MARKET ANALYSIS OF HORMONAL PRODUCTS IN INFERTILITY

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ABSTRACT

Since years predictions of a world population explosion have been set up by experts. But now the scenario seems to have taken a different turn and the world has been taken up by a burning issue-INFERTILITY. Studies indicate that about 15% of the couples in reproductive age show infertility or the inability to reproduce. Although infertility cannot be restricted to a particular gender, studies indicate that a majority of all cases of infertility arise on account of female(60%) conditions, while the rest 40% is either due to sperm disorders or unidentified factors. This goes with the fact that men can remain in their fertile phase up to a longer span than women. Depending on the cause and type of the infertility condition, various treatments such as surgery, hormonal medications, in vitro fertilizations and other medications can be aimed for. The present review article is aimed to take a brief look at the various hormonal products available in the current global market which are major players for the treatment of various types of infertility. It also provides an extensive analysis of the hormonal infertility industry drugs in terms of products, technology and geography.

KEYWORDS: Infertility, hormonal market, hormonal medications.
INTRODUCTION

In the present time when technology is advancing with each passing day there are many medications as well as treatments available for the treatment of infertility. Hence now the statement that infertility means never having a child has turned into a mere myth. Infertility has now become a condition which can be treated by appropriate medications and techniques.[1] The latest addition to the list of treatments is Assisted Reproductive Technology. The treatment varies from various medicated products to hormonal products and leads on to in-vitro fertilization. Since the human body is considered to be dominated by hormones, especially in the case of the reproductive system, the hormones are considered to play a vital role in the treatment of infertility. Various injectable hormones are available in the market for the treatment of infertility. They include Human Chorionic Gonadotropin, Follicle Stimulating Hormone, Human Menopausal Gonadotropin, Gonadotropin Releasing Hormone-agonist and antagonist, Luteinizing Hormone, Dihydroepiandrosterone, thyroid, testosterone, etc.[2] Table 1 showcase the dosage regime and availability of certain hormones used in the treatment of infertility.

Table: 1. Reviewed Hormonal Treatment for Infertility.

<table>
<thead>
<tr>
<th>SUBSTANCE</th>
<th>ADMINISTRATION</th>
<th>DOSAGE &amp; FREQUENCY</th>
<th>CURRENT AVAILABILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>GnRH</td>
<td>Subcutaneous infusion pump</td>
<td>25-200ng/kg per pulse every 2 hours</td>
<td>Only in specialty centres or in clinical trials</td>
</tr>
<tr>
<td>Human Chorionic Gonadotropin (HCG)</td>
<td>Subcutaneous/Intramuscular</td>
<td>1500-3000 IU 2 times/week</td>
<td>Available, FDA approved for treatment of infertility</td>
</tr>
<tr>
<td>Human Menopausal Gonadotropin (HMG)</td>
<td>Subcutaneous/Intramuscular</td>
<td>75 IU 2-3 times/week</td>
<td>Available, FDA approved for treatment of infertility</td>
</tr>
<tr>
<td>Highly purified or recombinant follicle stimulating hormone (rhFSH)</td>
<td>Subcutaneous/Intramuscular</td>
<td>100-150 IU 2-3 times/week</td>
<td>Available, FDA approved for treatment of infertility</td>
</tr>
</tbody>
</table>

Importance of hormones in fertility

Hormonal balance is an absolute necessity for conceiving and a healthy child bearing. The hormones control all the body processes including reproduction. And fertility issues are very often linked to hormonal imbalance. The hormones important for reproductive function are: estradiol, progesterone, luteinizing hormone, follicle stimulating hormone, cortisol, testosterone, and androgens. The imbalance in these hormones can be caused due to stress,
poor nutrition, xenohormones, lifestyle, genetics, etc.[3] There are various hormonal aspects in
infertility. Some of the key aspects are as listed below.

- Ovarian insufficiency: no ovulation even in presence of estrogens
- Luteal phase deficiency: ovulation occurs but pregnancy cannot be sustained due to lack
  of progesterone.
- Thyroid: prevent ovulation and may affect sperm count
- Cortisol: high levels during stress, affect ability to conceive.

**Market analysis of hormonal infertility products.**

For the detailed analysis of the hormonal market in infertility, the market dynamics and
trends such as the drivers, restraints and opportunities that influence the current nature and
future status of this field are to be looked into. The infertility market sizing depends upon the
following.[4]

- Market Definition
- Market Drivers
- Market Restraints
- Challenges and Opportunities
- Demand Analysis
- Others

The current worldwide market for infertility drugs is around USD3553.5 and the major
proportion of this market consists of products for issues related to female infertility. The
market in 2010 was USD 2500 million and since then it has shown a huge increase.
Estimations are being made that by the year 2017 the market will reach the figure of USD
4,776.4 million, growing at a CAGR of 4.3%. Compilation of various data suggest that with
respect to sales the leading brands belong to three major, namely, Gonadotropin, androgens
and erectile dysfunction. The drug brands in the category include Gonal-f, Follistim AQ,
AndroGel, Testim, Viagra, Cialis and Levitra/Staxyn.[5] One key trend leading to the
emergence of this market is the increased awareness. With increased awareness among the
public, the acceptability of infertility treatment options is expected to rise further. Also the
timely innovations in this field are introduced with reduction of side effects associated with
drugs; enhance qualitative and quantitative aspects of ovulation and spermatogenesis; and
improve overall fertilization.[6] Hence in order to make people aware and comfortable with
the utility of infertility products, the pharmaceutical companies are spending huge amounts in their marketing.

Figure: 1. Hormonal fertility drugs that pharmaceutical companies are paying most to promote (Prices in dollars).

