Chapter 8

THE POLITICAL ECONOMY OF DRUG QUALITY

8.1 INTRODUCTION

According to the neoclassical economic paradigm, goods may be broadly classified into three groups in terms of quality. First, there are ‘search goods’, whose quality can be ascertained by the consumers before purchase. Second, there are ‘experimental goods’, whose quality is revealed to the consumer only after it is bought. Third, there are ‘credence goods’, whose quality can rarely be ascertained even after consumption.\(^1\) To ensure minimum quality standards of credence goods, regulatory intervention by extra-market forces becomes essential. Medicines, by and large, fall under the credence goods category. Therefore specification and monitoring of quality standards in pharmaceuticals becomes a very important issue, driven by a complex political-economic process.

Earlier, physicians used to dispense medication (usually a simple mixture of various chemicals and plant materials) as part of the treatment process and the quality of medicines was monitored by the physician himself. Gradually, mass production of medicines (chemical and pharmaceutical manufacturing) started replacing this traditional method of ready-made mixtures made by physicians. The process of production and distribution of medicines became increasingly complex. New sets of economic agents like the manufacturer and the dispenser got involved in the process and the role of the physician became limited to prescribing medicines. Specification and monitoring of the quality of medicines now became an important issue, given the divergent objective functions of the different agents involved in the process.

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Developed countries responded to this problem by designing a pharmacopoeia, which specified the production process (technology) and the quality parameters of all drugs in details and by establishing an independent regulatory authority to screen all pharmaceutical products before it is brought to the market. Less developed countries, however, have largely ignored this issue. Although some of the LDCs, e.g. India, developed a pharmacopoeia, not much attention was paid to the question of medicinal quality.

The perspective has suddenly changed in LDCs in the last decade. The issue of medicinal quality has now gained particular importance in the Indian pharmaceutical industry as a result of a complex process of a new global order of liberalisation and globalisation characterised by a stricter IPR regime, a fast moving global technological frontier and a move towards international harmonisation of quality. There has been significant rethinking about quality of medicine across the board leading to structural changes in the process of technology generation as well as production organisation in the Indian pharmaceutical sector.

The objective of this chapter is to present an analysis of the political economy forces underlying this new conceptualisation of quality, the resultant structural changes and its consequences. This chapter is divided into 7 sections. In the following section 8.2 we describe the dynamic evolution of the concept of quality as a multidimensional construct. Section 8.3 presents an analysis of the perception of drug quality in India and how this perception has been changing with the emerging world order of the 1990s. Section 8.4 analyses the impact of increasingly stringent drug quality on employment and factor rewards. Section 8.5 traces the emerging market structure, while section 8.6 analyses quality led export and its impact on domestic output. Finally, section 8.7 draws some broad conclusions.
8.2 CONSTRUCTION OF QUALITY

The concept of medicinal quality has not remained static. It has evolved historically over time according to several social, economic, scientific and technological considerations. Some of the medicinal tragedies shaped the construction of quality specification and regulation. In the United States a tragic mistake in the formulation of a children's syrup in the 1930s was the trigger for setting up the product authorisation system under the Food and Drug Administration. In many countries in Europe the trigger was the thalidomide tragedy of the 1960s, which revealed that the new generation of synthetic drugs, which were revolutionising medicine at the time, had the potential to harm as well as heal. In the late 1950s, thalidomide was approved as a sedative in Europe. The drug was originally taken because it was believed to control sleep and nausea throughout pregnancy, but it was soon found that taking this drug during pregnancy caused severe deformities in the fetus. Many patients did not know they were taking an experimental drug nor did they give informed consent. Some 12,000 babies were born with severe deformities due to thalidomide. This tragedy proved to be a turning point in the conception and regulation of drug quality. The U.S. Senate 1962 passed the so-called "Kefauver Amendments" to the Food, Drug and Cosmetic Act into law. The amendments were passed to ensure drug efficacy and greater drug safety. For the first time, drug manufacturers were required to prove to FDA the effectiveness of their products before marketing them. Prior to this, marketing of drugs would require quality certification in terms of the presence of ingredients in quantities specified in labels.

Quality and the Pharmacopoeia

UK and USA were the pioneers in introducing the concept of pharmacopoeia in the early nineteenth century. The pharmacopoeia contributes to the overall control of the quality of medicinal products and provides a publicly available statement concerning the
quality of a product or any of its components that the drug is expected to meet at any time during its period of use. In a way, the pharmacopoeia acts as the regulatory body to specify and monitor quality of medicines as credence goods.  

