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# 2020 Market Analysis of Bioavailability & Bioequivalence Summit 2020 October 30-31, 2020 | Chicago, USA

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Bioavailability means the rate and extent to which the active drug ingredient or therapeutic moiety is absorbed and becomes available at the site of drug action. The property where two drugs with identical active ingredients or two different dosage forms of the same drug possess similar bioavailability and produce the same effect at the site of physiological activity is Bioequivalence.

## The scope of Bioavailability and Bioequivalence:

Many countries have established a number of procedures for the introduction of *generic pharmaceutical* products. These generic products should be demonstrated to be therapeutically equivalent to a previously approved product in order to protect the customer. The concept of *bioavailability* and **bioequivalence** became a public issue because of the concern that a *generic* product might not be as bioavailable as that manufactured by the innovator. The therapeutic equivalence of a generic and an innovator product is mostly based on the demonstrated *bioequivalence*, that is, clinically insignificant differences in the rate and extent of drug absorption usually assessed from pharmacokinetic measurements. Along with the growth of the worldwide generic pharmaceutical industry, **bioequivalence** has added another dimension to the issue of quality of drug products. In the last few decades, the **bioavailability** and *bioequivalence* of drug products have emerged as important national and international regulatory and scientific issues. The concept of **bioavailability/bioequivalence** plays an important role in drug research and development, especially in the generic-drug industry.

## Bioavailability, Bioequivalence and Drug Product Selection Process

- *Invitro & In-vivo* techniques for investigating drug metabolism
- Assessment of pharmaceutical quality & in-vivo performance of generic drugs
- Impact of physical and chemical properties of a drug
- Issues and concerns pertaining to **bioavailability** and *bioequivalence*

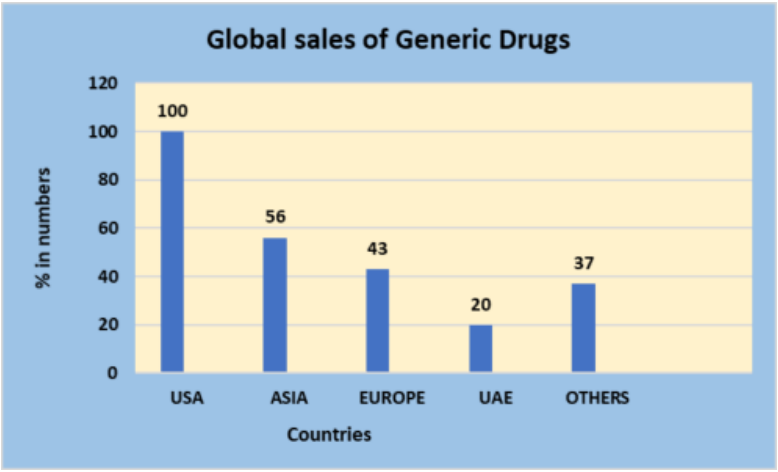
Global market for generic drugs was worth $81 billion in 2008, a figure that is expected to reach $84 billion in 2009. In 2014, the market is expected to amount to $168.7 billion, for a compound annual growth rate (CAGR) of 15% in the 5-year period. The global market for generic drugs should reach $533 billion by 2021 from $352 billion in 2016 at a compound annual growth rate (CAGR) of 8.7%, from 2016 to 2021. Sales of U.S. generic drugs are currently dominate the market, estimated at $33 billion in 2009 and projected to increase at a CAGR of 10.4% to $54 billion in 2014. And the Sales of generic drugs in Canada rose from $3.0 billion in 2006 to $5.5 billion in 2016 at a rate of growth similar to the other industrialized countries. And also Japan's generic drugs market is expected to have the highest rate of growth among major markets at 12.2%, increasing from $5.4 billion in 2009 to $9.6 billion in 2014. Generic drugs are also considered to be 74% of the volume of drugs in the Canadian pharmaceutical market in 2016 which is the third highest among the OECD countries after the United States and Germany. Canadians spent $165 per capita on generic drugs in 2016 which is the second highest among the OECD countries after the United States.

