TRENDS IN THE REGISTRATION OF THERAPEUTIC BIOLOGICS BY THE SAUDI Arabia(1989-MAY 2019)

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Background

The Ministry of Health (MOH) was the main body responsible for registration and price regulation of pharmaceuticals in Saudi Arabia until 2003.

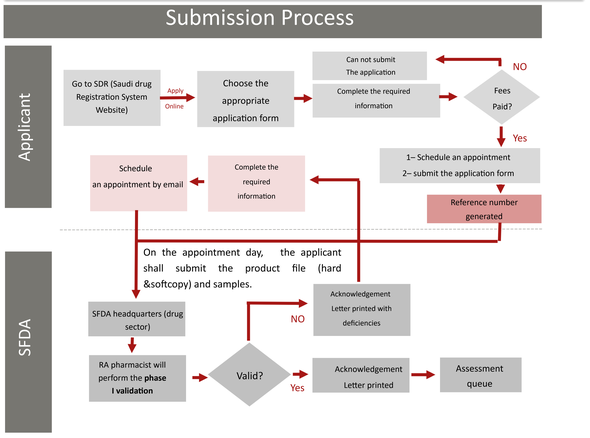
Since 2003, the Saudi Food and Drug Authority (SFDA) has became responsible for licensing of the manufacture, import, export, distribution, promotion and advertising of medications, assessing the safety, efficacy and quality of medications, and issuing marketing authorization, inspecting and surveillance of manufacturers, importers, wholesalers and dispensers of medication products.

In 2009, the SFDA started registering and pricing pharmaceutical products using a new Market Authorization Application (MAA) for therapeutic biologics and new drugs (Figure 1). The MAA has 4 steps in process before pricing and product licensing: validation, assessment, testing, and inspection. Lately, the utilization of biologics have grown dramatically in Saudi Arabia and the rest of the world. Despite their therapeutic importance, studies assessing trends in registration of biologics in Saudi Arabia are lacking.

Objectives

This study assessed trends in the registration of biologics license application licenses by the MOH and SFDA in the period January 1989 to May 2019.

Figure 1. Market Authorization Application Process



Methods

Regulatory information for biologic license applications (BLA) was collected from the SFDA website "Registered drugs and herbal product." Information collected included BLA number, brand and non-proprietary names, form, strength, registration date, legal status, marketing company, and authorization status. Descriptive statistics were performed in the analysis

Results

Figure 2. Trends in MOH/SFDA Registration of Biologics (1989-May 2019)

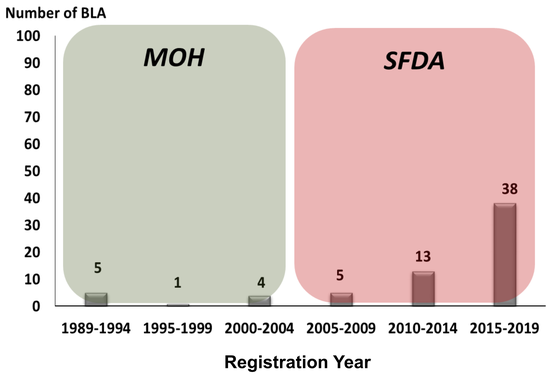


Figure 3. MOH/SFDA Registration of Biologics by ATC Therapeutic Class (1989- May 2019)

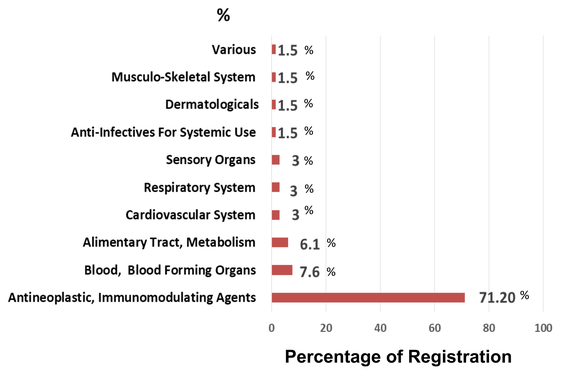


Table 1: Biologics Registered by SFDA by Pharmacological Class (1989-May 2019)

Pharmacological Class	Registrations
Anti-thrombotics Agent	1
Antianemic Preparations	3
Tyrosine Kinase Inhibitor	1
Anti-Diabetics	2
Antineoplastic	1
Enzyme	2
immuno-stimulants	10
Monoclonal antibodies	44
Selective immunosuppressants	2
Total	66

Table 2: Selected Biologics Registered by Pharmacological Class (1989-May 2009)

Category of Biological	Registration Year
Anti-thrombotic Agent	
Alteplase	1989
Immuno-stimulants	
Interferon alfa-2b	1992
Filgrastim	1993
Interferon gamma-1b	1997
Peginterferon alfa-2a	2002
Peginterferon alfa-2b	2002
Monoclonal Antibodies	
Etanercept	2006
Omalizumab	2006
Rtuximab	2008
Trastuzumab	2008
Antianemic Preparations	
Darbepoetin alfa	2006
Epoetin alfa	1991
Methoxy polyethylene glycol-epoetin beta	2010

The MOH and SFDA registered 66 therapeutic biologics with a total of 109 different formulations/strengths in the period of 1989-2019. There were 5 biologics (7.5%) registered in 1989-1994, 1 (1.5%) in 1995-1999, 4 (6.1%) in 2000-2004, 5 (7.5%) in 2005-2009, 13 (19.6%) in 2010-2014, and 38 (57.5%) in 2015-2019 (Figure 2). The largest number of registrations occurred in the class of antineoplastic and immunomodulating agents (n=47), followed by blood, blood forming organs (n=5) and alimentary tract, metabolism (n=4) (Figure 3). Alteplase was the first biologic drug registered in Saudi Arabia in 1989, and etanercept was the first monoclonal antibody registered in the country (Table 2). All the approved biologics had parenteral route of administration.

Conclusions

There was a substantial increase in the number of therapeutic biologics registered in the period 1989- 2019. Most of the registrations occurred in the last five years. There is no biosimilar registered yet by SFDA. Future research is needed to evaluate the effect of BLA approvals on patient outcomes and cost.

References