

BIO⁷ PHARMCOR

ADVANCING MEN'S HEALTH

**The Global Generic
Medications Market**



Overview

Generic drugs offer identical quality, benefit and safety when compared to branded medications.

The global generic medications market is expanding due to governmental and legislative factors, 3rd party payer/insurance trends, and consumer demand.



Overview

The IMS Institute for Healthcare Informatics reports spending on medicines will reach nearly \$1,100 billion USD in 2015, with generics accounting for \$400-430 billion USD of the total market.



Estimated 2016 Drug Spending

| Region | Per Person Medication Spending (USD) | Population (million) |
|----------------|--------------------------------------|----------------------|
| United States | 892 | 326 |
| Japan | 644 | 124 |
| Canada | 420 | 36 |
| European Union | 375 | 320 |



Same Quality, Same Performance

The diagram features two pill bottles on a grey surface. The bottle on the left is blue and labeled 'GENERIC' with a white pill icon. The bottle on the right is green and labeled 'BRAND' with a white pill icon. Between them are two grey boxes containing the text 'SAME QUALITY &' and 'PERFORMANCE'. Below the bottles is a white box containing three bullet points.

- FDA requires generic drugs to have the **same active ingredient, strength, dosage form, and route of administration** as the brand-name drug.
- The generic manufacturer **must prove its drug is the same** (bioequivalent) as the brand-name drug.
- All manufacturing, packaging, and testing sites **must pass the same quality standards** as those of brand-name drugs.



Generic Medications Are Key to Patient Care in the EU

“With an ageing European population and EU Member States’ healthcare budgets under pressure, generic and biosimilar medicines are now more than ever a key component of sustainable healthcare. Generic medicines create savings of over 30Bn Euros and newly established biosimilar medicines already generate around 1.4Bn Euros per year for European healthcare systems.”

Excerpt from EGA Vision 2015



Generic Medication and Consumer Savings in the United States

According to the Congressional Budget Office, “generic drugs save consumers [in the United States] an estimated \$8 to \$10 billion USD a year at retail pharmacies. Even more billions are saved when hospitals use generics.”

Today, nearly **8 in 10** prescriptions filled in the U.S. are for generic drugs.





Cumulative Hospital, Pharmacy, and Patient Savings of Generic Drugs

80-85% LESS

Average cost of a generic drug vs. its brand-name counterpart



In 2010 alone, the use of FDA-approved generics saved **\$158 billion**.

\$3 BILLION SAVED EVERY WEEK!

Sun

Mon

Tues

Wed

Thurs

Fri

Sat



Generic Medications in the EU Today

Generic medicines in Europe represent almost half of the pharmaceutical market by volume but around 18% of the total cost.¹

With several blockbuster medicines losing market exclusivity over the next few years, generic medications offer major healthcare savings opportunities for governments, insurers, and patients.



What is the Primary Driver to Reducing the Cost of Generic Medications?

Generic drugs do not undergo the large, expensive clinical trials required for brand-name medication approvals.

Quality of generic drugs is ensured through a standardized process known as an abbreviated new drug application (ANDA), and bioequivalence studies.



Global Trends for Generic Medications

Over the next five years, increased generic spending in developed markets will be driven by generic competition due to patent expiries, with some additional increases due to expanded generic use for off-patent molecules.¹

Patent expiries will reduce brand spending in developed markets by \$127 billion USD over the same time period.¹



Generic Medications: Key Contributors to Long-Term Societal Health

Generic drugs are affordable, gold standard medications for many major illnesses and allow treatment access to a greater proportion of global population

Deliver savings to national health bills, insurers, and consumers through the use of high quality treatments



Summary

The growing market footprint of generic drugs offers identical quality, benefit and safety when compared to branded medications, with significant cost savings for product development and to the consumer.

Disease and market-specific opportunities exist for Biopharmcor to develop new generic medications as patent exclusivity expirations occur.



Further Information

1. A 59 slide powerpoint presentation on generic drugs, as well as other useful information, is freely available on the FDA website.

<http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/UCM169283.pdf> and
<http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm>

2. European Medicines Agency Generic Medication Section.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000335.jsp&mid=WC0b01ac0580514d5c

3. Health Canada information for generic medications can be found at:

<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/med-gen-eng.php>

4. European Generic and Biosimilar Medicines Association at:

<http://www.egagenerics.com/>

BIO¹PHARMCOR

ADVANCING MEN'S HEALTH