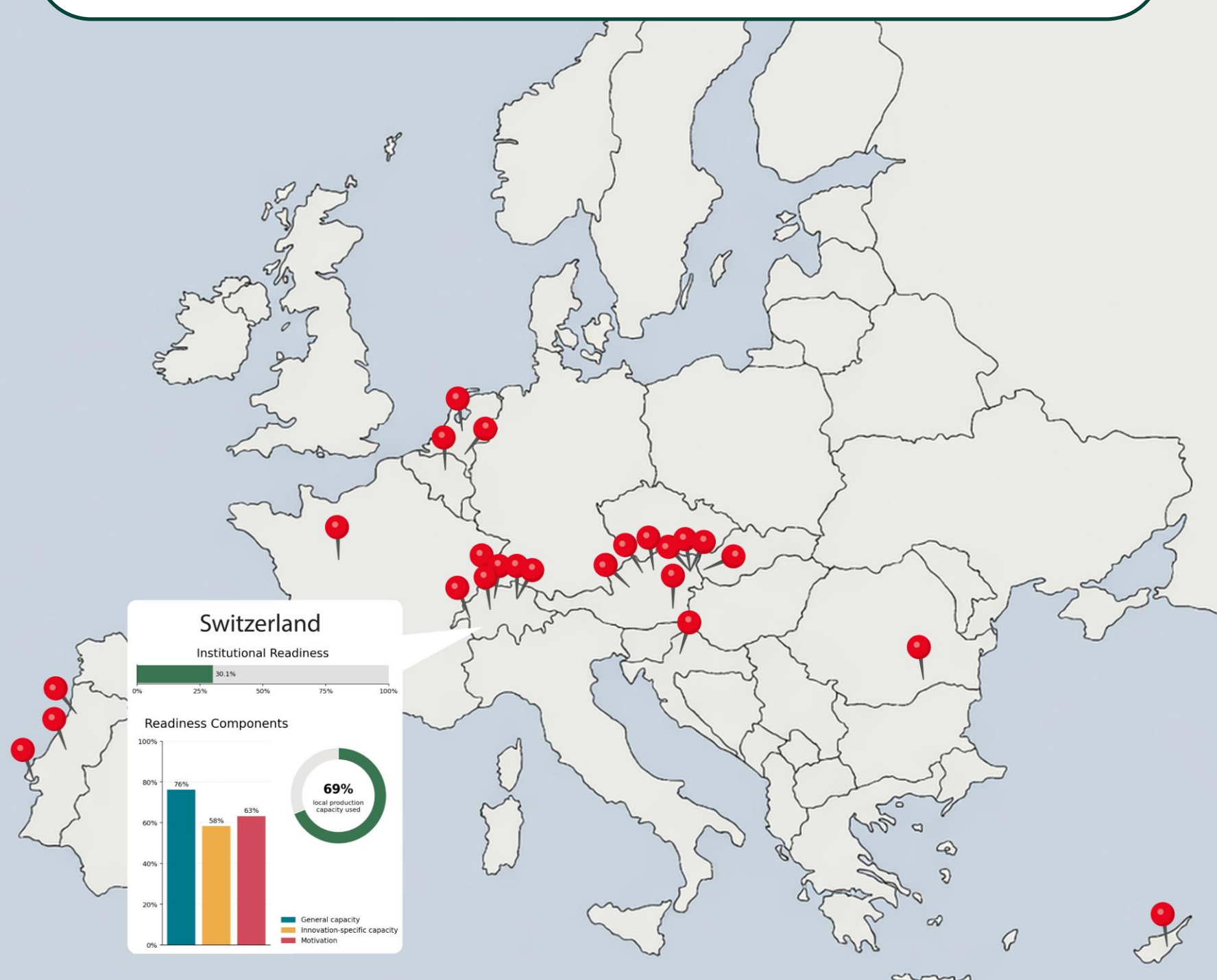
### DEFINITIONS DIRECTIVE 2001/83/EC

**Magistral formula:** "Any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient."

**Officinal formula:** "Any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question."

### PUT YOUR COUNTRY ON THE MAP

- Let us know how practice differs from legislation
- Share your compounding expertise through this survey



### RESULTS – Noticeable findings

- Lack of consistency between countries; no standard way of incorporating EU Directive in national legislation
  - E.g., Finland: ex tempore medicine; France: magistral, hospital, and officinal preparation

- Rarely mentioned restrictions:

- Scale: Finland – only for own operations; Germany – 100 packages/day; Netherlands – small scale
- Availability of registered alternative: France – magistral and hospital preparation not allowed; Denmark – compounding in public pharmacies not allowed (exceptions possible)

- Outsourcing is explicit in primary legislation of almost all countries: allowed under certain conditions; based on type of pharmacy; within network of pharmacies/ health services based on contracts between them, sometimes with additional approval from authority; by receiving additional permit from authority; or after notifying authority

### DISCUSSION – Implications & limitations

- Interesting contradictions/restrictions when comparing Directive 2001/83/EC to national legislation:
  - E.g., direct supply to patients of pharmacy vs. outsourcing permission

- Legislation is often ambiguous, possibly impacting compounding practices and therefore patient access across EU

- Limitation: only primary legislation. Further requirements may be defined in secondary legislation/policy
  - E.g., France has scale restriction (250 patients); Netherlands allows outsourcing

### CONCLUSION

Legislative frameworks for compounding are heterogenous across EU member states, leading to questions about equitable patient access and uncertainties for European policy makers. The findings of this study call for more harmonization. More research is required to understand differences between primary national legislation, policy and practice; and patient impact

