Electronic supplementary material

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Supplementary Table 1. Definitions of biosimilarity and interchangeability used in Australia, Europe and the USA.

	Biosimilarity	**Interchangeability**
Australia (TGA [5], PBAC [8])	A version of an already registered biological medicine (the reference medicine) that has demonstrable similarity in physicochemical, biological and immunological characteristics, efficacy and safety. The drug substance of a biosimilar and its reference medicine are essentially the same. However, as with the reference medicine, a biosimilar has a degree of natural variability. Not only are there minor differences between reference medicines and their biosimilars, there are minor differences between batches of the same medicines. This is because of the complex, biologically based methods of producing the medicines.	The TGA do not define or assess interchangeability of biologic medicines. The Pharmaceutical Benefits Advisory Committee decide whether a biologic medicine is suitable for automatic substitution at the pharmacy level on a case by case basis.
Europe (EC [15] EMA [4])	A biosimilar is a biological medicinal product that contains a version of the drug substance of an already authorised original biological medicinal product (reference medicinal product) in the European Economic Area. Similarity to the reference medicinal product in terms of quality characteristics, biological activity, safety and efficacy based on a comprehensive comparability exercise needs to be established.	The medical practice of changing one medicine for another that is expected to achieve the same clinical effect in a given clinical setting and in any patient on the initiative, or with the agreement of the prescriber. The decisions on interchangeability rely on national authorities and are outside the remit of the EMA.
USA (FDA [9])	The biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product.	The biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. Interchangeable products may be substituted for the reference product without the intervention of the prescribing healthcare provider.

EC, European Commission; EMA, European Medicines Agency; FDA, US Food and Drug Administration; PBS, Australian Pharmaceutical Benefits Scheme; TGA, Australian Therapeutic Goods Administration.

Supplementary Table 2. Professional societies position statements on biosimilar substitution.

Society	Position statement
ECCO [36]	Any decision to substitute a product should only be made with the prescribing health care provider's specific approval and patient's knowledge.
AAD [26]	Biosimilars must be carefully evaluated by a patient's physician and health care team to determine the benefits and risks of a biosimilar substitution. It is imperative that data be collected regarding efficacy and safety, and that these products have different names so that medical records can fully reflect the exact medication prescribed and taken.
ACR [22]	The decision to substitute a biosimilar product for a reference drug should only be made by the prescribing provider.
ADS [23]	We support substitution of insulins under appropriate medical supervision and with the involvement of the diabetes healthcare team including diabetes educators and practice nurses.
ARA [35]	The decision to prescribe any medication should rest with the prescriber, in consultation with an informed patient. Substitution should not occur without the knowledge and consent of the patient.
ASCO [24]	No system should be adopted that would limit physician choice among "biosimilar" products or require substitution of products that have been designated "interchangeable." In every instance, the physician should decide which among similar products should be prescribed.
CAG [32]	Subsequent entry biologics cannot be regarded as interchangeable with the reference biologic drug. Prescriptions for reference biologic drugs should not be automatically substituted for less expensive subsequent entry biologics by dispensing pharmacies.
ESMO [27]	Interchangeability and switching should only be permitted if: (1) the physician is well-informed about the products; (2) the patient is fully briefed by the physician and (3) a nurse is closely monitoring the changes and tracking any adverse events.
EULAR [37]	Many patients consider that leaving open the possibility of switching, interchangeability and substitution would introduce unacceptable uncertainties into that decision-making process. While appreciating the realities of economic pressure on health services and insurers across Europe, patients strongly believe that decisions about prescribing biosimilars should be made on clinical grounds and not on financial grounds.
GESA, AIBDA [33]	We strongly oppose such recommendations of biosimilars as interchangeable on the grounds of patient safety.
IG-IBD [28, 29]	An IBD patient being effectively controlled with an original biopharmaceutical should not be switched to a drug claimed to be that drug's biosimilar until preliminary data supporting such changes have been reported. In addition, the change must be approved by the specialist prescribing the original biologic and be implemented after obtaining the patient's written informed consent.
NRAS [25]	Substitution of a biosimilar product should only occur under the direct supervision and consent of the treating healthcare professional and with patient agreement.
SER [30]	The substitution of a biological with a biosimilar is a medical decision that should be made exclusively by the prescribing physician and with patient consent.

