

**Summer Training at
Lintac Solutions & consultants Pvt. Ltd., Gurgaon**

Infertility Market Assessment in India

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**MBA-Pharmaceutical Management (MBA-PM)
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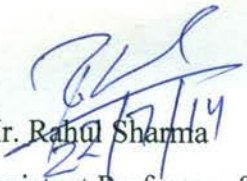
CERTIFICATE

This is to certify that Ms. **SHIPRA PANDEY** student of Institute of Health Management Research University, Jaipur has undergone summer training at **Lintac Solutions & Consultants Private Limited, Gurgaon** from April 2, 2014 to May 16, 2014.

The candidate has successfully carried out the project assigned to her during summer training & her approach to study has been sincere scientific & analytical.

This summer training is in partial fulfillment of the course requirements.

We wish her success in all her future endeavors.


Mr. Rahul Sharma
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IIHMR University, Jaipur

Col. (Dr.) Ashok Kaushik
Dean Academics & Student Affairs
IIHMR University, Jaipur



Lintac Solutions & Consultants Pvt. Ltd.

To whomsoever it may concern

This is to certify that Ms. **Shipra Pandey**, pursuing her Post Graduate Diploma in Pharmaceutical Management (1st year) from Institute of Health Management Research, Jaipur has successfully completed summer internship at Lintac Solutions & Consultants Pvt Ltd, Gurgaon; from 2nd April 2014 to 16th May 2014.

We found her hardworking, inquisitive and result oriented. She worked well as part of a team during his tenure. We take this opportunity to thank her and wish her all the best for her future.

Ila R.
Director Operations & HR



Rajesh Chauhan
Project Manager

Deepak Chugh
Project Manager

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ShipraPandey

27 June, 2014

ABBREVIATIONS

ITEM

AMH

CME

FSH

GIFT

HMG

HCG

ICSI

IUI

IVI

LH

OPD

WHO

DISCRIPTION

Anti Mullerian hormone

Continuing medical education

Follicle stimulating hormone

Gamete intra fallopian transfer

Human menopausal gonadotropin

Human chorionic gonadotropin

Intra-cytoplasmic sperm injection

Intra uterine insemination

In-vitro fertilization

Luteinizing hormone

Outpatient Department

World Health Organization

Contents

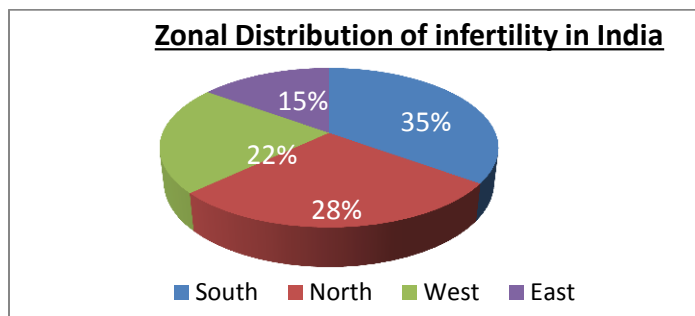
1. BACKGROUND OF STUDY.....	5
2. OBJECTIVEs OF STUDY	6
3. METHODOLOGY.....	6
4. RESEARCH FINDINGS.....	8
5. DISSCUSSION	20
6. RECOMMENDATIONS	22
7. REFERENCES	23

BACKGROUND OF STUDY

Approximately 30 million couples are infertile in India. Of these, 80% can be treated through simple therapies. Remaining 6 million couples need to undergo advanced infertility treatments such as IVF, intra-cytoplasmic sperm injection (ICSI), egg donation or surrogacy. It is estimated that about 80,000 IVF cycles and 270,000 cycles of IUI were performed in 2013.¹

Infertility incidence rate was estimated to be 10%-12% in 2013.¹

South India accounts for 35% of total infertile population, followed by North India at 28%. States witnessing rapid increase in infertility cases are Kerala, Tamil Nadu and Andhra Pradesh.



Source: NFHS-3

Male infertility treatment: Males are the affected partners in around 30%-40% infertility cases. In case of low sperm count/motility, doctors advise therapies such as Antioxidants, Low dose androgen therapy and Low dose clomifene citrate therapy.

