Cross-border ePrescription, univocal identification of medicines, and substitution - a European survey

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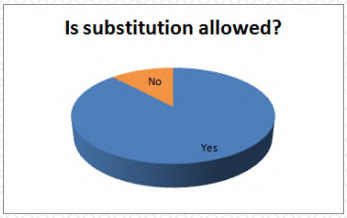
Dispensing an ePrescription for medicinal products for human use by a community pharmacist in a cross-border situation regularly poses two specific challenges:

- **The univocal identification of the medicine specified in the foreign prescription,**
- **If the product is not available or substitution is required, the dispensation of a similar medicine in line with national law,**

With respect to the first challenge, global efforts supported by openMedicine – in close cooperation with the European Medicines Agency (EMA), FDA, and others - focus on implementing the ISO IDMP (IDentification of Medicinal Products) suite of standards (ISO 11615/16, 11238-40). This presentation focuses on the second challenge.

Methods

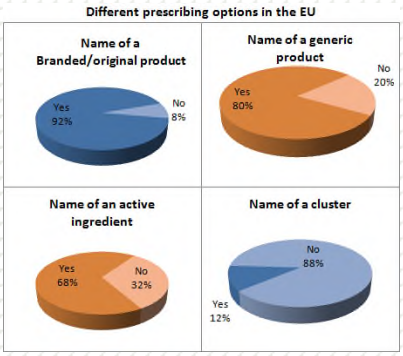
Based on a literature review, analyses of EU regulations and cross-border ePrescription guidelines, an analytical framework was established. Informal discussions with experts (pharmacists, physicians, regulators) revealed that substitution is a rather ill-defined concept, and its understanding is very much depending on the concrete experience and regulation in the respective country. Substitution at the point of dispensation is defined as the exchange of a medicinal product, univocally specified in a prescription, by another one which differs with regard to one or several attributes like name, quantity, dosage form, strength, route of administration. Defining a suitable set of well formulated questions (administered in English, but reflecting reality in 28 countries) for an empirical survey was a very complex process. Regular pre-testing of tentative formulations by uninvolved experts from diverse countries was applied.



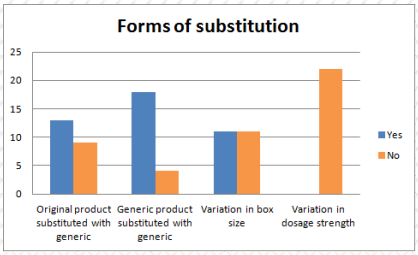
Data collection was via online LimeSurvey. Potential respondents were identified through a snowball system, involving known experts, membership of the Pharmaceutical Group EU and other associations

Results

Almost 100 persons responded, covering 25 of 28 EU member states. Data were analysed per country and compared across countries, after triangulating and integrating multiple results per country into a single file. Almost half of the countries have national or regional ePrescription systems. Four generic types of (e)Prescriptions prevail: specifying an individual originator medicinal product, a generic product, only an active ingredient (e.g. INN prescription), or a predefined set of



products (cluster prescription). Substitution occurs mostly at the brand name level (same producer, but different name in dispensing country), or generic substance level (originator or generic branded product by another generic product). Therapeutic substitution (different active ingredient and/or from a different therapeutic class) is virtually absent. Substitution along other dimensions like dosage form, strength, or route of administration is sometimes allowed within strict limits. INN or cluster prescriptions cannot be handled cross-border due to missing international data bases.



The Smart Open Services for European Patients (epSOS) project – implementing an infrastructure for the cross-border exchange of electronic patient summaries and ePrescriptions – identified substitution challenges as a major barrier to indeed safely and successfully dispensing a medicine specified in a foreign ePrescription. Global efforts to establish and maintain comprehensive data bases – fully structured and with mostly coded data elements - of medicinal (and pharmaceutical) products and their identifying attributes accessible in different languages will greatly facilitate coping with this challenge. Nevertheless, the great diversity of substitution options and regulations prevailing across countries suggests to better align regulation and/or reach agreements on how to handle this challenge.

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