Plasma Fractionation Industry Project in Turkey: Country's Experiences

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Plasma fractionation products (PFP) have been supplied by importation in Turkey since decades. Last decade this importation had a great increase due to several reasons.

Importation of plasma fractionation products is under the strict regulations of Ministry of Health (MoH) in Turkey. Blood collection is also under the control of MoH by "Blood and Blood Products Law" which is recently renewed at 14th April 2007.

Depending on the increased experience of the clinicians and awareness of the patients, motivation of the producers, population increase importation of plasma fractionation products is an important business in Turkey which will keep its position for more decades.

I. Market Analysis of Turkey for PFP

Most of the PFP producers have been in Turkish market since decades. Current list of those producers are listed below;

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Most of the PFP producers have been in Turkish market since decades. Current list of those producers are listed below;

a) Talecris
b) Baxter
c) Octapharma
d) Grifolds
e) Biotest
f) Behring
g) LFB
h) BPL
ı) Sanquin CLB
j) ISI
k) Centurion Pharma

List of the imported PFP are listed below;

1) FVIII
2) FIX
3) IVIg
4) Albumin
5) Anti-D Ig
6) Hiper immune IgG (HBV)

Turkey has around 72 000 000 population. Estimated annual need of plasma products are calculated below (table1:)

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Product Type	Estimated Annual Need
Albumin	200 kg / 1 million population / year x 72 =14 400 kg
IVIg	12,5 kg / 1 million population / year x 72 =900 kg
FVIII	60 patient /1 million population x 72 x 20 000 iu / patient / year = 86 400 000 iu
FVIX	86 400 000 iu ÷ 3 =28 800 000 iu

Table1: Estimated Annual Need of PFP

Compared importation quantities and importation costs of the 4 major PFP and estimated actual gap for national self – sufficiency in PFP are listed below (table: 2, 3, 4);

Product	National Need	Importation (2004)	Importation (2006)	Increase (%)
FVIII	86 000 000 iu	38 039 500 iu	54 690 000 iu	% 43,7
FIX	30 000 000 iu	6 467 300 iu	8 375 700 iu	% 29,5
IVIg	900 000 gr	649 288 gr	450 744 gr	% 31*
Albumin	14 400 000 gr	4 688 930 gr	5 441 442 gr	% 16

Table2: Compared importation quantities of the 4 major PFP

* Due to product shortage

Product	Importation Cost (2004)	Importation Cost (2006)	Increase (%)
FVIII	13 313 825 €	24 610 500 €	84,8
FIX	3 168 977 €	4 187 850 €	32,2
IVIg	16 985 374 €	19 431 573 €	14,4
Albumin	12 988 336 €	16 215 497 €	24,8
TOTAL	46 456 512 €	60 257 570 €	30

Table3: Average importation cost of the 4 major PFP

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Product	Annual Need	2006 Importation	Gap %
FVIII	86 000 000 iu	54 690 000 iu	% 36
FIX	28 800 000 iu	8 375 700 iu	% 70
IVIg	900 000 gr	450 744 gr	% 50
Albumin	14 400 000 gr	5 441 442 gr	% 62

Table 4: Estimated actual gap for national self – sufficiency in PFP

II – Plasma Source (Raw Material) For PFP

Main cost of the PFP comes from the cost of the raw material; human originated fresh frozen plasma (FFP). It is almost 40% of the total production cost of the PFP (diagram: 1).

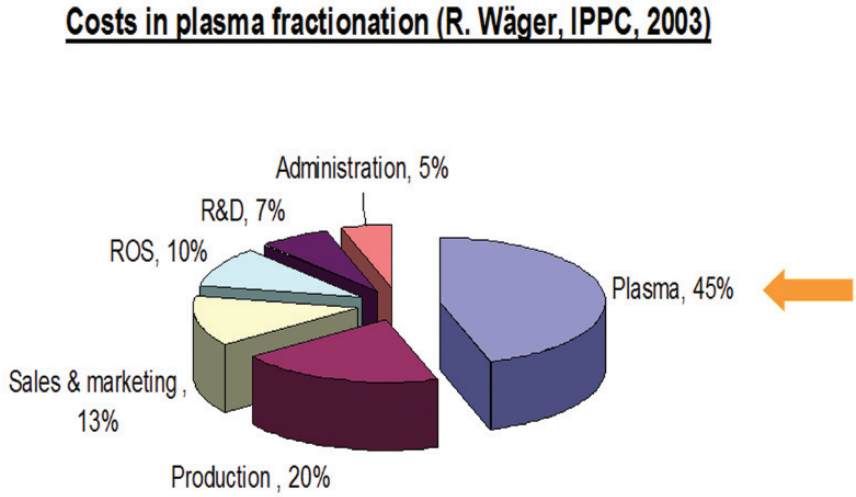

Diagram1: Costs in PFP

PFI supplies its raw material from two sources;

a) Random FFP; this FFP comes from the seperation of the whole blood into components. Each unit is around 0,2 litre and an healthy individual can donate ideally 6 times per year.