Female infertility Treatment: In case of no tubal blockage, clinicians recommend the following therapies:

1st line- clomifene citrate as 1st line therapy for a maximum duration of 3 cycles, one cycle lasts for 5 days. More than 90% patients are prescribed clomifene citrate.

2nd line- If 1st line fails, then combination therapy of clomifene citrate with gonadotropin (hMG or FSH). Average duration of second cycle is 14 days.

If combination therapy also fails, then therapy with FSH or hMG for 3 cycles.

OBJECTIVES OF STUDY

1. To assess recombinant product market across the reproductive therapy market in India.
2. To develop a suitable business model which would create a platform to grow the market for recombinant product laterally and vertically.

METHODOLOGY

The methodology involved combination of telephonic interviews along with selective information obtained through secondary research work.

Clinicians targeted- Gynaecologists, Gynaecologists with Infertility Practice, IVF Specialists, Embryologists

Geographic- India Metro's and Tier-I (Bangalore, Hyderabad, Ahmedabad)

Field interviews

Category	No of doctors
Gynecologist	129
IVF Specialist	121
Companies offering treatment options for target condition	50
Medical Associations	10
Other knowledgeable sources	10
TOTAL	320

Sample area:

Key Cities	Number of Interviews (Clinicians)
Delhi-NCR	39
Mumbai	32
Chennai	37
Kolkata	33
Hyderabad	34
Bengaluru	37
Ahmedabad	38
Total	250

RESEARCH FINDINGS

Use of urinary products:

Urinary products have high share of voice in infertility treatment. In 2nd line therapy protocols, clinicians prefer to prescribe urinary products in combination with clomifene citrate. During the study we observed that in case of recombinant protocols, clinician prescribe urinary product during the end stage of therapy just to limit the overall cost of the therapy.

Use of recombinant products:

Approximately 10% clinicians used recombinant products directly in combination with clomifene citrate in place of urinary products.

Combination protocol: 5 day rFSH+ 5 day hMG. Average duration of therapy for recombinant products is around 10-12 days.²

ALTERNATIVE THERAPIES FOR INFERTILITY TREATMENT

ORAL DRUGS	HORMONES	IUI/IVF PROCEDURES	SURGERY
• Clomifene • Metformin • Aromatase inhibitors	• Progesterone • LH • HMG • HCG • FSH • DHA	• ICSI procedure • ZIFT • GIFT • IVF • Surgical extraction of sperm through TESE, PESA and so on	• Tubal reanastomosis • Salpingectomy • Salpingostomy • Fimbrioplasty • Varicocelelectomy • Herneoraphy

Source: http://www.babycenter.com/0_fertility-treatment-your-options-at-a-glance_1228997.bc

Of total infertility patients, approximately 20% patients undergo IVF treatment; remaining are treated through drug therapies and IUI.

IUI : 10%-15%

IVF: 30%-35%

With Medicine only :6%-8%

Indian infertility market is dominated by urinary products in both value and volume. The market of urinary products was driven by low price and low penetration of recombinant products in the infertility segment. Gynecologists and Gynecologists with infertility practice preferred using urinary products for 1st line, 2nd line and IUI treatment whereas the usage of recombinant products was high amongst IVF Specialists.

Among the urinary products, Bharat Serum leads the market with a market share of around 40%, HMG, Urofollitropin, HCG, FSH and LH are the major category of urinaries.

In recombinants, Client had a market share of around 51%, followed by MSD at 22%. However within branded recombinants, Client had a market share of 69%

URINARY PRODUCTS

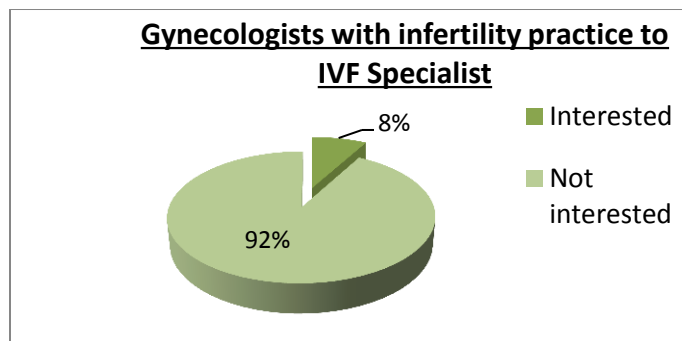
Molecule	Brand	Company
HCG	Hucog	Bharat Serum
	IVF C	LG Life Science
	Ovipure HP	Bharat Serum
	GHM	Sun Pharma
	Eema HP	Corono Remedies
HMG	Humog	Bharat Serum
	Lupi HMG	Lupin
Urofollitropin	Foliculin	Bharat Serum
	Follimon	LG Life Science
Molecule	Brand	Company