AAD, American Academy of Dermatology; ACR, American College of Rheumatology; ADS, Australian Diabetes Society; AIBDA, Australian Inflammatory Bowel Disease Association; ARA, Australian Rheumatology Association; ASCO, American Society of Clinical Oncology; CAG, Canadian Association of

Gastroenterology; ECCO, European Crohn's and Colitis Organisation; EULAR, European League against Rheumatism; ESMO, European Society for Medical Oncology; GESA, Gastroenterological Society of Australia; IG-IBD, Italian Group for the study of Inflammatory Bowel Disease; NRAS, United Kingdom National Rheumatoid Arthritis Society; SER, Sociedad Espanola de Reumatología (Spanish Society of Rheumatology).

Supplementary Table 3. Overview of switching studies.

Reference	Treatment	Indication for treatment	Study design	Comparators	Patients, N	Age, years	% male	Reason for switch
Abdalla *et al*. 2017 [43]	INX	Inflammatory arthritis	Observational, retrospective (pre-switch)/ prospective (post-switch)	Pre-switch (originator INX; mean duration: 70 months) vs post-switch (biosimilar INX; mean follow-up: 16 months)	34	Mean: 55 (range: NR; SD: 13)	50	Non-medical (cost)
Ala *et al*. 2016 (abstract) [44]	INX	IBD (CD)	Observational, prospective	Baseline (INX RP) vs post-switch (biosimilar, 6 months)	20	NR	NR	Non-medical (cost)
Arguelles-Arias *et al*. 2017 [45]	INX	IBD (CD, UC)	Observational, prospective	Switched (originator INX; median duration: 297 weeks, or INX-naive) vs naïve (post-switch biosimilar INX; follow-up: 6 months)	120	CD, median: 41 (SD: 13); UC, median: 44 (SD: 13)	CD: 53; UC: 58	Non-medical (NR)
Bennett *et al*. 2016 (abstract) [46]	INX	IBD (CD, UC)	Observational, prospective	Pre-switch (INX RP; week 0, median time on INX-RP: 162 weeks) vs post-switch (CT-P13; follow-up: 6 months)	104 (73 CD; 31 UC)	Mean: 43 (range: 17–71)	52	Non-medical (cost)
Benucci *et al*. 2017 [47]	INX	SpA	Observational, prospective	Pre-switch (originator INX; median duration: 74 months) vs post-switch (biosimilar INX; follow-up: 6 months)	41	Median: 51 (range: 23–80; SD: NR)	NR	Non-medical (cost)
Buer *et al.* 2017 [48]	INX	IBD (CD, UC)	Observational, prospective	Pre-switch (originator INX; data from 6 months pre-switch) vs post-switch (CT-P13; follow-up: 6 months)	143	Median, CD: 36 (range: 17–83); UC: 35 (range: 19–72)	64	Non-medical (cost)
Dapavo *et al.* 2016 [49]	INX	Plaque Psorisis	Observational, prospective	Pre-switch (INX RP; median duration: 237 weeks) vs post-switch (CT-P13; median follow-up: 23 weeks, median 4 cycles)	35	Mean: 52 (range: 28–86)	87 (switch group)	Non-medical (NR)

