



Available online at
ScienceDirect
www.sciencedirect.com

Elsevier Masson France
EM|consulte
www.em-consulte.com/en



Correspondence

Biosimilars: complements and comments on the recent statement of the SFR and CRI. Comment on: “Biosimilars: An opportunity. Position statement of the French Rheumatology Society (SFR) and Inflammatory Rheumatic Disease Club (CRI).” Schaefferbeke et al. *Joint Bone Spine* 2018;95:399-402



ARTICLE INFO

Keywords:

Biosimilars
 Rheumatology
 Extrapolation
 Interchangeability
 Shared decision making
 Nocebo

We have read with interest the editorial of Schaefferbeke T. et al. [1] explaining the position of the SFR and CRI on biosimilars and we would like to comment on it.

One of the core concepts of biosimilarity is the concept of extrapolation. It is worthy to note here, that the clinical data obtained in the more sensitive indication (enabling the detection of some difference if any) are not enough and are completed with non-clinical data (structural, physicochemical, biochemical, functional). The most important criterion is the mode of action of the molecule, which must be the same in all the therapeutic indications (identical target, receptor and active dose) [2].

Moreover, in order to avoid any confusion, it seems appropriate to distinguish clearly between the act of substitution exercised by pharmacists defined legally in France and the interchangeability corresponding to a decision of the physician to prescribe a biologic to replace another one, concept not defined legally. Note also that the status of interchangeable biosimilar is unique to the United States and corresponds to the substitution in the European sense of the term.

Recently, the French public authorities have put in place measures to promote the use of biosimilars: to reach a target of 70% of prescription in initiation of treatment, while encouraging interchangeability [3]; to obtain a penetration rate of 80% in 2022 for hospital prescriptions dispensed by private pharmacies in ambulatory settings [4]; to develop information and promotion of biosimilars with the Regional Health Agencies (ARS) and the national health insurance; to deploy targeted financial incentive schemes for biosimilar prescribers (etanercept and insulin glargine) [5]. On this last point, an indicator on the information of the patients and the production of evidence of the means of communication employed is planned.

A recent study has shown that while half of French patients adhere to the principle of economy with biosimilars, more than

9 out of 10 patients request that information be given to them and their consent requested at initiation and during the treatment follow-up [6]. These two elements have the force of law since the Social Security Financing Act for 2017. The French National Authority for Health (HAS) [7] as, in the field of rheumatology, international experts [8] and European patient organizations also recalled this imperative to converge towards a shared medical decision for biosimilars (concept valued by the SFR in its recommendations).

Only 66.6% of rheumatologists think that patients must accept the principle of being treated with biosimilars to achieve savings [9]. Changing treatment for economic reasons despite a remission is destabilizing and it seems essential that empathy guide the prescriber. Regarding the nocebo effect, we can question the emphasis of the subjective part in case of failure [10] while it is willingly taken into account in case of success and even valued via Patient Reported Outcomes [11]. The transition from the decision for others to free choice implies that the person best placed to determine the right candidate is the patient himself.

Disclosure of interest

Dr Jean-David COHEN.

Financial interests: none.

Lasting or permanent link: none.

Punctual interventions: Abbvie, Pfizer, UCB.

Indirect interests (as congress): Abbvie, Lilly, Nordic, Novartis, Roche-Chugai, UCB, Pfizer.

Other: member of the CERBER group, Member of the BIOSIMILAIRES Think Tank.

Mrs Sonia TROPÉ.

Financial interests: none.

Lasting or permanent link: none.

Punctual interventions: Abbvie, Biogen, Nordic, Pfizer, Roche-Chugai, Sandoz, UCB.

Indirect interests: L'ANDAR reçoit des soutiens de Abbvie, Boehringer Ingelheim, Biogen, Lilly, Médac, MSD, Nordic, Novartis, Roche-Chugai, Sandoz, UCB, Pfizer.

Other: Initiator of the CERBER group, Member of the BIOSIMILAIRES Think Tank, Mrs Audrey MUNOS.

Financial interests: none.

Lasting or permanent link: none.

Punctual interventions: Biogaran, Amgen, Pfizer, Abbvie, Roche.

