The term “biosimilar” refers to a biologic product developed with no clinically meaningful difference between the biosimilar and an existing licensed, originator biologic in terms of safety, efficacy, and immunogenicity.\(^1\)

Biosimilars cannot be considered generic equivalents to the originator biologic because even minor changes in manufacturing processes can produce post-translational structural differences.\(^1\)

Biosimilars are approved under regulatory guidelines adapted by the European Medicines Agency, the US Food and Drug Administration, Health Canada, or World Health Organization. And, they are one available treatment option for many diseases.

There is a need for patient education so patients can make informed decisions when considering biosimilars as treatment options. We conducted a survey on biosimilars and biologic therapies to determine current patient awareness and knowledge to enable appropriate development of patient education programs.

METHODS

**Respondents**

- The following populations were included:
  1. **Diagnosed Patients**: Adults aged 18+ year, with chronic disease, ulcerative colitis, rheumatoid arthritis, or psoriasis (mild to severe for >6 mo and had seen a doctor in past 12 mo about the condition, or had breast, lung, or colorectal cancer, or non-Hodgkin’s lymphoma in the past 2 yr).
  2. **Diagnosed Advocacy**: Patients aged 18+, with above-described diseases who had participated in support groups. These respondents were separate from the Diagnosed group, not a subset.
  3. **Caregiver**: Individuals, aged 18+ year, involved in decisions or advice about medication or therapy options for a loved one with these conditions.

**General Population**: Individuals, aged 18-64 yr, without any of the listed diseases nor had loved ones with these conditions; there was no limit for any other diseases in this group.

Upper age limit was set to represent the General Population, which tends to be younger than older adults with the listed diseases. No attempt was made to match respondents in this group to demographics of the two patient/s Caregiver groups; nationally representative demographic targets were set for each country.

**Survey**

- Interviews were conducted in the US and EU (UK, France, Spain, Germany, and Italy) from 24 April to 19 May 2014.

- The survey was conducted via online interviews (desktop or laptop computer only) by an independent survey company (Edelman Research Worldwide, Los Angeles, CA, USA) and contained 56 closed-ended (yes/no or ranking answers) and open-ended questions, depending on the population assigned.

- Interviews ranged 10–20 min, depending on group assignment and the country in which the respondent lived.

**Analysis**

- Statistical analyses were conducted among groups using the column proportions test with a 95% confidence interval (CI).

**RESULTS**

- 3198 respondents were interviewed (Table 1).

- Demographics were generally similar among groups (Table 2).

- Attitudes and awareness of Caregivers generally reflected those of the Diagnosed/Diagnosed Advocacy groups; therefore, detailed results from the Caregiver group are not presented.

**Biologic Therapy**

- Percentage of respondents reporting at least a “general awareness” of biologics was higher among patients vs the General Population; participation in advocacy groups further increased awareness of biologics (Table 3).

- Participation in advocacy groups was associated with a significant increase in percentage of respondents reporting current use of biologic therapies compared with patients not currently participating in support groups (P<0.05).

**Biosimilars**

- Awareness of biosimilars was low across all groups (US and EU): only 6–30% of respondents reported at least a general impression and ≥70% reporting they had never heard of biosimilars (Table 3).

- Current use of biosimilars was significantly higher among respondents in the Diagnosed Advocacy group compared with the Diagnosed group (P<0.05).

**Biosimilarity Safety and Efficacy Perceptions vs Biologics**

- Several gaps in perceptions about biosimilars were noted between patients who were aware of biosimilars and those who were unaware, regardless of their participation in advocacy groups (Figure 1).

- Overall, the widest gap in perceptions was in efficacy. - Wide gaps in the perception of safety were also noted. - Differences in the perceptions about access and price of biosimilars were also considerable.

**Biosimilarity Safety and Efficacy Perceptions vs Biologics**

- When patients who were aware of biosimilars were asked about their perception of biosimilars relative to biologics, additional gaps were noted (Figure 2).

- Perception about safety and efficacy of biosimilars was slightly higher than for biologics, whereas perception about access and price favoured biosimilars.

- The widest gap in perception among patients aware of biosimilars was in regard to efficacy.

- Although there were gaps in the perception of safety favouring biologics, these gaps were narrower for efficacy.

**Clinical Trial Perceptions**

- Overall, respondents had positive perceptions of clinical trials.

- Many respondents in the Diagnosed group were willing to participate in clinical trials.

- 24% and 31% of respondents from the US and EU, respectively, stated they were either “very interested” or “extremely interested” in participating in a clinical trial.

- Perceived barriers led to 16–30% of patients responding no interest in joining a clinical trial.

- The top 3 reasons patients cited were concerns about side effects, assignment to a placebo rather than active treatment, and time commitments required for participation.

- Involvement in advocacy groups increased interest in participating in clinical trials.

**SUMMARY AND CONCLUSIONS**

- This survey indicates several areas in which additional education about biosimilars, biologic therapies, and potential treatment options are necessary.

- These results are supported by a similar survey (N=382) conducted by the American Autoimmune Related Diseases Association indicating that patients need more education about biologic and biosimilar therapies.\(^1\)

- Overall awareness levels about biosimilars were lower than those reported for biologic therapies, indicating there is a great need for patient education about biosimilars across all groups.

- One potential resource for developing and expanding patient education is through partnerships between healthcare providers and advocacy groups.

- A key area in which to develop informative educational programs concerns clinical trial participation, particularly those investigating potential biosimilars.

**REFERENCES**