RECOMBINANT MOLECULES

Molecule	Brand	Company
Rfsh	Gonal F	Client
	Recagon	MSD
	Folligraf	Bharat Serum
	Newmon R	LG Life Science

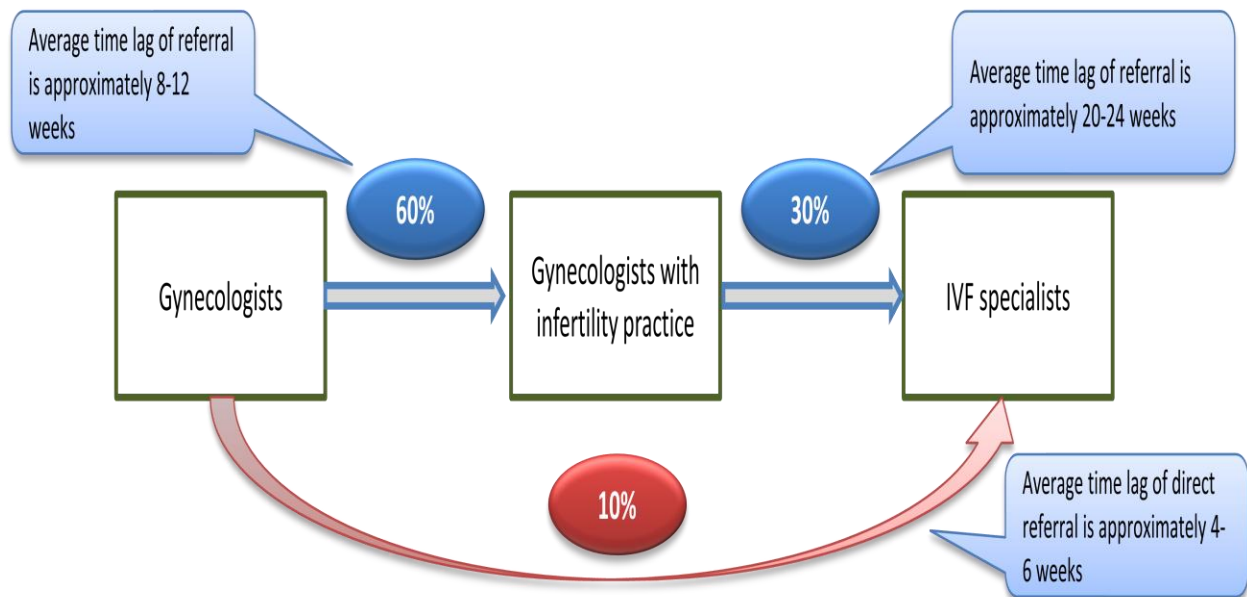
There are around 500 IVF specialist compared to 3,500 gynecologists with infertility practice and 26,000 gynecologists, across India.

Only 8% gynecologists with infertility practice were interested in becoming IVF specialists; this can be attributed to reasons such as, Low patient turnover thus, less revenue. High clinic establishment investments. Low adherence of patients. Low success rate (30%-35%only).Scope only in metro and tier I cities.



Source: http://www.fogsi.org/index.php?option=com_content&view=article&id=3&Itemid=23

NETWORKING



There exists a networking gap in existing referral pattern of infertility patients; as a result, most patients either visit IVF centers directly or frequently change their gynecologists for treatment of infertility.

Patients receiving treatment from gynecologists and gynecologists with infertility practice usually stay with the clinician for an average duration of 2-3 months and 6-8 months, respectively. However, treatment received by the patients at these care points is driven by urinary products. Recombinant products have very low usage in second line therapy and IUI procedures.

