Perceptions of Quebec and French hospital pharmacists about biosimilars

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Introduction

Europe is ahead of the USA and Canada on approval, regulatory and marketing aspects of biosimilars. However, there is still uncertainty about interchangeability and substitution of biosimilars.

Objective

The objective is to assess pharmacists' perceptions about biosimilars in Quebec and in France.

Setting and Method

A cross-sectional study was carried out in June 2016. Hospital pharmacists from Quebec and France were invited to respond to an online survey of nine questions (Surveymonkey®, Palo Alto, CA, USA). The survey focuses on pharmacist's exposure to biosimilars (general knowledge, dispensing) and their perceptions about biosimilars. A 5-item Likert scale (Totally agree, partially agree, do not know, partially disagree, totally disagree) was used for 15 statements based on key issues about biosimilars. Levels of agreement (% who agreed) on biosimilar key issues were evaluated (e.g. sum of totally agree + partially agree).

Results

Global response rate : 27% (N=229/880)

Table 1 – Demographics	Quebec (N)	France (N)
Response rate	62% (141)	38% (88)
Hospital pharmacists	99% (139)	43% (38)
Pharmacy residents	1% (2)	57% (50)
Pharmacists or residents who attended at least to one conference on biosimilars	58% (81)	74% (65)
Pharmacists or residents who have already dispensed a biosimilar	7% (10)	82% (72)

Table 2 – Perceived level of knowledge of pharmacists on biosimilars	Quebec % agree (N)	France % agree (N)
Biosimilars are produced in living systems	96% (120)	96% (78)
The manufacturing process of biosimilars is expensive	100% (132)	92% (81)
Biosimilars have a high potential of immunogenicity	98% (130)	95% (84)
A biosimilar is bioequivalent to the reference product	33% (46)	58% (51)
Clinical studies involving biosimilars versus the reference product are needed to obtain approval	94% (115)	975 (75)
Automatic substitution of biosimilars is possible	6% (8)	8% (7)

Table 3 – Perceptions of pharmacists about biosimilars	Quebec % agree (N)	France % agree (N)	p
1- Biosimilar substitution can be compared to generic substitution	31% (43)	43% (38)	**0.072**
2 - Pharmacists and physicians are both responsible for the interchangeability between a biosimilar and its reference product	89% (122)	95% (84)	**0.092**
3 - Considering safety and efficacy parameters to monitor during a treatment, I believe that only physicians can decide to interchange a reference product to a biosimilar	24% (32)	28% (24)	**0.496**
4 - Uncertainty and doubts about interchangeability of biosimilars are exaggerated and encouraged by pharmaceutical companies to keep their market position	53% (72)	58% (51)	**0.427**
5 - Uncertainty and doubts about interchangeability of biosimilars are similar to those evoked when generic drugs were introduced on the marker	44% (60)	47% (41)	**0.716**
6 - In case of a shortage of a biosimilar or a reference product, it is certainly possible to interchange the prescribed drug with another biosimilar	64% (87)	74% (64)	**0.09**
7- As for generic drugs, I am comfortable to use a biosimilar for any indications of the reference product whatever is indicated in the biosimilar monography	22% (30)	36% (31)	**0.024**
8 – Prescribing a biosimilar using the international non proprietary name should be avoided considering the risk of confusion between the reference product and the biosimilar when dispensing	60% (81)	69% (59)	**0.174**
9 - In retail pharmacy, a patient should be systematically notified of a substitution between a reference product and a biosimilar	94% (129)	86% (76)	**0.045**
10 - In a health care facility, a patient should be systematically notified of a substitution between a reference product and a biosimilar	69% (94)	85% (75)	**0.005**
11 - I think that the pharmacist should verify that a patient has not experienced an immunogenic reaction before dispensing a reference product or a biosimilar	82% (111)	63% (55)	**0.001**
12 – The publication of a list of reference products and their respective biosimilars could encourage physicians to prescribe biosimilars	85% (117)	86% (75)	**0.867**
13 – Clinicians should proactively conduct clinical studies about interchangeability to confirm this option	83% (113)	75% (65)	**0.128**
14 - Governments should support financially clinical studies about interchangeability to confirm this option	79% (108)	86% (75)	**0.164**
15 - The lack of recommandations about drug substitution and interchangeability of reference product and biosimilars limits the prescription of biosimilars and substitution of biosimilars	85% (117)	84% (73)	**0.761**

Conclusion

Perceptions of Quebec and French hospital pharmacists about biosimilar issues are very similar. This study highlights the need to deal with the lack of clarity of national guidances. Clinical studies on biosimilar interchangeability must be conducted in the future to help pharmacists and physicians to take clear-headed decisions.

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