Reference	Treatment	Indication for treatment	Study design	Comparators	Patients, N	Age, years	% male	Reason for switch
Fiorino *et al*. 2017 [50]	INX	IBD	Observational, prospective	Treatment-naive then CT-P13 vs INX RP (mean 18 infusions) then CT-P13 vs other anti-TNF biologic then CT-P13 (follow-up: 6 months)	547 (naive/CT-P13: 311; INX RP/CT-P13: 97; other/CT-P13: 139)	NR	66 (switch group)	Non-medical (study design)
Gentileschi *et al*. 2016 (letter to editor) [51]	INX	Rheumatic diseases	Observational, prospective	Pre-switch (INX RP [Remicade]; mean duration: 72 months) vs post-switch (CT-P13 [Inflectra]; mean duration: 1.7 months)	23	NR	NR	Non-medical (local regulatory issues)
Glintborg *et al*. 2016 (abstract) [105] and 2017 [52]	INX	Mixed (rheumatoid arthritis, SpA and PsA)	Observational, prospective	Pre-switch (INX RP; duration: 6.8 years) vs post-switch (CT-P13; median follow-up: 413 days)	802	Median: 55 (range: 44–66)	59	Non-medical (national guidelines)
Jorgensen *et al.* 2017 [53]	INX	Mixed (CD, UC, SpA, RA, PsA, chronic plaque psoriasis)	RCT (NOR-SWITCH)	Pre-switch (INX RP; mean duration: 6.8 years) vs post-switch (CT-P13; follow-up: 52 weeks)	482	Mean, INX RP: 48 (SD: 15); CT-P13: 48 (SD: 15)	INX RP: 59; CT-P13: 64	Non-medical (study design
Jung *et al.* 2015 [54]	INX	IBD	Observational, retrospective	Treatment-naive then CT-P13 vs INX RP (duration NR) then CT-P13 (duration: up to 54 weeks)	110 (CT-P13 only: 74; INX RP/CT-P13: 36)	CT-P13 only: CD, mean: 28 (range: NR; SD: 13); UC, mean: 39 (range: NR; SD: 14)	CT-P13 only: 74; INX RP/CT-P13: 69	Cost reported as main reason (proportion of patients and other reasons NR)
Kay *et al.* 2015 (abstracts and poster) [55, 56]	INX	Rheumatoid arthritis	Open label extension of RCT	Continuation (54 weeks BOW015) vs switch (16 weeks INX RP then 38 weeks BOW015)	RCT: 189 (BOW015/BOW015: 127; INX RF/BOW015: 62); then open label: 157	Mean: 45 (range or SD: NR)	12	Non-medical (study design)

Reference	Treatment	Indication for treatment	Study design	Comparators	Patients, N	Age, years	% male	Reason for switch
Kolar *et al*. 2017 [57]	INX	IBD	Observational, prospective	Baseline (Wk 0, INX RP; mean duration: 3 years) vs post-switch (biosimilar INX; duration: 56 weeks)	74 (56 CD, 18 UC)	Mean: 34 (range: 21–57)	51	NR
Nikiphorou *et al*. 2015 [58]	INX	Rheumatic diseases	Observational, prospective	Pre-switch (INX RP; mean duration: 4 years) vs post-switch (CT-P13; follow-up: 11 months)	39	Mean: 53 (range: 19–74)	68	Non-medical (scientific evidence, emerging policies, spending expectations)
Park *et al*. 2015 [59]	INX	IBD	Open-label, prospective, post-marketing	Treatment-naive then CT-P13 vs INX RP (duration NR) then CT-P13 (duration: 30 weeks)	173 (CT-P13 only: 113; INX RP/CT-P13: 60)	CT-P13 only, mean: 39 (range: 18–74); INX RP/CT-P13, mean: 34 (range: 19–64)	CT-P13 only: 71; INX RP/CT-P13: 60	NR
Park *et al*. 2017 [61]	INX	AS	RCT (PLANETAS) and open-label extension	Continuation (102 weeks CT-P13) vs switch (54 weeks INX RP then 48 weeks CT-P13)	174 (CT-P13/CT-P13: 88; INX RP/CT-P13: 86)	CT-P13/CT-P13, median: 36 (range: 18–69); INX RP/CT-P13, median: 39 (range: 18–66)	CT-P13/CT-P13: 77; INX RP/CT-P13: 86	Non-medical (study design)
Rahmany *et al*. 2016 (abstract) [62]	INX	IBD (CD, UC)	Observational, prospective	Pre-switch (INX RP; median treatment duration, CD: 46 months, UC: 25 months) vs post-switch (CT-P13, most recent infusion, 4–6 months)	78 (63 CD, 15UC)	Mean, CD: 43; UC: 42	NR	Non-medical (cost)
Razanskaite *et al.* 2017 [63]	INX	IBD (CD, UC)	Observational, prospective	Pre-switch (INX RP; median number of infusions 10) vs post-switch (CT-P13; follow-up: ≥ 3 infusions)	143 (118 CD, 23 UC: 23, 2 unclassified)	Median: 39 (range: 17–87)	43	Non-medical (cost)