Required interventions for networking gap

- Involvement of gynecologists in infertility training and knowledge sharing platform.
- Introduction of wet-labs for demo and workshop in infertility practices.
- Increased participation of gynecologist in infertility related conferences and symposium, chaired by eminent IVF experts .

COST COMPARISION

LEADING URINARY BRAND

Brands	MRP in INR(Smallest available SKU)
Humog	618
Menogon	775
Folliculum	1110

LEADING RECOMBINANT BRANDS

Brands	MRP in INR(Smallest available SKU)
Gonal F	1,700
Recagon	1,475
Folligraf	1,850
Newmon R	1,350

Cost of the IUI therapy performed with urinary product is approximately 40-50% lesser as compared to cycle with recombinant product.

This ratio increases many folds in case of IVF cycles as the amount of Gonadotropin used in IVF is almost 3-4 times than used in IUI cycles. Use of Gonadotropins in IVF cycles is almost 5 times higher than its use in IUI cycles thus, increasing overall IVF cycle cost; hence, use of recombinant products makes IVF cycle unaffordable for lower and middle income group of patients.

Many pharmaceutical companies offer lucrative discount schemes on purchase of recombinant products, however, reach is limited to IVF centers and hospitals.

MARKETING STRATEGY OF KEY PLAYERS

MERCK SERONO

- Participation in Infertility surveys in support of research bodies like Indian Society for Assisted Reproduction, Asia Pacific Initiative on Reproduction (ASPIRE) etc.
- Launched a website in association with a national infertility association RESOLVE (2012)
- Well trained sales force in good numbers for effective coverage.
- Focus on gynecologists with infertility practice along with core infertility specialists.
- Wide range of products in infertility basket.
- Offering schemes and discounts on products upto 40%
- Participation in CMEs, conferences.
- Sponsoring KOL for conferences.

BHARAT SERUM

- Targets leading gynecologists and IVF specialists for promotion of products.
- Key promotional strategies pursued by company for infertility products are:
 - Distributes IVF specialist interview CDs to IVF centers to assist them in patient counseling.
 - Offers fertility tests at discounted rates and provides counseling through an infertility specialist, for example DrAnup, DrMallika, DrSabhaMajumdar, DrKaveri, DrKuldeep Jain—activity is conducted every alternative month.
 - Conducts clinician-specific activities such as CMEs and RTMs.
 - Offers schemes ranging from 100%-110% discounts on products.
- Bharat Serum & Vaccines have two division in Gynecology & Infertility range
(Coverage of approximate 20,000 Gynecologists)

LG LIFE SCIENCE

- Focuses only on institutional sales. Target customers– leading institutions and corporate hospitals.
- Key strategies pursued by company include:
 - Conducts CMEs and other activities such as patient awareness programs, OPD camps on regular basis.
 - Provides promotional assistance to ART centers.
 - Offers lucrative discount schemes on products.

MSD

- Markets its recombinant products to IVF specialists and leading gynecologists with infertility practice through field force of 21 personnel.
- Key strategies pursued by MSD are:
 - Offers discounts ranging from 50%-100% and free samples to target customers.
 - Counseling to patients on ART.
 - Training of paramedical staff regarding use of recombinant FSH during ovulation and induction.

OTHERS

- Sun Pharma have strategic tie up with Reliance Life Sciences for manufacture and supply of recombinant FSH.
- Intas has recently launched its recombinant FSH in market and is targeting gynecologists and select CPs and GPs along with gynecologists with infertility practice and IVF specialist.

IVF SPECIALIST PERCEPTIONS(121)

Recombinant product consumption among IVF specialists is higher than among gynecologists. Recombinant products are believed to be more efficacious in addition to promoting rapid growth of follicles.

10% clinicians prescribed recombinant products as 1st line therapy in combination with clomifene citrate for rapid recruitment of follicles. Approximately 5-6% of the clinician were also found to use rHCG (Ovidrel) along with rFSH for the treatment of infertility.

FACTORS FOR HIGH USAGE OF RECOMBINANT PRODUCTS AMONGST IVF SPECIALIST

Clinicians gets the desired outcome from usage of Clomifene citrate along with recombinant product combinations.