Generic medicine are the medicines that are prescribed and sold-out beneath the non- proprietary name of their active ingredients or not below the brand or trade name.it is only under the general descriptive name.

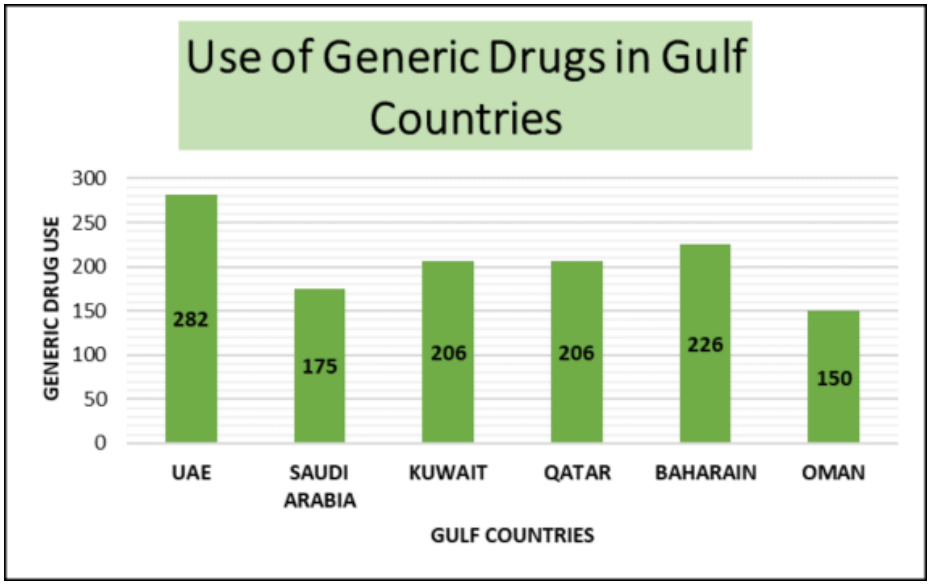
Generic drugs only produced after the patent on a drug expires. Generics drugs are same quality as well as the branded drugs, but it is less expensive due to the lower cost using for the research and development.

The total revenue from drug sales across the UAE stands at $1.2 billion a year (Dh4.4 billion); the Department of Health, Abu Dhabi announced 25 per cent of this was from sale of generic drugs, known as generics in short. The prices of the drug in UAE are very high other than the global markets so it needs to be reduced as soon as possible by using the Generic drugs.

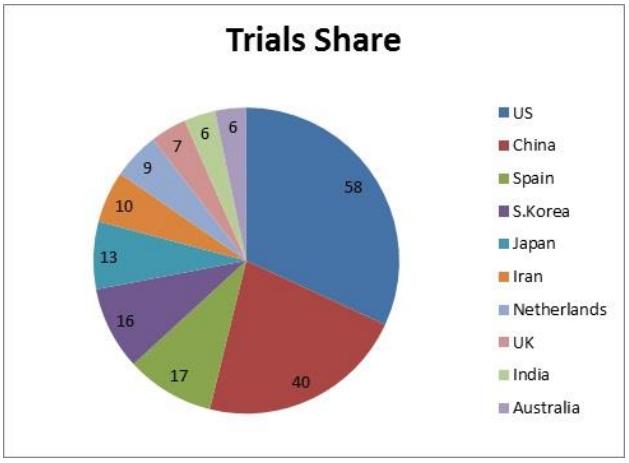
In last decade generic drugs have saved $1.67 trillion in the U.S. health care system and generated $253 billion savings only in 2016. Medicare savings are $77 billion and Medicaid savings are $37.9 billion. Generics dispensed are 89% of prescriptions total drugs cost is 26%. During 2011-2017 CAGR of 13% growth has been witnessed in the generic drug market.



