MINISTRY OF HEALTH

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Biosimilar Regulation in ISRAEL
WCBP January 2019, Dr. Vered Ben Naim

IMOH guideline #127: Policy of Registration conditions and use of Biosimilar produced May 2016:

- EMA policy is adopted
- Product is approved in "Recognized Countries" with the same indications
- Comparability of quality, safety and efficacy, no meaningful differences
- Reference Product must be registered in Israel
- Pharmacovigilance, Labeling, Indication, Extrapolation of Indications
- Ad-hock committee regarding each biosimilar substitution/inter-changeability policy

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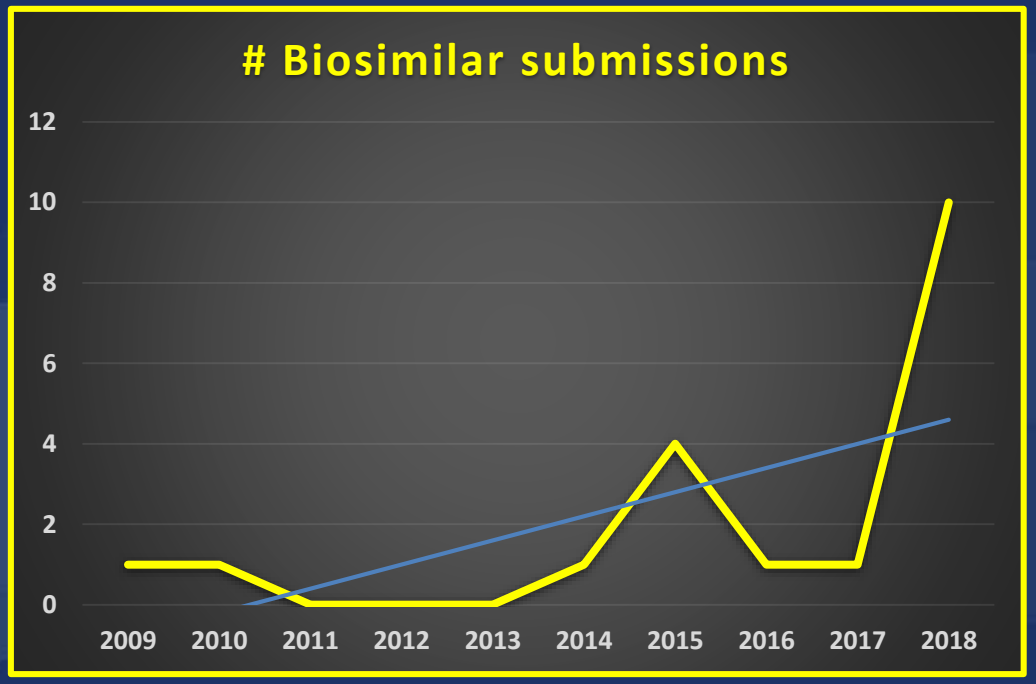

All Recombinant Proteins

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Natural sources Biosimilar Products – Some of the Challenges:

- Variable source materials
- Different manufacturing processes
- Complex molecules
- Wide Biosimilarity criteria
- LMWH- different regulation approaches (generic, biologic?)
  - Lack of comparable efficacy trials
  - Tested only with healthy volunteers