Authorizations of Therapeutic Biologics in Saudi Arabia and the US (1982-2021)

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Background

Biologics are complex structures derived from living sources and are used to treat diseases. In the US, biologics are regulated by the FDA through a comprehensive evaluation process known as the Biologic License Application (BLA) process, while in Saudi Arabia, the responsibility falls under the purview of the Saudi Food and Drug Authority (SFDA) through a Market Authorization Application (MAA) process.

Both regulatory agencies have established expedited approval pathways to ensure the availability of safe and effective drugs that address unmet medical needs.

The SFDA has established priority review, verification, and abridged review processes, while the FDA has established several expedited approval pathways, including priority review designation, fast track designation, and breakthrough therapy designation. In 2010, the US Congress created a regulatory pathway for the review and approval of biosimilar products by the FDA. A similar process is available in Saudi Arabia.

Methods

The data of all biologics approved by the FDA was obtained from the FDA website. For the SFDA, data was obtained from the FDA website.

A descriptive analysis was conducted on all variables included in the study. Logistic regression was used to evaluate the factors associated with the likelihood of the authorization of a therapeutic biologic by the FDA and the SFDA. The IBM SPSS 26 statistical software and Microsoft Excel were used for the analysis.

Results

Table 1. Therapeutic Biologics Authorized by the FDA and SFDA, 1982-2021

Period	FDA Authorizations	SFDA Authorizations	Time lag from FDA to SFDA authorization (Average ± SD)
1982-1989	10	3	4.2 ± 2.8
1990-1999	37	7	9.5 ±7.1
2000-2009	50	20	6.3 ±4.7
2010-2019	93	59	2.5 ±1.7
2020-2021	28	19	1
Total	**218**	**108**	**4.6 (±4.7)**

In the study period, the FDA authorized 218 therapeutic biologics, while the SFDA authorized 108. The lag between the FDA and SFDA approval was a median of 3 years (range 0-24 years), where most of the biologics were first approved in the US.

In the regression analysis, we found that the availability of biologics in SA was associated with approval by the European Medicines Agency (EMA) ($p < 0.05$) and the date of approval of the biologics ($p < 0.05$). Therapeutic classes were also associated with the availability of biologics in SA, antineoplastic and immunomodulating agents ($p < 0.05$), and blood and blood-forming organs ($p < 0.05$).

Table 2. Regression Analysis Results

Therapeutic class	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Alimentary Tract and Metabolism	0.997	0.548	1.82	0.069	-0.077	2.071
Antineoplastic and Immunomodulating Agents	1.039	0.375	2.77	0.006	0.303	1.774
Blood and Blood Forming Organs	1.236	0.566	2.18	0.029	1.258	2.347
EMA approved	2.270	0.370	6.13	0.000	1.544	2.996
Orphan designation	-0.531	0.324	-1.64	0.102	-1.168	0.105
Constant	-2.412	0.500	-4.82	0.000	-3.394	-1.431

Logistic regression — LR chi2 (6) = 66.97
Log likelihood= -117.61147 — Prob > chi2 = 0.0000
Number of obs = 218 — Pseudo R2 = 1.2216

Conclusions

Our analysis found that the FDA has authorized more biologics than the SFDA, and the time gap between SFDA and FDA approval varies widely, averaging over 4.5 years.

Factors affecting the time gap include the sponsored company, regulatory designations, and approval status in other countries.

These results offer insights into biologic approvals in the US and Saudi Arabia, informing future research on their impact on patient access.