Reference	Treatment	Indication for treatment	Study design	Comparators	Patients, N	Age, years	% male	Reason for switch
Rubio *et al*. 2016 (abstract) [64]	INX	Rheumatic diseases	Observational, prospective	INX RP (Remicade; duration: NR) vs biosimilar (Remsima; follow-up: 9 months)	78 (25 naive, 53 switched)	NR	NR	NR
Schmitz et al. 2017 [67]	INX	Mixed (rheumatoid arthritis, PsA, AS, SpA, psoriasis, arthritis with UC)	Observational, prospective	Pre-switch (baseline; INX-RP) vs post-switch (CT-P13; immediately, approx. 6 months and approx. 12 months post-switch)	27	Median: 60 (IQR: 48–68)	37	Non-medical (cost)
Sheppard *et al*. 2016 (abstract) [65]	INX	Rheumatic diseases	Observational, prospective	Pre-switch (INX RP; duration: NR) vs post-switch (CT-P13; duration: NR)	25	NR	NR	Non-medical (cost)
Sieczkowska *et al.* 2016 [66]	INX	IBD (paediatric)	Observational, prospective	Pre-switch (INX RP; mean duration: 67 weeks) vs post-switch (CT-P13; mean follow-up: 8 months)	39 (CD: 32; UC: 7)	CD: 11 (range: 3–15); UC: 12 (range: 9–15)	NR	Non-medical (local regulatory, availability)
Smits *et al*. 2016 [68]	INX	IBD	Observational, prospective	Pre-switch (INX RP; median duration: 25 months) vs post-switch (CT-P13; duration: 16 weeks)	83	Median: 36 (range: 18–79)	34	Non-medical (local directives)
Smolen *et al*. 2016 (abstract) [69]	INX	Rheumatoid arthritis	RCT and extension	Continuation (78 weeks INX RP or SB2) vs switch (54 weeks INX RP then 24 weeks SB2)	396 (INX RP/INX/RP: 101; SB2/SB2: 201; INX RP/SB2: 94)	NR	NR	Non-medical (study design)
Tanaka *et al*. 2017 [70]	INX	Rheumatoid arthritis	Open-label single-arm extension of RCT	Continuation of CT-P13 vs switch to CT-P13 from INX RP	104	Mean, continued CT-P13: 54 (SD: 12); switch: 57 (SD: 11)	21	Non-medical (study design)

Reference	Treatment	Indication for treatment	Study design	Comparators	Patients, N	Age, years	% male	Reason for switch
Tweehuysen *et al.* 2016 (abstract) [71]	INX	Mixed (rheumatoid arthritis, PsA, SpA)	Observational, prospective	Pre-switch (innovator INX, month 0) vs post-switch (biosimilar INX, 6 months)	Rheumatoid arthritis: 65; PsA: 50; SpA: 67	NR	NR	Non-medical (cost)
Yazici *et al.* 2016 (abstract) [72]	INX	Rheumatoid arthritis	Retrospective chart review	Continuation (INX RP) vs switch (to CT-P13)	3018 (continuation: 2870; switch: 148)	Mean: 44	49	Non-medical (cost)
Yoo *et al*. 2017 [73]	INX	Rheumatoid arthritis	PLANETRA RCT open-label extension	Continuation (102 weeks CT-P13) vs switch (54 weeks INX RP then 48 weeks CT-P13)	CT-P13/CT-P13: 158; INX RP/CT-P13: 144)	CT-P13/CT-P13, median: 50 (range: 18–73); INX RP/CT-P13, median: 49 (range: 23–74)	CT-P13/CT-P13: 21; INX RP/CT-P13: 15	Non-medical (study design)
Haag-Weber *et al*. 2009 [74]	ESA epoetin alfa)	Renal anaemia	Open-label extension	Continuation (56 weeks HX575) vs switch (28 weeks ESA RP [Eprex/Erypo] then 28 weeks HX575)	386 (HX575/HX575: 249; ESA RP/HX575: 137)	Reported only for RCT part – HX575, mean: 62 (range: 23–90); ESA RP, mean: 63 (range 24–88)	Reported only for RCT part – HX575: 56; ESA RP: 60	Non-medical (study design)
Harzallah *et al*. 2015 [75]	ESA (epoetin alfa)	Renal anaemia	Cross-over (blinding NR)	Pre-switch (1st epoetin NR then 15 days epoetin alfa RP [Hemax]) vs post-switch (epoetin alfa biosimilar [Epomax] for 43 days)	53	Mean: 48 (range: 27–81)	34	Non-medical (study design)
Hörbrand *et al*. 2013 [76]	ESA (epoetin alfa [short- and long-acting], beta, delta, theta or zeta)	Renal anaemia	Observational, retrospective (insurance database study)	Pre-switch (≥ 3 months) vs post-switch (≥ 3 months)	6177 (of whom 507 switched therapy)	67 (range: NR; SD: 67)	53	NR

