ORIGINAL RESEARCH

Global disease burden amelioration index in pharmaceutical research: Is it time?

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ABSTRACT
The pharmaceutical industry has a unique characteristic that differentiates it from other industries, namely the fact that it directly impacts human lives and public health. Humanity's universal and strong desire for healthy conditions and prolonged lifespans makes the pharmaceutical industry indispensable and attractive, creating constant demand. This may be mainly attributed to the difficulties that are involved in drug discovery and development, such as long periods of lead/candidate identification, time-consuming process of clinical trials, high development cost per product, and extremely low rate of successful outcomes.

Key words: Global, Disease, Pharmaceutical

INTRODUCTION

According to World Health Organization (WHO) Global Health Estimates 2016, the leading causes of disease burden around the world, reflected by Disability Adjusted Life Years (DALY), are constituted by ischaemic heart disease (7.6%), stroke (5.2%), lower respiratory infections (4.9%) and other morbidities.[1]

Many previous studies have highlighted a gap between global health needs and the drug research and development process.[2-4]This study intended to examine the international drug/biologic approvalsby US Food and Drug Administration (FDA)[5], European Medicine Agency(EMA)[6] and the SWISSMEDIC (SMC)[7]during the past five year period from 2014 to 2018 from the perspective of their therapeutic areas and their relevance to global disease burden.

METHODOLOGY

The drug/biologic approvals along with their therapeutic indications, by the three regulatory agencies (FDA, EMA and SWISSMEDIC) during the period from 2014 to 2018 were extracted/downloaded from their official websites and entered in the form of a database.The entities which were approved by more than one agency were accordingly clubbed under different categories as shown in Table 1. The final database comprised 460 unique drug/biologics approved by any of the three agencies during this period. The relevant ICD-10 code for each entity, wherever possible,was found using WHO ICD-10, version 2016 tool.[8]The relevance of the indications of newly approved drugs was compared to the leading causes of DALYs globally derived fromWHO Global Health Estimates, 2016 summary tables.[1]

The data was entered in the form of a data matrix in Microsoft® Excel ® and descriptive statistical analysis performed for variables of interest.

RESULTS

Table 1: Table showing the distribution of approving agencies for drug approvals

Agency	Frequency	Percentage
EMA	144	31.3
FDA	115	25.0
SWISSMEDIC	31	6.7
EMA and FDA	40	8.7
EMA and SWISSMEDIC	23	5.0
FDA and SWISSMEDIC	9	2.0

ALL THREE AGENCIES	98	21.3
TOTAL	460	100.0

Table 1 shows the distribution of approvals according to the three regulatory agencies. Out of a total of 460 unique entities, 98 (21.3%) were approved by all the three agencies, 40 (8.7%) by EMA and FDA, 23 (5.0%) by EMA and SWISSMEDIC and 9 (2.0%) by FDA and SWISSMEDIC. The drugs approved solely by EMA, FDA and SWISSMEDIC were 144 (31.3%), 115 (25.0%) and 31 (6.7%) respectively.

Table 2: Table depicting the ICD-10 parent classification for approved drugs

ICD-10 code	Therapeutic area	Frequency	Percentage
01	Certain infectious and parasitic diseases	67	14.6
02	Neoplasms*	107	23.3
03	Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism*	23	5.0
04	Endocrine, nutritional and metabolic diseases	61	13.3
05	Mental and behavioural disorders	14	3.0
06	Diseases of the nervous system*	30	6.5
07	Diseases of the eye and adnexa	12	2.6
08	Diseases of the ear and mastoid process	1	0.2
09	Diseases of the circulatory system	14	3.0
10	Diseases of the respiratory system	20	4.3
11	Diseases of the digestive system	16	3.5
12	Diseases of the skin and subcutaneous tissue	12	2.6
13	Diseases of the musculoskeletal system and connective tissue	9	2.0
14	Diseases of the genitourinary system*	11	2.4
15	Pregnancy, childbirth and the puerperium	1	0.2
17	Congenital malformations, deformations and chromosomal abnormalities	1	0.2
18	Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	3	0.7
19	Injury, poisoning and certain other consequences of external causes	5	1.1
	Multiple uses/diseases	44	9.6
	Others	9	2.0
	Total	460	100.0

*Associated drugs also included

Table 2 depicts the distribution of approvals across ICD-10disease categories. The largest number of drug approvals belonged to the category of neoplasms (n=107, 23.3%), followed by infectious and parasitic diseases (n=67, 14.6%), endocrine, nutritional and metabolic diseases (n=61, 13.3%), diseases of the nervous system (n=30, 6.5%) and diseases ofthe blood and blood-forming organs and certain disorders involving the immune mechanism (n=23, 5.0%).

Table 3: Distribution of approved drugs in relation todiseases with high global burden (n=450)

Disease	Frequency	Percentage
Ischaemic Heart Disease	11	2.4
Stroke	4	0.9
Lower respiratory infections	22	4.8
Diarrhoeal diseases	5	1.1
Chronic Obstructive Pulmonary Disease	10	2.2
Diabetes Mellitus	24	5.2

Table 3 shows the distribution of approved drugs according to their therapeutic indication in relation to leading causes of DALYs according to WHO Global Health Estimates 2016. The maximum number of approved drugs among the most important causes belonged to the group of diabetes mellitus (n=24, 5.2%), followed by lower respiratory infections (n=22, 4.8%) and ischaemic heart disease (n=11, 2.4%).

DISCUSSION

This study found a disconnect between global health needs and drug development priorities at an international level. According to worldwide DALY rates, the most needed drugs belong to the domains of ischaemic heart disease, stroke and lower respiratory infections, which in fact are not being developed at priority.The new medicines entering into the pharmaceutical pipeline for clinical trials and

subsequent approvals in the developed world tend to cater to a large extent, the reasons of morbidity in these nations only.[9] The predominant causes of disease burden at a global scale are being left largely unaddressed by the current drug research and development activities. It is now probably time for the public health professionals across the globe to come together and develop a "global disease burden amelioration index" for any new drug entering into the clinical trials. This index could take into account the advantage the drug would confer towards decreasing the global burden of disease, in case it gets approved by the regulatory authorities.In coming times, the national health policies in all countries across the world, and especially the developed countries which contribute to the bulk of drug research, could develop a framework for putting aside a minimum proportion of national pharmaceutical research budget to drugs having a high global disease burden amelioration index.

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