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GaBI Educational Workshops

First MENA Educational Workshop on
SIMILAR BIOTHERAPEUTIC PRODUCTS/BIOSIMILARS

1 September 2015, Le Meridien Dubai, United Arab Emirates

Biosimilars regulations in Saudi Arabia

Ali M Al Homaidan, PhD

1 September 2015

GaBi
GENERICS AND BIOSIMILARS INITIATIVE
Building trust in cost-effective treatments

PPCI
Pro Pharma Communications International

Outline

- Biosimilars Approval Pathway in Saudi Arabia

- Biosimilar products.

Biosimilars are not generics

- Biosimilars are much larger and complex molecules than small-molecule generics.

- The biosimilar approval pathway is a new initiative in Saudi Arabia with many scientific and administrative challenges

Biosimilars are not generics II

- There are major challenges to developing a copycat version of a biologic with the same properties and risk/benefit profile as the original

- Due to the complexity of biosimilars, demonstration of **comparability** rather than **bioequivalence** is required

Biosimilars are not generics III

- A biosimilar is highly similar but not identical to an already market approved biologic product in terms of:
  - Quality
  - Safety
  - And efficacy

Quality

- Manufacturing Process
- Comparability Exercise
- Physicochemical Characterisation
- Biological Activity

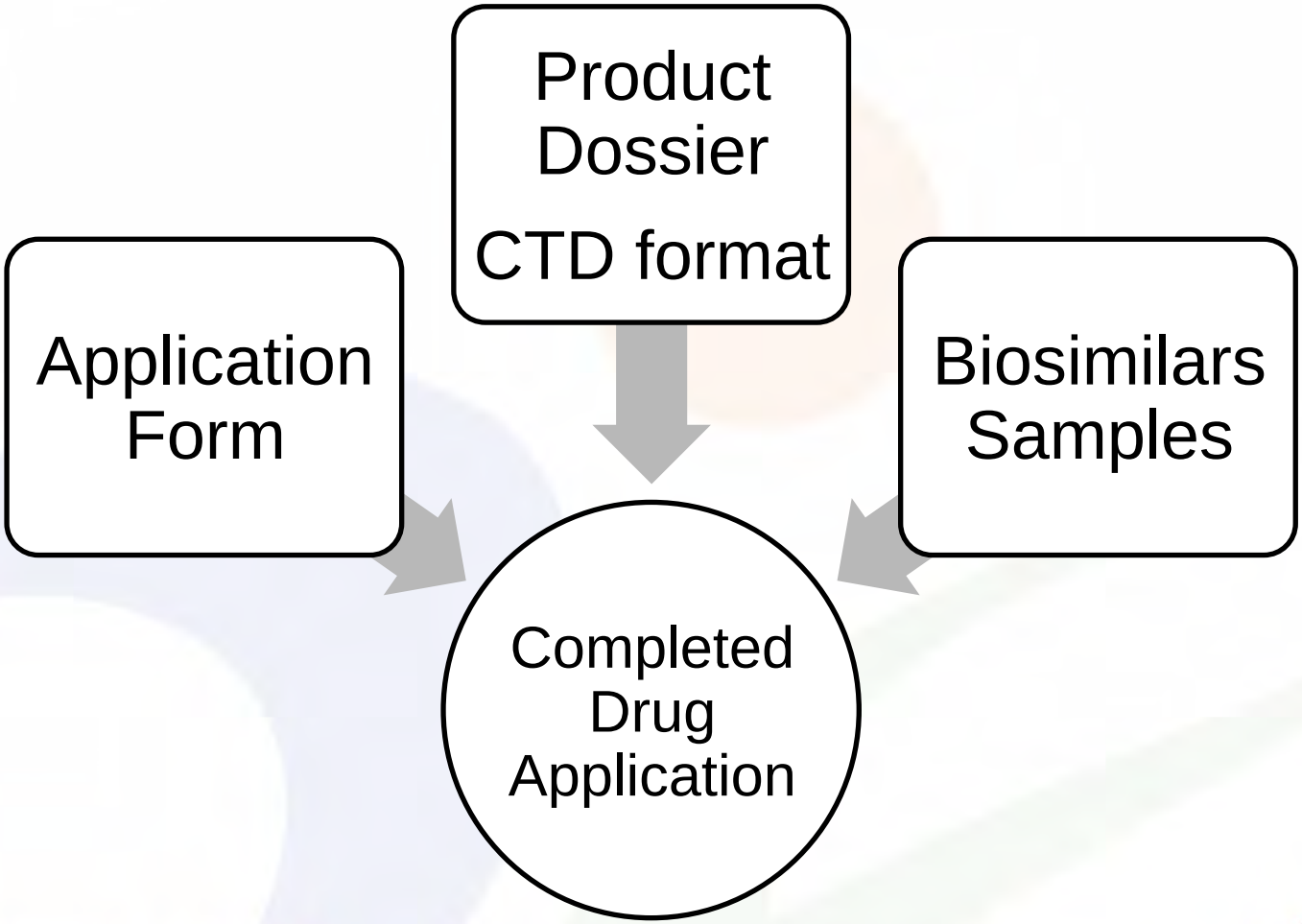
Safety

- Analytical Studies
- Comparative *In vitro* studies
- *In vivo* studies

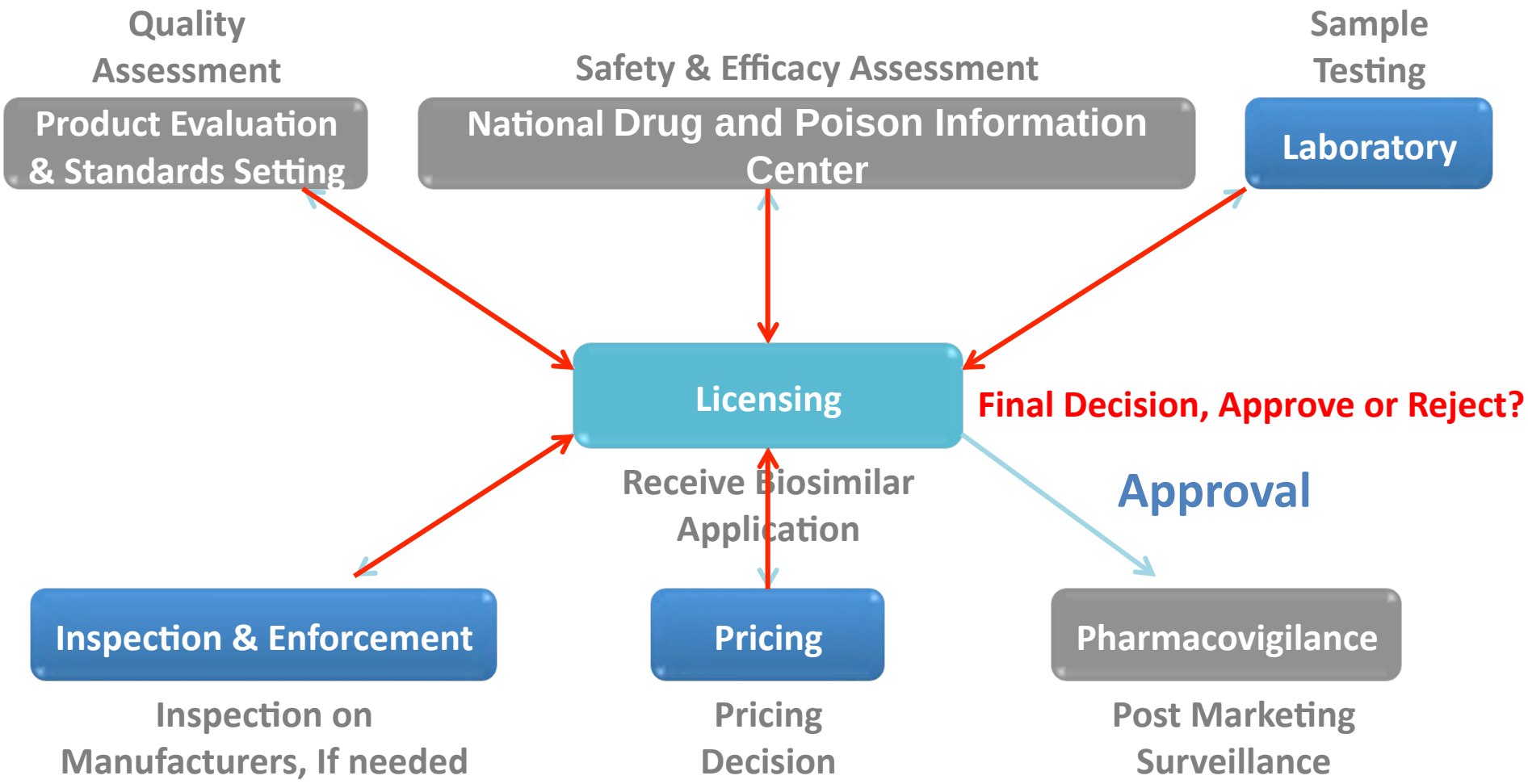
Efficacy

- Pharmacokinetic studies
- Pharmacodynamic studies
- Efficacy and safety trials, to demonstrate comparability