High price of the products tends to increase the therapy cost and is not affordable by all category of patients, thus the usage of recombinant product is dependent of socio economic class of patient as well. Although the cadre of patients visiting IVF clinics belongs to high middle and middle income group thus the usage of recombinant products is high in IVF centers as compared to gynecologists.

PARAMETERS FOR DRUG THERAPY SELECTION

IVF specialists cited efficacy and safety as key parameters in therapy selection. Cost emerged as key criterion for selection of recombinant products.

Use of recombinant products is primarily driven by patient's socioeconomic status. Cost is perceived as only hindering factor for prescription of recombinant product whereas in efficacy and safety terms recombinant products were perceived to be superior, leading to high usage among IVF Specialistpatients by assisting them in diagnostic procedures and medication.

PARAMETERS FOR BRAND SELECTION

IVF specialists cited availability of fertility portfolio as a key factor in therapy selection. Efficacy and cost effectiveness plays critical role in brand selection.

We also observed that IVF centers introduce packages for all patient groups therefore, inclusion of medicine in packages, determines cost of package and therapy.

Choice of treatment

<u>IUI</u>	<u>IVF</u>
● Ovulation problem ● Premature ejaculation ● Unexplained infertility ● Clomifene citrate as a 1st line drug in combination of urinary and recombinant product	● Poly-cystic ovarian syndrome ● Advanced age of patients ● Damaged/blocked fallopian tubes ● Male factor infertility ● Unexplained infertility ● Failure of IUI

GYNECOLOGIST PERCEPTIONS(129)

Gynecologists primarily consider urinary drugs as preferred formulation type for infertility treatment. Urinary products are also prescribed as 2nd line of treatment both alone or in combination with clomifene citrate. Hucog was the most preferred brand because of: High efficacy, Proven results, Cost effectiveness.

Around 5%-8% of clinicians prescribing urinary products also favor highly purified urinary products such as Ovugro HP, GMH HP and so on. However, use of HP products was limited on account of high costs.

FACTORS FOR LOW USAGE OF RECOMBINANT PRODUCTS

High costs, Efficacy similar to that of urinary products, Low focus of pharmaceutical companies on gynecologists for promotion of recombinant products, Lack of promotional activities among gynecologists translates into low awareness of recombinant products.

Use of recombinant products was high in South India compared to North and West India—because of high awareness among clinicians and patients in southern region.

PARAMETERS FOR DRUG THERAPY SELECTION

Gynecologists rated efficacy and safety as the most important parameters in therapy selection. Cost along with easy availability of urinary products on the retail chemists was also perceived as an important factor by clinicians.

Gynecologists perceived the efficacy of recombinant similar to that of Urinaries, whereas self experience of clinicians with urinary products was a major contributing factor in drug therapy selection.

PARAMETERS FOR BRAND SELECTION

Lupi HMG, Hucog and Humog were the most preferred urinary brands among gynecologists

Gonal F, Folligraf and Fostirel are the most highly prescribed recombinant brands. Gonal F enjoys good brand equity among gynecologists; however, its consumption is limited on account of high costs.

GYNECOLOGIST vs IVF SPECIALIST PERCEPTION ON RECOMBINANT THERAPY

Clinician cited cost as a determining factor for the selection of the therapy. However in case of gynecologists this factor was rated as most important along with perceived efficacy of the product.

Most of the gynecologists perceived that there is no added benefit of using recombinant products over urinary products as the end results of both the category of products were found to be very similar in their practice.

Availability was also an important parameter for selection of the drug as most of the pharmaceutical companies target only IVF specialist for promotion and distribution of the recombinant products. We also observed regional differences in availability of the recombinant drugs. There is a persistent need of training and awareness amongst gynecologists on usage and benefits of recombinant products.

FACTORS FOR TREATMENT CHANNEL SELECTION

There are numerous factors responsible for selection of clinicians for infertility treatment. Gynecologists are first line of reference for treatment and management of infertility. Selection of gynecologists is also driven by convenience and apprehension amongst patients about infertility, especially in rural and suburban areas.

Approximately 40% cases received by IVF specialists are referral cases from gynecologists and consulting physicians.

To lure patients, IVF centers are introducing IVF/IUI packages and promoting those facilities through advertising and marketing.

Strategic tie-ups with diagnostic labs and referral fees to referring clinicians can be given. Separate marketing division to promote clinic/center and Tie -up with pharmaceutical firms for supply of medicine and assistance to market center.

