Timely and Correct Transposition of Pharmacovigilance across Member States

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There has long been a vague supposition that the European Union (EU) has a transposition problem (Groenleer et al. 2010; Kaeding 2006, 2007a, b, 2008a, b, c, 2012; Kaeding and Versluis 2014; Klika 2015a, 2015b; Mastenbroek and Kaeding 2006, 2007; Schmälter 2017; Steunenberg et al. 2006; Steunenberg and Kaeding 2009). This chapter offers a first assessment of the timeliness of national transposition processes for all EU Member States and their respective national pharmacovigilance systems.

When the timeliness of national transposition processes of pharmacovigilance for all EU Member States is considered, this assessment shows that many countries have a serious transposition problem in their national pharmacovigilance systems.

4.1 Timely Transposition of Directive 2010/84/EU across Member States

Fig. 4.1 calculates the difference between the transposition deadline set in the EU pharmacovigilance Directive (21.07.2012) and the date of publication of the first and last national transposition instruments. The figure shows the delays in weeks for the 101 national implementing measures of Directive 2010/84/EU.

Whereas the average number of implementing measures needed to transpose the EU pharmacovigilance directive was 3.6, 12 Member States communicated only one transposing instrument. However, Malta, Hungary and Lithuania needed nine, 13 and 14 instruments, respectively.

In addition, only 16 out of the 101 (15 percent) national implementing measures were transposed on time. On the extreme end of the late transposition continuum are Finland, Spain, Poland and Slovenia; they transposed their first national implementing measures more than one year after the transposition deadline had expired.

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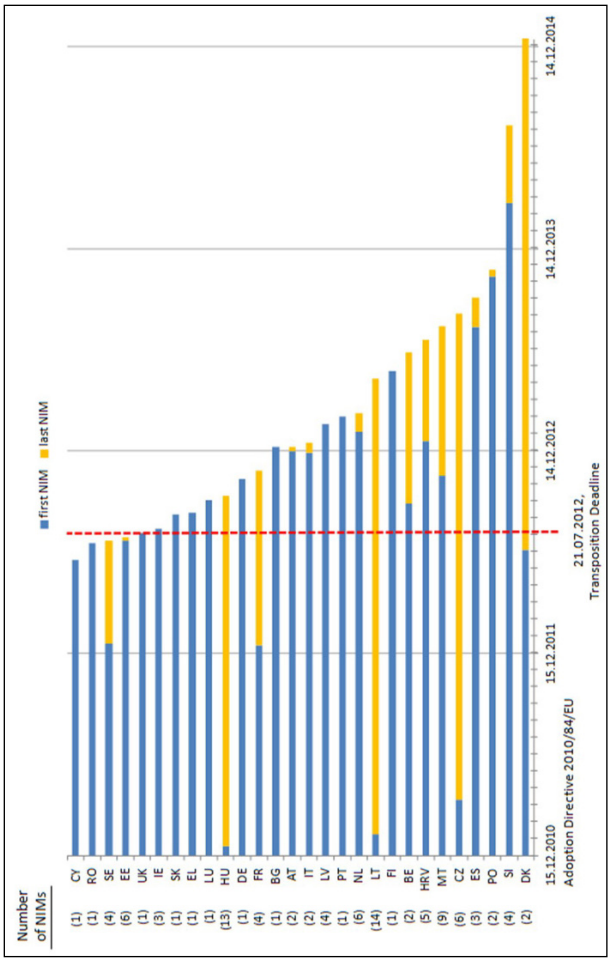

Fig. 4.1 Timely transposition of Directive 2010/84/EU across EU Member States (provided by the European Commission)

Overall, it appears that EU transposition deficits in European pharmacovigilance are not a statistical illusion. Almost 85 percent of the national transposition instruments are not transposed on time, and in fact are delayed up to more than two years.

Cross-country variance in transposing the EU pharmacovigilance Directive is significant. There is a significant difference between the laggards (Denmark and Slovenia) and the champions (Cyprus, Romania, Sweden, Estonia, the United Kingdom and Ireland).

4.2 Correct Transposition of Directive 2010/84/EU across Member States

Many Member States have endorsed so-called guiding principles for transposing EU legislation. These principles aim at policy makers and lawyers across government bodies and explain what is needed to correctly implement EU legislation.

When EU legislation is transposed, the aim should be to avoid going beyond the minimum requirements of the legal instrument being transposed. Taking such an approach will ensure that EU legislation does not create unnecessary legislative burdens. Furthermore, any gold-plating by extending the scope, adding in some way to the substantive requirement, not taking full advantage of any derogations, retaining pre-existing national standards where they are higher than those required by EU law, or implementing early before the date given in a directive, should be either avoided or eventually cleared by a reducing regulation committee. Another guiding implementation principle is to always use copy-out for transposition where it is available, except where doing so would adversely affect national interests.

In the following sections, the report analyses all national implementing measures for the six Member States (the United Kingdom, Finland, Poland, France, Portugal and Germany) under investigation. To assess whether they followed the above-mentioned guiding implementing principles, we split the analysis according to two aspects: processes and actors on the one hand, and quality and content on the other hand.

4.2.1 Correct Transposition – Processes and Actors

Table 4.1 summarises the findings of the "processes and actors" analysis and is guided by the order of the following questions:

1. What is the name, what is the type of legal instrument and who signed the national implementing measure (NIM)?
2. Was there a transposition plan, and did the actors' legal departments participate in this plan?
3. Is there a reducing regulation committee or similar, were expert groups consulted and does the NIM provide for a ministerial review?

