TRENDS IN THERAPEUTIC BIOLOGICS AUTHORIZED BY FDA, EMA AND SAUDI ARABIA IN THE PERIOD 1996-2018

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Background

Therapeutic biologics are produced in living cell cultures or through genetic engineering of proteins. They are effective in the treatment of multiple diseases, including rheumatoid arthritis, multiple sclerosis, and cancer. Studies assessing differences in the authorization of biologics by different regulatory agencies are lacking.

Objectives

The objectives of this study were to compare trends and to assess differences in year of authorization and therapeutic category for therapeutic biologics approved by FDA, EMA and Saudi MOH/FDA (SFDA) from January 1996 to May 2018.

Methods

Regulatory information for biologic license applications (BLA) authorized in the period of analysis were collected from the FDA website "Approved drug products with therapeutics equivalence evaluation" (Orange Book) and Drugs@ FDA databases, the SFDA website "Registered drugs and herbal product" and the EMA website.

Information collected included non-proprietary name, approval date, orphan designation by the FDA or EMA, biosimilar authorizations, and authorization status.

Insulins, vaccine and some hormones were excluded from analysis. Descriptive statistics were performed in the analysis using IBM SPSS v.24.

Results

Figure 1. Cumulative Number of Therapeutic Biologics Authorized by EMA, FDA and Saudi MOH/SFDA (1996-May 2018)

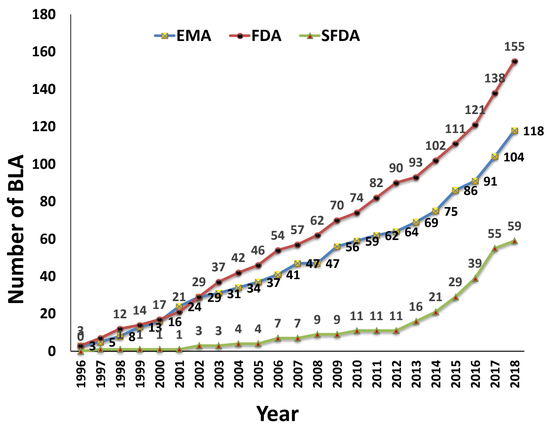

Figure 2. Therapeutic Biologic Authorization by First Authorizing Agency (1996-May 2018)

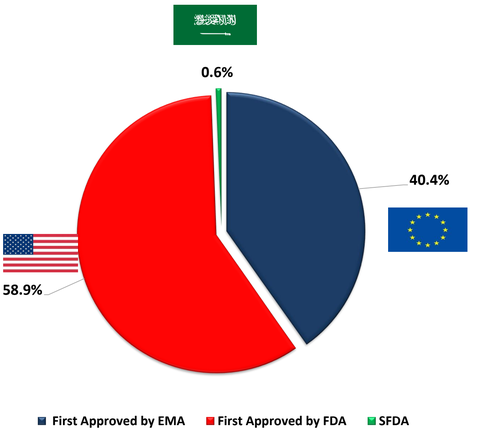

Figure 3. Number of Therapeutic Biologics Authorized by EMA, FDA and MOH/SFDA (1996-May 2018)

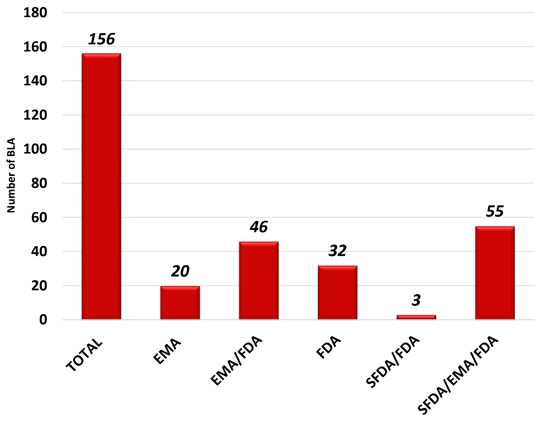

Table 1. Therapeutic Biologics Authorized by EMA, FDA and MOH/SFDA by Therapeutic Class (1996-May 2018)

ATC Class	EMA	EMA/ FDA	FDA	MOH/SFDA / FDA	All agencies	Total
Alimentary Tract, Metabolism	1	9	2	1	3	16
Anti-Infectives For Systemic Use		1	3		1	5
Antineoplastic, Immunomodulating Agents	9	18	18	2	39	86
Blood, Blood Forming Organs	4	5	1		3	13
Cardiovascular System					2	2
Dermatological					1	1
Musculo-Skeletal System	1	3	6		1	11
Nervous System		3				3
Respiratory System		2			2	4
Sensory Organs		1	1		2	4
Systemic Hormonal Preparations*	1	1				2
Others	4	3	1		1	9
Grand Total	20	46	32	3	55	156

**Excluding Sex Hormones and Insulins*

There were 183 therapeutic BLA authorized by FDA, EMA and MOH/SFDA in the period of 1996-2018. The FDA authorized 155 biologics (84 % of the total), EMA 118 (64%) and the MOH/SFDA 59 (32%) **(Figure 1).**

The FDA authorized 16 biosimilars and EMA 48. No biosimilars were authorized by the SFDA. The FDA authorized first 50% of the biologics, EMA 34% and SFDA 0.5% **(Figure 2).**

There were 55 biologics authorized by the three agencies, 46 by EMA and the FDA, 3 by the SFDA and the FDA, 32 only by FDA, and 20 only by EMA (**Figure 3).** There were 110 BLA registered in at least FDA or EMA but not by the SFDA.

The highest number of authorizations occurred in the therapeutic classes antineoplastic and immunomodulating agents (n=86), alimentary tract and metabolism (n=16) and blood, blood forming organs(n=13)(**Table 1).**

Conclusions

This is one of the first studies comparing trends in the authorization of therapeutic biologics by regulatory agencies in US ,Europe and Saudi Arabia. The FDA authorized the highest number of biologics and also authorized half of these drugs first. Only one third of the biologics were authorized by the SFDA.

References

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