Reference	Treatment	Indication for treatment	Study design	Comparators	Patients, N	Age, years	% male	Reason for switch
Lopez *et al*. 2014 (abstract) [77]	ESA	Chemotherapy-induced anaemia	Retrospective chart review	Pre-switch (epoetin alfa, darbepoetin alfa; 12-month period) vs post-witch (epoetin zeta; 12-month period)	28	NR	NR	Non-medical (cost)
Minutolo *et al*. 2016 [78]	ESA	Undergoing haemodialysis	Observational, retrospective	Pre-switch (epoetin, darbepoetin; duration: NR) vs post-switch (HX575, SB309; duration: NR)	149	Mean: 71(range: NR; SD: 13)	61	NR
Morosetti *et al*. 2017 [79][a]	ESA	Chronic renal failure	Observational, prospective	Pre-switch (ESA; 6 month vs post-switch (biosimilar; 6 months)	87	Mean: 65	41	Non-medical (cost)
Ohta *et al*. 2014 [80]	ESA	Renal anaemia	Observational, retrospective	Pre-switch (epoetin beta; duration: 3 months) vs post-switch (epoetin kappa; duration: 3 months)	30	Mean: 63 (range: NR; SD: 11)	87	NR
Wiecek *et al.* 2010 [81], Wizeman *et al*. 2008 [82]	ESA	Renal anaemia	Induction RCT and open-label extension; *post hoc* analysis	Pre-switch (≥ 12 weeks) vs post-switch (≥ 12 weeks) from epoetin alfa to epoetin zeta or vice versa	239 (switch group 1: 118; switch group 2: 121)	Median: 57 (range: 20–77; SD: NR)	59	Non-medical (study design)
Wiecek *et al.* 2010 [81]	ESA	Renal anaemia	Maintenance RCT and open-label extension; *post hoc* analysis	Pre-switch (≥ 12 weeks) vs post-switch (≥ 12 weeks) from epoetin alfa to epoetin zeta or vice versa	242	Median: 54 (range: 20–76; SD: NR)	59	Non-medical (study design)
Balili *et al*. 2015 (abstract) [83]	Insulin	T2DM	Observational, retrospective	Pre-switch (Humulin 70/30; duration NR) vs post-switch (Wosulin 70/30)	24	Mean: NR (range: 40–77)	33	Non-medical (cost)
Hadjiyianni *et al*. 2016 [84], Ilag *et al*. 2016 [85]	Insulin	T1DM	RCT (Element 1)	Pre-study insulin vs insulin-naive at study entry; in RCT, patients randomized to insulin glargine RP (IGlar; Lantus®) or biosimilar (LY IGlar)	With pre-study IGlar treatment: 452	Mean: 41 (range: NR; SD: 14)	59	Non-medical (study design)