Initially, physicians dominated the composition of the pharmacopoeial committee in both the USA and UK. In course of time, pharmacists were also given an important role in the designing of the pharmacopoeia. With the progress of the art and science of medicine and pharmacy, experts from other fields like chemistry, engineering, biotechnology, bio-informatics, gene-therapy etc. were brought on board. The users of the pharmacopoeial specifications, like, manufactures, suppliers, health-care professionals, patients (or those acting on their behalf) were also involved in the pharmacopoeial decision making process. Such a heterogeneous and diversified composition of the pharmacopoeial committee has resulted in the evolution of quality as a multi-dimensional concept.

A Comprehensive Multi-dimensional Definition of Quality

A comprehensive definition of quality should describe all conceivable quality-parameters as perceived by different sets of economic agents (producers, pharmacists, physicians, patients and the government) involved in the specification of quality standards for medicines.  

First and foremost, quality must be linked to therapeutic efficacy and safety. In other words, the final formulation must be effective in treating the patient. But at the same, a high quality drug should not produce any toxicity or side effects.  

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2 According to the mission statement of USP adopted in 1990-95: “The United States Pharmacopoeia promotes the public health by establishing and disseminating the officially recognised standards of quality and authoritative information for the use of medicine and related articles by health care professionals, patients and consumers.”

3 One should note that standard economic theory has often assumed quality to be a unidimensional concept, where better quality means more product services relative to the cost of production. See, for instance, Grossman and Helpman (1991).

4 The Thalidomide Tragedy of 1962 added new dimensions to this safety aspect in quality specification and control.
A second and most commonly stated parameter of quality pertains to the impurity profile and stability of chemical ingredients, which have been subjected to increasingly stringent specifications. Another related quality parameter affecting product purity is contamination during the production process. In recent years, this dimension of quality has assumed greater importance especially in technologically advanced nations. The emphasis is not only to reduce impurity, but also to maintain consistency in the specified impurity profile over all batches of production irrespective of the varying locational, climatic, technological, skill and input conditions. This consistency of impurity profile is to be monitored not only at the final stage, but also at different intermediate stages in the production process through in-process checks. Such in-process check also minimises costs by reducing the rate of rejection and batch failures. Detailed documentation of all the production stages along with the quality control operations constitutes an added dimension of quality specification as it creates institutional memory and makes the entire production process transparent to all concerned parties.

The third set of quality parameters considers environmental issues. The production process should be environment friendly and should not create any health hazards within and outside the production unit. The intermediates and excipients of the production process must be non-hazardous and environment-friendly.

The relative importance of each of these diverse parameters in the final quality specification would vary from country to country depending on the composition of the pharmacopoeial committee and socio-economic priorities of the government.

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5 There is evidence that a lenient but consistent "between batch" specification is preferred to a more stringent (with stricter upper and lower limits of permissible quality variations) but fluctuating specification.

6 Consequently, there has been a rising tendency towards automation of the production technology to eliminate input variations, human touch, and produce consistent batches with detailed documentation. The far-reaching socio-economic impact of this increased automation will be discussed later.

7 Increased automation might take care of the problems of "unsafe" contact of labour with hazardous chemical ingredients and processes. Another way to solve the problem is to replace chemical processes by bio-technological processes as being done in developed nations.
Even within a fairly heterogeneous compositional structure, the *British Pharmacopoeia* (BP) continued to be dominated by Physicians. Accordingly, the quality specifications in BP are perhaps largely guided by patients' well-being, focusing primarily on therapeutic efficacy and safety.

The *US Pharmacopoeia* (USP) on the other hand remained largely in the hands of pharmacists and technologists. Accordingly USP's objective has been to establish drug standards using *state-of-the art technology* and to *keep pace with technological progress* in various fields. "*As science and technology evolve so do USP standards to keep pace with the evaluation of scientific truth*". For instance, the remarkable transition in the technology of drug standardisation and medicinal chemistry in the decade 1950-60 was promptly incorporated in the USP. The USP specifications have thus evolved with an in-built bias towards increasingly stringent norms for impurity profile through sophisticated instrumentation and analytical methods.