Biosimilars Submission Guidance



Departments involved in the evaluation of biosimilars



Duration and Fee

Type of Application	Duration	Fee
Biosimilar product	290 days	95,000 SAR About 25,000 USD

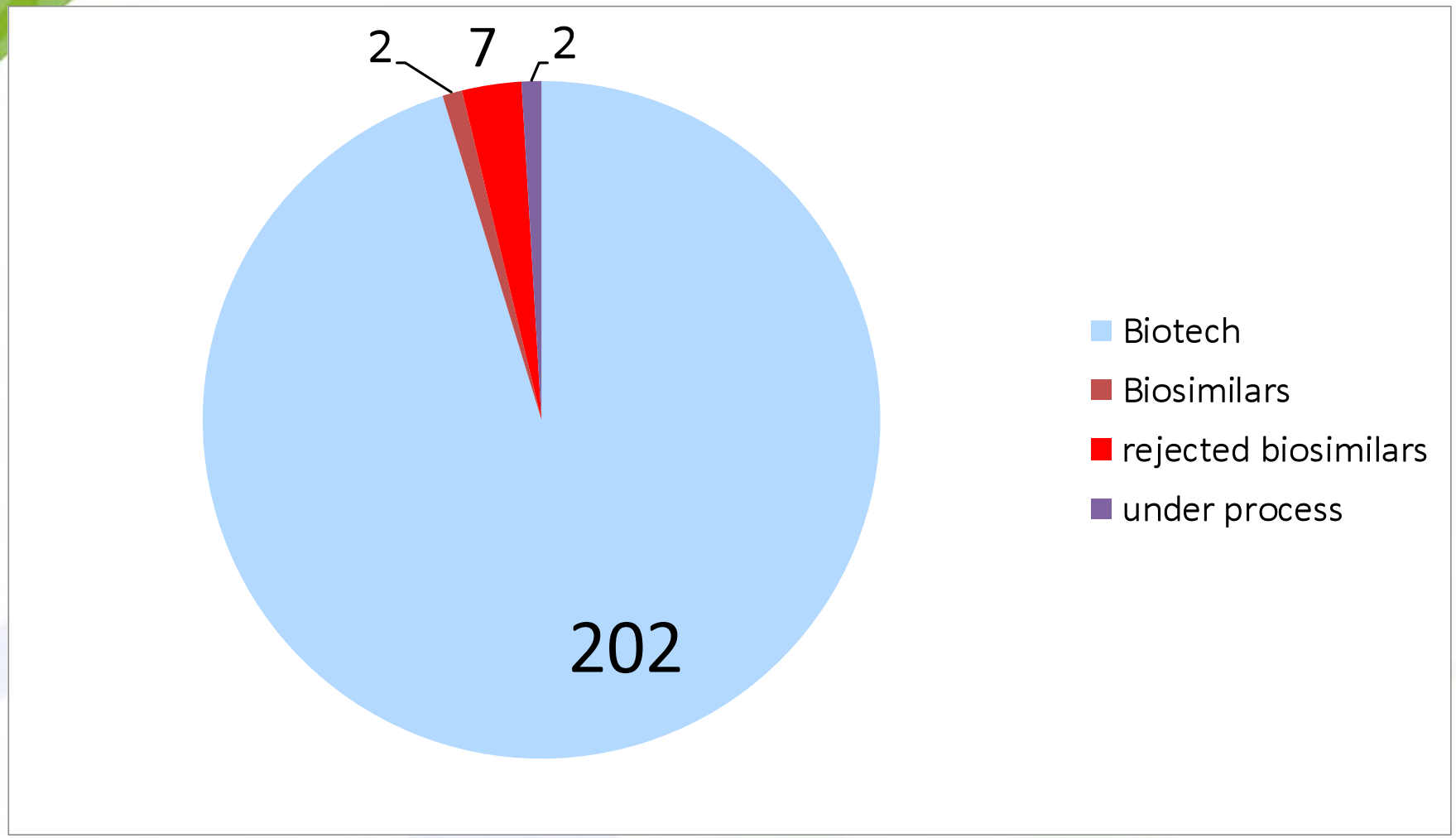
Dossier Requirements

Small Molecule Generic

- Demonstration of Bioequivalence
- Modules 1, 2 and 3 in addition to a bioequivalence study

Biosimilar

- Demonstration of Comparability to RMP
- Modules 1-5 are required
- Expensive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Biotech
Biosimilars
rejected biosimilars
under process

