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Biosimilar Naming

“Don’t Name So Close to *Me*”

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Definitions

- “Generic” - small molecule drug that is chemically synthesized and thus can be an exact copy of a brand/innovative drug.
- “Biologic” - large molecule drug with a complex protein structure that is made from living organisms.
- “Biosimilar” - highly similar (but not identical) version of a complex biologic drug

What is a “Biosimilar”?

- It is a “biological medicine highly similar to another already approved biological medicine” in terms of structure, biological activity and efficacy, safety and immunogenicity profile (the intrinsic ability of proteins and other biological medicines to cause an immune response).
- It is technically not a “generic”, because the natural variability (from using living cells or micro-organisms) and more complex manufacturing of biological medicines do not allow an exact replication of the molecular micro-heterogeneity. In fact, even different batches of the original reference biologic will have slight variations - factors such as health, age and metabolism of the cells/micro-organisms used in the manufacturing process can impact the final product.
- But no clinically meaningful difference in terms of safety, purity, potency, quality and efficacy.

Generic



Biosimilar



Naming of Biosimilars

- FDA determined that, in addition to different four-letter suffixes and the generic name, proprietary (brand) names were required
- Four-letter suffix required only by FDA; EMA & Health Canada disagreed; they do not require suffix
- Biosimilars should bear unique brand names - why?
 - a) Helps healthcare providers distinguish between drugs
 - b) Helps in the accurate reporting of adverse events; but it does create more work for biosimilar companies
 - Biosimilar companies have to do some marketing (at least to insurance companies, etc.)
 - Might prove more difficult to convince physicians, etc. to switch even in cases of “interchangeability.”

There appear to be three general options for naming a biosimilar (the first two are not much different from naming an innovative pharmaceutical):

- 1) Independent, fanciful names:
 - Benepali®, biosimilar of Enbrel® (etanercept)
 - Wezenla®, biosimilar of Stelara® (ustekinumab)
 - Wyost®, biosimilar of Xgeva® (denosumab)

2) A name that plays off the INN or indications:

- a) Inflectra® (infliximab)
- b) Movymia® (teriparatide, for osteoporosis; taking the drug may help you “move” better)
- c) Ranivisio® (ranibizumab; plus it treats eye disease; “Visio”)

3) A name that evokes the complementary brand name

a) Remsima® for biosimilar of Remicade®

b) Hukyndra® for biosimilar of Humira®

This presentation will focus on Category #3:

How often does this occur in US and EU?

a) First three letters identical - I've found the following examples:

Herzuma - Herceptin (US & EU)

Herwenda - Herceptin (EU)

Remsima - Remicade (US & EU)

Steqeyma - Stelara (US & EU)

Hercessi - Herceptin (US)

b) First two letters identical - I've found the following examples:

Avzivi - Avastin (US & EU)

Eydenzelt - Eylea (EU)

Hukyndra - Humira (EU)

Hulio - Humira (US & EU)

Renflexin - Remicade(US)

Riabni - Rituxan(US)

Starjemza - Stelara (US)

Tyruku - Tysabri (US & EU)

c) Last three letters- I've found the following example:

Merilog® - Novolog® (insulin aspart)

Is This a Problem? Should it Be?

As you can see, EMA and FDA do not seem too concerned

Why? Perhaps because a substitution or “medication error” should not harm the patient

The biosimilar has been approved to treat the same disease and the same patient population

Also, the different suffixes can also help distinguish the biosimilar from the reference product (at least for doctors and hospitals in the US)

So, that's the background for the debate:

One note: No written opinions, on this issue (to my knowledge)

The Debate:

In favor of the biosimilar company:

A) As noted, patient harm is unlikely

B) No real “consumer confusion”

- i) biosimilars are generally not advertised
- ii) sold to insurance companies, pharma plans (sophisticated purchasers)
- iii) if for some reason the patient is confused when they take the pill, or a mis-prescription, likely no medical harm

In certain situations, another rationale:

C) If brand name “encodes” the INN or indications, why can’t the biosimilar do the same thing?

- innovative name is less distinctive under these circumstances

OR

If Brand name encodes some other positive attitude, like “Pro-” or “Hum-”?

- if such a name was approved, why can’t biosimilar use similar language?
- how to avoid this issue, if you are the innovator: Pick “blue sky”/blank slate names; less of a legitimate reason for biosimilar name to resemble

Factors in favor of Innovator (“stay away”):

A) Name very unique - (one syllable - TALTZ, e.g.)

B) If the innovator product has only become generic for certain indications, but not others,

- a) confusion/misperception could arguably cause patient harm.
- b) innovator may still be advertising; biosimilar can bask in the glow of this advertising (inequitable)

C) If innovative product has extremely large goodwill (Viagra®, Humira®, etc.), Brand owner may feel that biosimilar company is “riding on its coattails”

Is this an emotional response or business driven?

D) “dilution” claim (or “famous marks” in other jurisdictions)

- Could innovator assert dilution claim?
 - possible but difficult to prove
 - marks must be identical or very similar
 - doubtful health authority would approve such a brand name

E) Any other causes of action?

Conclusion

- 1) If innovators are concerned,
 - a) try to stay away from INN or indication - related brand names (of course, some countervailing issues in naming → whether biosimilar name could be a problem, largely hypothetical - not central concern)
 - b) if biosimilar comes close, and business considerations warrant, be aggressive.

2) Biosimilar perspective

- a) Is it necessary to evoke innovator name?
 - i) If innovator name evokes INN, then perhaps yes
 - ii) but if so, probably take minimal amount
 - first 1 or 2 letters OK, 3 is borderline
 - iii) frankly, most biosimilar companies want to avoid any issues - name not as important for advertising, etc.