EMERGING AVENUES IN IVF TREATMENT

There is an emerging trend for IVF center promotion through advertising and introducing attractive packages to lure patients. Many IVF centers have patient referral tie-ups with gynecologists and other clinicians who are first line of contact for infertility treatment.

International marketing is also an emerging avenue for infertility treatment. This mode of promotion is more prominent in corporate and chain hospitals.

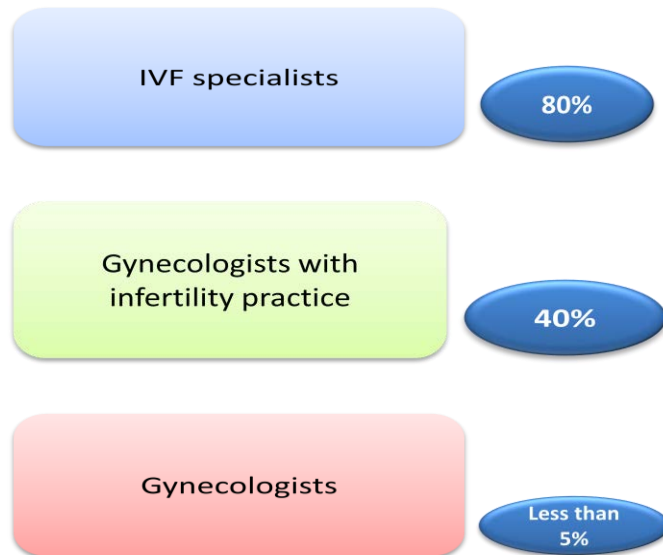
TRAINING REQUIREMENTS

Gynecologists are the first line of reference for infertility treatment in India; they also account for a greater chunk of clinicians who refer patients to IVF specialists and other gynecologists with infertility practice.

All gynecologists interviewed, mentioned that no pharmaceutical company or any other organization extends assistance in terms of training programs to clinicians for infertility treatment beyond primary therapy. Many pharmaceutical companies do not promote high-end infertility products such as recombinant follitropins to gynecologists.

About 25% gynecologists were interested in pursuing training to enable themselves to treat infertility; additional 7% gynecologists demonstrated interest in receiving training provided they are assisted by pharmaceutical companies.

MARKET PENETRATION OF GONAL-F AMONG SAMPLE POPULATION



Gonal F was mostly prescribed by IVF specialists, followed by gynecologists with infertility practice. However, a large proportion of clinicians perform IVF cycles with urinary and biosimilar products. Limited focus of pharmaceutical companies on gynecologists which can be attributed to their low infertility patient base. Greater focus on promotion of Gonal F among gynecologists and gynecologists with infertility practice will help Client to increase its market share.

Gonal-F was used in IUI cycles after failure of Clomefene cycle, due to the Confidence of clinician in recombinant therapy over urinary therapy in IUI procedure and Economic eligibility of patient

There is a huge scope for growth in infertility treatment by conversion of urinary protocols into recombinant protocols.

South India accounts for approximately 42% of total Gonal-F sales, followed by North at 28%. So, Increased promotional activities in low sales regions will help Client to increase its brand equity uniformly across India

DISSCUSSION

REQUIRED INTERVENTIONS AT CLINICIAN LEVEL

Regional equilibrium: Client is a market leader in the recombinant segment, although the position of the company is not alike in all regions. For example in the southern region the equity of the company is perceived to be very high as compared to other regions of India. Thus Lintac would recommend Client to increase its marketing activities across all the regions to enhance its share.

Focus on rural and suburban market: Infertility is considered as rampant and rising steadily, clinicians included in the study indicated that the patient population from rural and suburban areas has also increased, Client needs to expand its focus on cities other than metro and tier I cities.

Focus on gynecologists: Merck Sereno has inadequate coverage and substantially very low focus within the gynecology segment. Merck Sereno needs to take the initiative to reach out the gynecology community by educating them about infertility practice which will enable them to prescribe recombinant products for the treatment of infertility.

Education program and trainings: Orientation of the education program and trainings with specific requirements of target clinicians. Hands on training and workshops on treatment protocols and basic therapies for infertility treatment, to aspiring gynecologists.