Indirect interests: none.

Other: member of the CERBER group, Member of the BIOSIMILAIRES Think Tank, Dr François Bocquet.

Financial interests: none.

Lasting or permanent link: none.

Punctual interventions: ADPHSOLAROPHA, Amgen, BMS, Biogaran, Biogen, Celgene, Hospira, IMS Health, IQVIA, Mylan, Pfizer, Roche, Sandoz, Synpreph, Takeda.

Indirect interests: member of the working group about biologics medico-economic evaluation in rheumatoid arthritis (CEPS, HAS).

Other: member of the CERBER group.

References

- [1] Schaeverbeke T, Pham T, Richez C, et al. Biosimilars: an opportunity. Position statement of the French Rheumatology Society (SFR) and inflammatory rheumatic disease club (CRI). *Joint Bone Spine* 2018;85:399–402.
- [2] Declerck P, Danesi R, Petersel D, et al. The language of biosimilars: clarification, definitions and regulatory aspects. *Drugs* 2017;77:671–7.
- [3] Instruction N° DGOS/PF2/DSS/1C/DGS/PP2/CNAMTS/2017/244 du 3 août 2017 relative aux médicaments biologiques, à leurs similaires ou « biosimilaires », et à l'interchangeabilité en cours des traitements.
- [4] Décret no 2017-1866 du 29 décembre 2017 portant définition de la stratégie nationale de santé pour la période 2018-2022 - JO du 31 décembre 2017.
- [5] Instruction N° DSS/1C/DGOS/PF2/2018/42 du 19 février 2018 relative à l'incitation à la prescription hospitalière de médicaments biologiques similaires, lorsqu'ils sont délivrés en ville.
- [6] L Frantzen, JD Cohen, S Tropé, et al. Patients' concerns about and perception of biosimilars in rheumatology : a french survey, on behalf of CERBER : Comité d'Etudes et de Réflexion sur les Biosimilaires en Rhumatologie. DOI: 10.1136/annrheumdis-2018-eular.4888.
- [7] Haute Autorité de Santé, Fiche bon usage, les médicaments biosimilaires, novembre 2017.
- [8] Kay J, Schoels MM, Dörner T, et al. Task force on the use of biosimilars to treat rheumatological diseases. Consensus-based recommendations for the use of biosimilars to treat rheumatological diseases. *Ann Rheum Dis* 2018;77:165–74.
- [9] Cohen JD, Bocquet F, Fayet F, et al. Sous l'égide du groupe CERBER. Biosimilaires en rhumatologie : information et opinions des rhumatologues hospitaliers français, résultats de l'étude BRIO. *Rev Rhum* 2017;84S:A313.
- [10] Fleischmann R. Editorial: the American college of rheumatology white paper on biosimilars: It is not all white-there is some gray and black. *Arthritis Rheumatol* 2018;70:323–5.

- [11] Fautrel B. Call for action: how to improve use of patient-reported outcomes to guide clinical decision making in rheumatoid arthritis. *Rheumatol Int* 2018;38:935–47.

Jean-David Cohen^{a,*}

Sonia Tropé^b

Audrey Munos^c

François Bocquet^{d,e,f}

^a Rheumatology department, Lapeyronie hospital, Montpellier university hospital center, 34295 Montpellier Cedex 5, France

^b French national patient organization against rheumatoid arthritis (ANDAR), 75014 Paris, France

^c BioCube institute, groupe IMT, 37000 Tours, France

^d Law and health economics department, faculty of pharmacy, Paris Descartes university, Sorbonne Paris Cité, 4, avenue de l'Observatoire, 75006 Paris, France

^e Health law institute (Inserm UMR S1145), Paris Descartes university, Sorbonne Paris Cité, 45, rue des Saints-Pères, 75006 Paris, France

^f Pharmacy department, general agency of equipments and health products (AGEPS), 7, rue du Fer à Moulin, 75005 Paris, France

*Corresponding author at : Département de rhumatologie, 371, avenue du Doyen-Gaston Giraud, 34295 Montpellier Cedex 5, France.
E-mail address: jd-cohen@chu-montpellier.fr
(J.-D. Cohen)

Available online 27 October 2018