Approved Products

- Omnitrope: Recombinant Somatropin (RMP is Genotropin)
- The biosimilar is 37% cheaper
- Biosimilar Uptake

Rejected

- Follitropin alfa: Failure in Clinical comparability

- 6 Insulins: Failures in quality, safety and efficacy

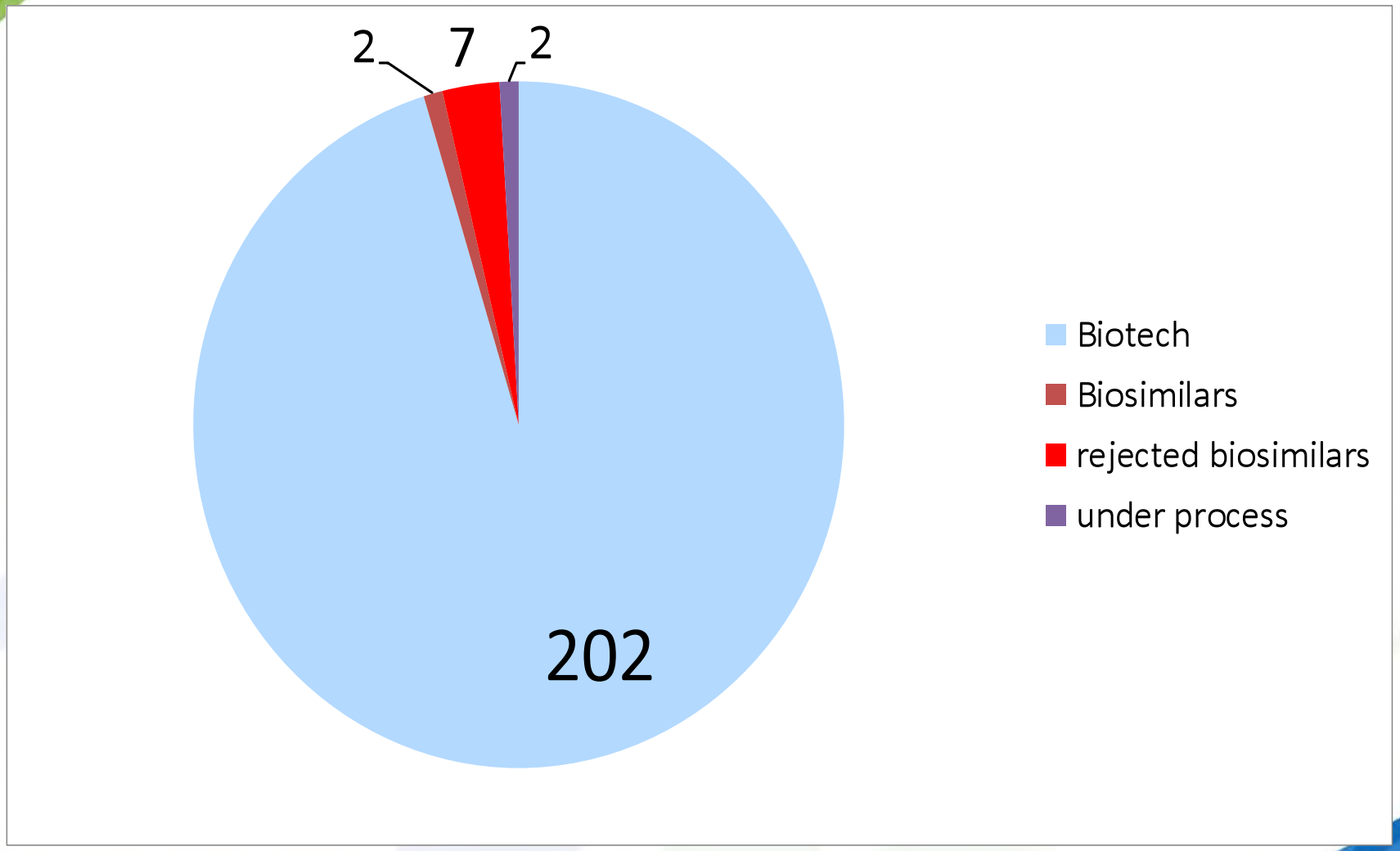
Under Process

- Infliximab
- Filgrastim

How much cheaper will biosimilars be?

- The process of bringing a biosimilar to market will likely require many of the strategies used to bring a branded product to market
- This will impact the commercialization of the products and will likely reduce potential cost savings

Conclusion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Thank You
Questions or Comments

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