Tab. 4.1 Correct transposition of Directive 2010/84/EU across EU Member States – processes and actors

	United Kingdom	Finland	France	Poland	Portugal	Germany
Name	UK Statutory Instrument 2012 No 1916. The Human Medicine Regulation 19/07/2012.	Laki 330/2013. Amendment to the Medicines Act.	Loi del'Etat 2011-2012. Décret 2012-1244. Arrêté du 8 novembre 2012 (R.5121-21). Arrêté du 8 novembre 2012 (R.5121-45)..	Ustawa z dnia 27 września 2013 r. o zmianie ustawy. Rozporządzenie Ministra Zdrowia z dnia 5 listopada 2013 r. zmieniające rozporządzenie w sprawie wymagań dotyczących oznakowania opakowań produktu leczniczego i treści ulotki.	Decree Law 20/2013 (14th February 2013).	Zweites Gesetz zur Änderung arzneimittelrechtlicher und anderer Vorschriften.
Which Type?	Statutory Instrument (Regulation by Secretary of State and Minister).	Amendment to existing legislation.	Law. Presidential Decree Law. Ministerial Enactment.	Law. Ministerial Order.	Governmental Decree Law.	Law.
Who Signed?	Secretary of State; Minister for Health, Social Services and Public Safety.	President of the Republic; Minister of Social Affairs and Health.	President of the Republic; Prime Minister; Minister of Justice; Minister of Economy, Finances and Industry; Minister for Work, Employment and Health; Minister of Higher Education and Research; Prime Minister Minister of Social Affairs and Health; Managing Director for Health (in delegation by Minister); Managing Director for Health (in delegation by Minister).	Adopted by Parliament Signed by President and the Minister of Health.	Prime Minister; Minister of Health; Approved by President.	President; Chancellor; Minister of Health.

	United Kingdom	Finland	France	Poland	Portugal	Germany
National Transposition Plan?	Impact Assessment available.	No evidence.	No evidence.	No.	No evidence.	Plan of action (*Aktionsplan 2013-2015*).
Participation of Legal Departments?	No evidence.	No evidence.	No evidence.	No evidence.	No evidence.	No evidence of participation, although the Health Ministry has its own legal department (*Justiziarrat*).
Participation of Reducing Regulation Committee?	Yes. Cooperation with the Reducing Regulation Committee.	No evidence. There is, however, the cross-ministry expert group (Better Regulation Consultative Committee).	No.	No evidence. There is, however, a Supreme Audit Office to reduce bureaucracy.	No evidence. There are, however, two programmes for legislative simplification that are currently running (*Programa Simplex / Programa Legislar Melhor*).	No evidence. There is, however, a reducing regulation committee (*Nationaler Normenkontrollrat*).
Consultation of Expert Groups?	Public consultation on implementation of Directive. More than 500 parties were contacted (Consultation MLX 374 from 06.12.2011 to 28.02.2012).	No evidence.	No evidence.	No evidence.	Consultation of healthcare professionals' associations, pharmaceutical industry associations and patients' organizations.	Consultation of 36 associations and seven experts.

4.2.2 Correct Transposition – Quality and Content

Table 4.2 summarises the findings of the "quality and content" analysis based on the following questions:

1. Has Directive 2010/84/EU been copied, or has new or existing legislation been used?
2. Is the national implementing measure longer than the original legislation?
3. Does the national implementing measure exceed the requirements of Directive 2010/84/EU?
4. Was the national implementing measure transposed before the transposition deadline on July 21st, 2012?

Tab. 4.2 Correct transposition of Directive 2010/84/EU across EU Member States – quality and content

	United Kingdom	**Finland**	**France**	**Poland**	**Portugal**	**Germany**
Has Directive 2010/84/EU Been Copied?	Copy-out method. Only minor changes in wording that do not affect the meaning.	No similarities with the Directive's text can be found.	No similarities with the Directive's text can be found.	No similarities with the Directive's text can be found.	Copy-out Method Only minor changes in wording that do not affect the meaning.	No similarities with the Directive's text can be found Meaning of Article 102 (e) was weakened by saying that national authorities *can impose* further measures to ensure correct identification and traceability of biological products.
New or Existing Legislation?	Adapting and replacing already existing legislation.	Adapting and replacing already existing legislation.	Adapting and replacing already existing legislation.	Adapting and replacing already existing legislation.	Adapting and replacing already existing legislation.	Adapting and replacing already existing legislation.
Length of NIM	53 words for transposing Article 102 (e).	Three Articles out of 17 Articles of the NIM relate to Article 102 (e).	Loi de l'Etat (25 pages, 48 Articles). Décret (16 pages). Arrêté (each one page).	Law (30 pages). Ministerial Order (three pages).	112 pages (205 articles and four annexes).	36 pages in total. Article 102 implemented in three articles, each nine sentences.
Risk of Gold-Plating?	No.	Difficult to detect because the Directive was not transposed word by word.	Difficult to detect because the Directive was not transposed word by word.	No.	No.	No.
Transposition of NIM before Deadline?	19 days before the deadline's expiration.	Delayed.	Delayed.	Delayed.	Delayed.	Delayed.

All in all, however, Member States hardly pay any attention to the above-mentioned guiding implementing principles. The EU also has a transposition problem in terms of incorrect transposition. Processes, the number of actors, the quality and the content of national implementing measures vary greatly across the selected EU Member States, leading to a great deal of diversity across Europe.

This chapter demonstrated that the transposition of EU legislation into national law remains a challenge across the EU. Yet by now, the formal transposition of Directive 2010/84/EU on pharmacovigilance has been completed in all Member States. In the following chapter, we analyse whether the transposition is also complied with in practice. With a focus on six EU Member States (the United Kingdom, Finland, Poland, France, Portugal and Germany), we depict national ADR reporting systems, examine which challenges remain, and identify best practices in order to improve existing pharmacovigilance frameworks.

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