Availability: As availability of recombinant product was rated low as compared to urinary products. Lintac suggests Client to establishment of robust distribution channel for coverage of target regions.

REQUIRED INTERVENTIONS AT MARKET LEVEL

Penetration in urinary cycles: IUI is a difficult segment to penetrate due to extreme price pressure and presence of more than 60 players in the segment. Client can tap the market by penetrating into urinary IVF cycles by conversion of urinary cycles into combo cycle thus increasing use of recombinant in existing cycles.

Discounted diagnostic packages for patients: As per Lintac's previous experience in other chronic therapeutic areas, Client can associate with the selected IVF centers to provide the assistance in diagnosis of the disease in terms of providing free/discounted packages such as hormonal level test, USG and so on to the patients in collaboration with IVF centers and IVF specialists.

This would help Client to increase its brand penetration and usage amongst IVF specialists. Lintac would recommend Client to associate with the IVF centers and to get the brand included in the various packages offered by the center.

Introduction of combo package: Client could possibly come up with a combination package containing rFSH and uFSH in a single package offering. This model would assist Client to increasing the penetration of recombinant products in the price sensitive clinicians. It would assist the company in conversion of urinary cycles into combo cycles and increased use of Gonal-F in pick up cycle.

In other therapeutic segments like Diabetes and Oncology, many of the companies introduced combinations or bundle packages, combining branded product with the generic product like MSD launched its blockbuster molecule Sitagliptin in 2008, which was followed by launch of combination product of Sitagliptin with Metformin in a single combo package. Presently Sitagliptin+Metformin is a preferred brand of choice and have surpassed the sales of the original single package molecule, Sitagliptin.

Combination package: Lintac recommends Client to come out with a combination package offering the main target product with a supporting product, used for the infertility treatment.

IVF specialists suggested that they tend to use urinary products towards the end of the cycle to limit the overall cost as amount of Gonadotropin used in one IVF cycle is almost equivalent to amount of Gonadotropin used in 3-4 IUI cycles.

Price reduction: Very few clinicians preferred full rFSH therapy and most protocols were either combo or urinary protocols. 10% non users demonstrated interest in prescription of rFSH provided it is available at lower prices.

RECOMMENDATIONS

Strategic tie ups

Lintac recommend Client to establish strategic tie up with the potential institutes and organization for assistance in infertility treatment. Tie up with IVF centers and to collaborate and register recombinant product with in government reimbursement segments such as CGHS, ESIC, Defense, Railways, State Governments, PSUs and so on. Also a market research study within reimbursement segment to understand business dynamics for infertility segment was recommended.

Training & Education

Training & education evolved to be a dire need especially in case of gynecologists. Lintac recommend client to initiate a training launch pad for the budding gynecologist aspiring to be an infertility specialist /IVF specialists. Client could collaborate with the selected IVF centers for conduction hands on training under eminent IVF experts. Also Client should work out a model of training and certification for the interested clinicians in the field of infertility. This will not only help in expansion of infertility clinician base but would also create the loyal customers for Client.

Co-promotion

Client should strategically tie up with a potential organization for exclusive co-marketing of the target product as it would assist Client in expanding the market coverage. Lintac believe that Serum Institute of India is a potential partner for the co marketing alliance due to the availability of trained sales force, Wide product portfolio, Good brand equity in market, Experience of handling recombinant product, Strong distribution network and Good presence in reimbursement institute.

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KEY DEFINITIONS

<u>ITEM</u>	<u>DEFINATION</u>
Gynecologist	A medical clinician dealing with the health of female reproductive system and treating infertility upto primary level.
Gynecologist with infertility practice	A medical clinician treating infertility patients by carrying out IUI procedures along with other common problems of female reproductive system.
IVF Specialist	A medical clinician specialized in advance infertility treatment procedures like IUI IVF and so on.
Biosimilar	Biosimilarare the officially approved subsequent version of innovator biologic drug, produced by different organization.
IVF Procedure	In vitro fertilization is an advance method of assisted reproductive technology in which the egg is fertilized by sperm outside the body.
IUI Procedure	Intra uterine insemination is a process in which a best lot of sperms is put directly inside uterus at the expected time of ovulation.