Key Hormonal Products in infertility

Fertility drugs come across as the primary step in treatment for women with fertility disorders. These medications work by increasing the level of hormones that either trigger or regulate the maturity and release of one or more eggs each month. In males too, the products work by increasing certain hormone levels. Fertility drugs are also necessary as part of some assisted reproductive techniques such as in vitro fertilization.\textsuperscript{[7]} Hormonal products used in case of infertility can be given in various forms. However, the most common dosage form is through injections. Table 2 displays various products which have contributed in the success of hormonal infertility market are as below.\textsuperscript{[8-9]}

Table: 2. Key hormones used in infertility with their popular brand names.

<table>
<thead>
<tr>
<th>Hormone</th>
<th>Mechanism of action</th>
<th>Brand Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Chorionic Gonadotropin (HCG)</td>
<td>Triggers ovaries to release eggs</td>
<td>Novarel, Ovidrel, Pregnyl, Choragon and Profasi.</td>
</tr>
<tr>
<td>Follicle Stimulating Hormone(FSH)</td>
<td>Stimulates the development and growth of eggs in the ovaries</td>
<td>Bravelle, Fertinex, Follistim, Menotropins, Puregon and Gonal-F.</td>
</tr>
<tr>
<td>Human Menopausal Gonadotropin(HMG)</td>
<td>Combination of Follicle Stimulating Hormone and Luteinizing Hormone(LH)</td>
<td>Merional, Menopur, Metrodin, Pergonal, and Repronex.</td>
</tr>
<tr>
<td>Gonadotropin Releasing Hormone(GnRH)</td>
<td>Stimulates release of FSH and LH</td>
<td>Factrel and Lutrepulse</td>
</tr>
<tr>
<td>Gonadotropin Releasing Hormone Agonist</td>
<td>Promote ovulation</td>
<td>Lupron, Zoladex.</td>
</tr>
</tbody>
</table>
Gonadotropin Releasing Hormone Antagonist | stop ovulation until the eggs are ready to be collected | Antagon and Cetrotide, Orgalutran
Progesterone | help to maintain pregnancy | Cyclogest, Gestone and Crinone

Apart from these, Dihydroepiandrosterone (DHEA) and testosterone therapy are also used in treatment of infertility issues. Gonadotropins offer the widest ranges of hormonal treatments for infertility. They are the most preferred drugs before going for the surgical ways. They have a huge market spread across in Europe, Asia, North America and other regions. The popularity of gonadotropins goes with the results obtained and the fact that it can be used for both male and female issues. It can be used to treat sperm issues as well as ovulation issues.

![Gonadotropin Milestones](image)

Figure: 2. Milestones in the development of Gonadotropin preparations since 1931 to 2015.

**Major Market Players**

There are various market players contributing in the growth of the global infertility market such as Bayer Healthcare Pharmaceuticals, Pfizer, Teva Pharmaceutical Industries, AstraZeneca, Ferring, Merck & Co, Merck Serono.

- Bayer is a leading pharmaceutical company in the field of products related to women health. The leading products are Fostine (FSH), Menodac (HMG), Ovidac (HCG) and Vageston (progesterone). The annual revenue of the firm from the biological products is
USD 3453 million as estimated in the year 2014. It has shown a great leap from the USD 2011 million collections from 2011.\textsuperscript{[11]}

- Ferring Pharmaceuticals is yet another leading company in the hormonal products of infertility. It has ample of products to offer to the couples suffering from infertility.\textsuperscript{[12]} The products range from Bravelle (Urofollitropin), Menopur (Menotropins), Endometrin (Progesterone), and Repronex (Menotropins) to Novarel (HCG). Ferring has its own production facilities in several European countries and in South America, Israel and China. It is also into establishment of new facilities in the US and India. It contributes in the infertility market with estimated revenue of USD 550 million.\textsuperscript{[13-14]}

**Key Geographical Regions**

As per the geographical segmentation study of the infertility products, the entire market is broadly divided into three segments.\textsuperscript{[15]}

- North America : USA, Canada
- Europe: United Kingdom, Germany, Italy, France, Spain, Russia
- Asia specific: India, China, Japan, South Korea, Thailand
- Rest of the World

These are the specific regions which are in terms of manufacturing and marketing of the hormonal products used to treat infertility. All these geographies have shown a potential rise in the fertility market since 2010. There has been an annual growth of 2.3% recorded annually from 2010-2015 and the sales are predicted to raise more with an impressive CAGR in the coming years till 2020.

![Figure: 3. Geographical segmentation of hormonal infertility products.](image-url)
CONCLUSION

Fertility patterns in the world have changed dramatically and a rise in the infertility rates have been observed since the last two decades. Even though newer assisted techniques such as in-vitro fertilization have been well developed, still fertility drugs are the first choice for treatment of infertility issues. And even in the fertility drugs category, the hormonal products are preferred the most. Since the human body is governed by hormones, infertility is considered to be caused due to the abnormal play of the hormones. Hence normal regulation of the hormones is very necessary. Due to increased awareness among couples, the infertility market has taken a major leap and in the coming years it is expected to show more potential rise. Various hormonal products are available for infertility treatment, the market being ruled by gonadotropins. The different potential market players have been showing rise in the revenue with each passing year. Newer and better products are being launched by the market players and also more firms are likely to be associated with the infertility market. Also specific geographies have marked a decent rise in the annual collections. By the analysis of the hormonal market in infertility, it can be concluded that the infertility market has a scope to rise potentially in the upcoming years. This can act as a ray of hope in improving the conditions of infertility which has been in prevalence.

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