Reference	Treatment	Indication for treatment	Study design	Comparators	Patients, N	Age, years	% male	Reason for switch
Hadjiyianni *et al*. 2016 [84], Ilag *et al*. 2016 [85], Rosenstock *et al*. 2015 [86]	Insulin	T2DM	RCT (Element 2)	Pre-study insulin vs insulin-naive at study entry; in RCT, patients randomized to insulin glargine RP (IGlar; Lantus®) or biosimilar (LY IGlar)	With pre-study IGlar treatment: 299	Mean: 60 (range: NR; SD: 10)	47	Non-medical (study design)
Segal *et al*. 2013 [87]	Insulin	T1DM, T2DM	Observational, prospective	Pre-switch (Actraphane, Humulin 30/70 or Insuman; insulin duration: 7 years) vs post-switch (Biosulin 30/70; duration: 6 months)	77	Mean: 50 (range: 26–75; SD: NR)	47	Non-medical (study design)
Flodmark *et al*. 2013 [88] (commentary: Ekelund *et al*. 2014 [129])	rhGH	Growth disturbances	Observational, prospective	Pre-switch (genotropin RP; duration NR [graph suggests up to 2 years]) vs post-switch (Omnitrope; duration NR [graph suggests up to 1.5–2 years])	98	mean/median: NR (range: 1–15; SD: NR);	53	Non-medical (cost)
Gila et al. 2014 (abstract) [89]	rhGH	Growth disturbances	Observational, retrospective	Pre-switch (rhGH RP; duration: 38 months) vs post-switch (Omnitrope; follow-up: 36 months)	20	Mean: 15 (range: NR)	75	Non-medical (hospital-level switch)
Rashid *et al*. 2014 [90]	rhGH	Growth disturbances	Observational, retrospective	Pre-switch (Humatrope, Norditropin, Nutropin and/or Saizen, duration: ≥ 15 months) vs post-switch (Omnitrope, duration: 15 months)	103 (Growth hormone deficiency: 57; ISS: 26; Turner Syndrome: 20)	Growth hormone deficiency, mean: 11 (range: 2–17); ISS: mean 13 (range: 10–17); Turner Syndrome: mean: 10 (range: 5–14)	Growth hormone deficiency: 53; ISS: 65; Turner Syndrome: 0	Non-medical (health fund formulary change)

Reference	Treatment	Indication for treatment	Study design	Comparators	Patients, N	Age, years	% male	Reason for switch
Romer *et al*. 2011 [92] (modelling Belleli *et al*. 2015 [91])	rhGH	Growth disturbances	Analysis and modelling using data from 3 RCTs, one of which was a switch study	Continuation (15 months omnitrope powder then 69 months omnitrope solution) vs switch (9 months genotrope then 75 months omnitrope solution)	166	Mean: 7–9 (range: NR; SD: 2.4–2.8)	47–63	Non-medical (study design)
Engert *et al*. 2009 [93]	G-CSF	Chemotherapy-induced neutropenia	RCT	Continuation (XM02 in all chemotherapy cycles) vs switch (filgrastim RP in 1st cycle, then XM02)	92 (XM02/XM02: 63; filgrastim RP/XM02: 29)	XM02/XM02: mean: 50 (range: 18–83; SD: 16); filgrastim RP/XM02: mean: 57 (range: 33–83; SD: 15)	XM02/XM02: 49; filgrastim RP/XM02: 59	Non-medical (study design)
Gatzemeier *et al*. 2009 [94]	G-CSF	Chemotherapy-induced neutropenia	RCT	Continuation (XM02 in all chemotherapy cycles) vs switch (filgrastim RP in 1st cycle, then XM02)	240 (XM02/XM02: 160; filgrastim RP/XM02: 80)	XM02/XM02: mean: 59 (range: 34–78); filgrastim RP/XM02: mean: 58 (range: 34–78)	XM02/XM02: 80; filgrastim RP/XM02: 77	Non-medical (study design)
Krendyukov et al. 2017 (abstract) [95]	G-CSF	Prevention of neutropenia (breast cancer)	RCT	Filgrastim RP vs switch from filgrastim RP to biosimilar in cycles 2–6	218	NR	NR	Non-medical (study design)
Papp *et al*. 2017 [97]; Gooderham *et al*. 2016, (abstract) [96]	Adalimumab	Plaque psoriasis	RCT	Continuation (ABP501 or adalimumab for 52 weeks) vs switch (adalimumab for 16 weeks then ABP501 for 36 weeks[b])	350 (ABP501: 175; adalimumab or adalimumab/ ABP501: 175)	ABP501, median: 46 (IQR: 35–54); adalimumab RP: 41 (IQR: 33–56) (at initial randomisation)	66	Non-medical (study design)