b) Apheresis FFP; this FFP comes by apheresis of healthy individual. Each unit is around 0,6 litre - 0,8litre and

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an healthy individual can give 23- 26 times per year. According to European Union regulations a healthy individual can supply 40 litres of FFP per year. This is 48 litres in Food Drug Association (FDA) regulations in US. Each year almost 25 million litres of FFP is used for production of PFP in the world. Details of the FFP source is listed below (table5).

Source	Volume (litre)	%
Apheresis FFP	17 648 000	% 68
Random FFP	8 471 000	% 32
TOTAL	26 119 000	% 100

Table5: FFP sources of the PFI

Main raw material source of FFP comes from plasmapheresis. US is the main supplier of apheresis FFP to the PFI all around the world. Usually each machine performs 1 000 plasmapheresis per year and collects around 600 litres of FFP.

Annual blood collection in Turkey is around 1 200 000 units / year and Turkish Red Crescent (TRC) supplies around 1 000 000 units / year. Rest is collected by hospitals.

Blood collection is also under the control of MoH by "Blood and Blood Products Law" which is recently renewed at 14th April 2007. Private and paid blood collection are not allowed by this law but some promotions can be given to the donors.

Blood consumption of Turkey has been switched from around 96% whole blood to 40%. TRC stoped to issue whole blood to the hospitals for transfuson since 2005.

III – Legal Status for PFP

PFP are accepted as pharmaceutical products in Turkey like EU and US. Importation of plasma fractionation products, FFP sources of Turkey and local PFI are under the strict under the control of of MoH by "Blood and Blood Products Law" which is recently renewed at 14th April 2007.

Turkey has accepted to comply EU pharmacopei in pharmaceutical products almost a decade. Local PFP should comply EU pharmacopei.

IV – Basic Technical Information of PFI for Turkey

Annual production capacity of the lo-

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cal PFI will be 150 000 litres which will be increased to 250 000 litres by minor modifications.

Production technology will be based on modified Cohn fractionation. Safety and purity wise the production technology should have highest standarts. Basic products, their main spesifications and the minimum estimated yields will be as below;

a) FVIII; double virus inactivated (one should be S/D) with the minimum yield of 180 iu/litre

b) FVIX; double virus inactivated (one should be S/D) with the minimum yield of 250 iu/litre

c) IVIg; double virus inactivated (one should be S/D) with the minimum yield of 3,5 gr/litre

d) Human albumin with the minimum yield of 27 gr/litre

V – Basic Finacial Information of PFI for Turkey

Finacial part of this Project should be evaluated under 2 main topics;

1) Establishment cost of the plant

a) Cost of detailed project preperation

b) Cost of construction

c) Cost of equipments & installation

d) Cost of technology transfer

e) Cost of acreditation

f) Cost of testing production

g) Cost of the land

h) Establishment cost of apheresis centers

2) Production cost of the plant

a) Cost of FFP

b) Cost of consumables

c) Cost of labour

d) Cost of administrative activities

e) Cost of marketing & sale

b) Cost of insurances (product, plant, etc)

c) Cost of R & D

Depending on our dedicated interest to this field since 1994 and previous activities in Turkey for having a local PFI; we estimate that establishment cost of the plant will be returned to the investor around 6 or 7 years.

Actual confirmation of the finacial figures should be necessary. This finalization should be done with a selected experts. Cost of this service is will be covered by the investor.

VI – Human Resource

There will be no major problem for qualified local staff for runing the PFI. 1 or 2 core staff will be employed for a limited period.

VII – Time Table

After the compliting all official procedures 36 – 40 months will be enought to starting the production

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at local PFI.
"Toll fractionation" can be used not only as aquality control mechanism of the potential know how transfer company but also as a financial income untill the plant will start production.

VIII – Conclusion

PFI had great profits between 1990 and 2000. This high profit gradually came to acceptable levels. Even the field is not as profitable as before stil it is a good field to invest.
80 % of the patients who need FVIII and FIX, 96 % of the patients who need Ig, 97 % of the patients who need alpha –1 antithyripsin can not get those products. Cost and/or shortage of the products are the reason of this insufficiency. Because of this reality PFI has targeted their affords to "emerging countries". Emerging countires have high population, high birth rate, high incidence of illnesses due to various reasons, etc but they can afford the cost of PFP. Turkey is already a big market which will keep its position for decades.

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