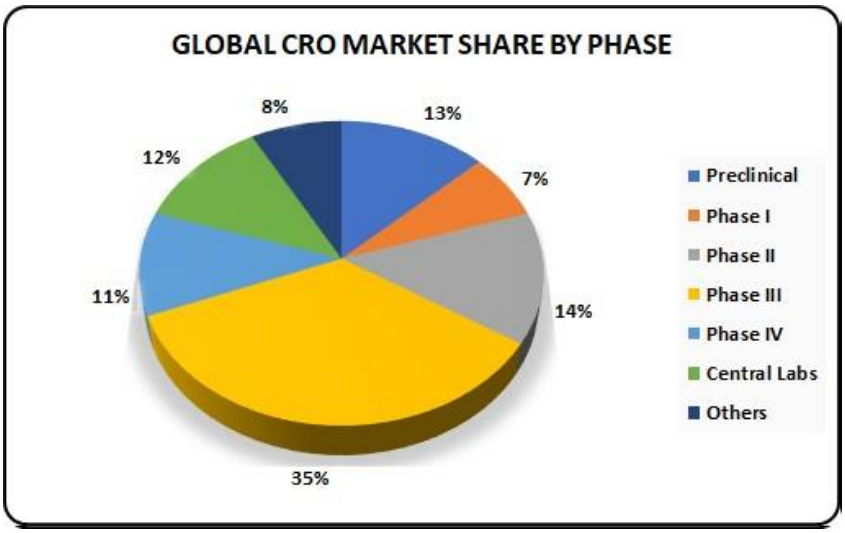

The GCC countries, comprised of Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the UAE, make up an integral part of the Middle East's pharmaceutical sector. The gradual lowering of medicine prices within the Gulf region, growing awareness of generic drugs, and increasing insurance coverage within the GCCis shown below. BMI has taken this opportunity to survey the landscape of the generic drugs market in the region and assess the market's growth over the coming years.

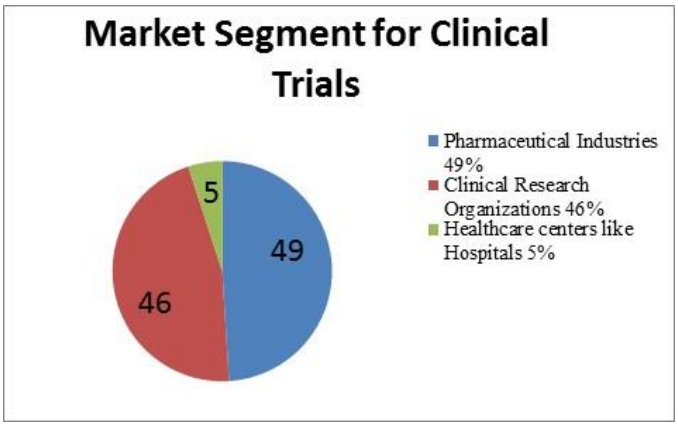



The global clinical trial market having the probability to reach USD 65.2 billion. Many fields like increase development of clinical trials in international level( called Globalization), development of new treatments such as individual medicine, evolution in technology, and increasing demand for CROs to conduct clinical trials are impacted by the key drivers.




The globalization of clinical trials has prompted increment in interest in development of new product in known countries, positively affecting the general market. By giving them the choice to outsource what they believe is past their center mastery, the accessibility of the huge range of administrations from sedate revelation to post-showcasing reconnaissance has additionally streamlined the life for medium size and little scale pharmaceutical and biotechnological association. For example, Pfizer put 3 CROs working, at present for improving the item portfolio and advancement. According to the association associated with ICON in 2011, Pfizer would protect the merchandise for the preliminaries and studies directed by ICON, consequently enabling the organization to center and further build up its abilities in clinical preliminary outlining.



Now-a-days, the chances of disease and incidence of new disease would be increased. So the clinical trial market should be boosted. The overall population has different diseases profile with developing nations having the most different illness profile. For discovering the sponsors, boost of the clinical trial of new and uncommon sickness is required. More number of patients with a particular infection would be the goof feature for biopharmaceutical organizations to show more clinical trial for a disease segment.