Reference	Treatment	Indication for treatment	Study design	Comparators	Patients, N	Age, years	% male	Reason for switch
Weinblatt *et al*. 2016 (abstract) [98]	Adalimumab	Rheumatoid arthritis	RCT	Continuation (52 weeks SB5 or 52 weeks adalimumab) vs switch (24 weeks adalimumab then 28 weeks SB5)	506 (SB5/SB5: 254; adalimumab/ SB5: 125; adalimumab/ adalimumab: 127	NR	NR	Non-medical (study design)
Nasanov *et al.* 2016 (abstract) [99]	Rituximab	Rheumatoid arthritis	RCT; patients re-randomised at week 24 (switch phase)	Pre-switch (24 weeks RTX RP or 24 weeks BCD-020) vs post-switch (24 weeks BCD-020 or 24 weeks RTX RP)	160	NR	NR	Non-medical (study design)
Park *et al*. 2017 [60]	Rituximab	Rheumatoid arthritis	RCT open-label extension	Continuation (up to 128 weeks CT-P10) vs switch (up to 72 weeks rituximab then up to 56 weeks CT-P10)	58 (CTP-10/CT-P10: 38; rituximab/CT-P10: 20)	CT-P10/CT-P10, mean: 51 (SD: 11); rituximab/CT-P10, mean: 50 (SD: 11)	CT-P10/CT-P10: 8; rituximab/CT-P10: 10	Non-medical (study design)
Roy *et al*. 2013 [100]	Rituximab	Non-Hodgkin's B cell lymphoma	Observational, retrospective	Rituximab RP (Mabthera), biosimilar (Reditux) vs both (i.e. switched) (≥ 4 cycles with 1 brand)	223 (of whom 29 switched)	Mean: NR (range: NR; SD: NR)	70	NR
Emery *et al*. 2016 (abstracts) [101, 102]	ETN	Rheumatoid arthritis	Open-label (extension of 52-week RCT)	Continuation (52 weeks SB4 in RCT then 48 weeks SB4) vs switch (52 weeks ETN RP in RCT then 48 weeks SB4)	245 (SB4/SB4: 126; ETN/SB4: 119)	NR	NR	Non-medical (study design)
Griffiths *et al.* 2017 [103]	ETN	Chronic plaque psoriasis	RCT	Pre-switch (GP2015 or ETN, 12 weeks) vs post-switch (patients with PASI improvement ≥ 50% re-randomised to same treatment with different dosing schedule or to series of 3 treatment switches to week 30, then continuation on last assigned treatment to week 52)	531	Mean, GP2015: 42 (SD: 12); ETN RP: 43 (13)	GP2015: 60; ETN RP: 64	Non-medical (study design)

Reference	Treatment	Indication for treatment	Study design	Comparators	Patients, N	Age, years	% male	Reason for switch
Strowitzki *et al*. 2016 [104]	Follicle-stimulating hormone	Ovarian stimulation	RCT open-label extension	Continuation (Ovaleap [1 cycle in RCT plus ≤ 2 cycles in extension study]) vs switch (Gonal-f [1 cycle in RCT] then Ovaleap [≤ 2 cycles in extension study])	147	Mean: 32 (range: NR; SD: 3)	0	Non-medical (study design)

[a]Data extracted from English-language abstract (full text in Italian).
[b]Of 175 patients on adalimumab, those with PASI ≥ 50 at 16 weeks were re-randomized 1:1 to remain on adalimumab or switch to ABP501.
ABP501, adalimumab biosimilar; AS, ankylosing spondylitis; BOW015, infliximab biosimilar; CD, Crohn's disease; CT-P10, biosimilar rituximab; CT-P13, biosimilar infliximab; ESA, erythropoietin-stimulating agent; ETN, etanercept; G-CSF, granulocyte colony-stimulating factor; HX575, epoetin alfa biosimilar; IBD, inflammatory bowel disease; INX, infliximab; ISS, idiopathic short stature; NR, not reported; PK/PD, pharmacokinetics/pharmacodynamics; PsA, psoriatic arthritis; RCT, randomised controlled trial; rhGH, recombinant human growth hormone; RP, reference product; SB2, infliximab biosimilar; SB4, etanercept biosimilar; SB5, adalimumab biosimilar; SD, standard deviation; SpA, spondyloarthritis; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus; UC, ulcerative colitis.

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