Likewise almost all developed countries independently designed their own quality specification and regulatory standards for pharmaceutical products. Although different regulatory systems were based on the same fundamental obligations to evaluate drug quality, the relative emphasis on different quality parameters might have varied according to the nature of the dominant pressure group(s) in the regulatory body. As a result the detailed technical requirements for quality specification and control differed across countries. Perhaps this divergence widened over time.

The industry in USA and Europe, at the same time, is becoming more international and seeking new global markets. But registration of medicines remains a responsibility of the national governments as per their independent regulatory mechanisms. Their divergent technical requirements compel the industry to replicate

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8 See USP-23 (1995-2000) page: liii
many test procedures including clinical trials in order to market new products in different countries. This raises not only their financial costs but also the time cost by shortening the effective life-span of the new drug in face of limited patent period and a fast moving technology frontier.

To overcome this problem, the governments of the three largest pharmaceutical markets (US, EU and Japan) have jointly initiated a move towards harmonisation of drug quality through the International Conference on Harmonisation (ICH) from the late 1980s. The urgent need to rationalise and harmonise regulation has been stated to be “… impelled by concerns over rising costs of health care, escalation of the cost of R&D and … delay in making safe and efficacious new treatments available to patients in need.”

However the genesis of quality harmonisation can be traced back to the Belgium Conference in 1902. The USP has been particularly active since the 1930s in establishing international standards for pharmaceuticals, unification of pharmacopoeias and creating a Pharmacopoeia Internationalis (PhI) under the auspices of the World Health Organisation. The latter draws heavily upon the USP. It is worth noting that USP’s stated objectives include: (1) becoming a global leader in providing authoritative standards and information for pharmaceuticals and related products and technologies, (2) making USP information, products and services relevant to the special needs of culturally, demographically, economically and socially diverse populations, (3) becoming more effective in ICH. It is not difficult to foresee the direction in which the quality harmonisation is likely to proceed. The philosophy of the USP will perhaps dominate the overall framework for unification of quality standards.

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9 This bias could also be a reflection of the litigation-prone US society. Documentation of a stringent impurity profile would protect the manufacturer from legal action in case of drug failure.
8.3 QUALITY IN INDIA

Quality in the Pre-1990 era:

The issue of medicinal quality has never been given adequate importance in less developed countries. In fact, very few LDCs have designed any pharmacopoeia and if at all, rather loosely specified as in India. Particularly quality parameters like impurity, consistency and documentation have been largely ignored. This may be due to several reasons.

First of all, firms have to incur various fixed and variable costs in order to conform to high quality specifications: fixed costs of sophisticated quality control equipment and variable costs of documentation and employment of high skilled personnel to monitor quality. This would translate into higher price for medicines with higher quality specifications, irrespective of whether the firm follows mark-up pricing or marginal cost pricing. Given India’s skewed income distribution, policy makers often face a trade-off between ‘high quality to few people’ and ‘moderate quality to the masses’. The second option has been given priority in India and therefore strict quality specification and enforcement received less attention.

Secondly, the large firms can spread the fixed costs associated with high quality over larger quantities of output, reducing the average cost. This means that larger firms will be able to conform to higher quality specifications more efficiently than small firms. India’s policy stance to protect small and medium entrepreneurs prevented it from imposing strict quality requirements.

The administrative cost of monitoring the quality is also prohibitively large in country like India, with thousands of small-scale producers actively participating in drug manufacturing. This has been made possible because there are no major economies of

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10 See website www.ifpma.org
scale in the production of pharmaceuticals and the knowledge of the production process (the chemistry formulae) acts as the only criteria to enter the market, especially within a weak IPR.

A third reason could be the lack of awareness about the environment and pollution. Prior to the emergence of a strong environmentalists’ lobby in LDCs recently, there was a widespread belief that LDCs have low share of global pollution and therefore a higher assimilative capacity. The shadow price of pollution measured in terms of scarcity of natural resources will be lower encouraging the use of plentiful ‘hazardous’ chemicals against ‘scarce’ non-hazardous ones.

As a result of a loosely specified Pharmacopoeia, the quality of medicines in the pre-1990 era has, by and large, remained far below the international standards.11

Post-1990 and the New Global Order

The new global order of the post-1990 has been characterised by a strict IPR regime, a fast moving technology frontier and a move towards international harmonisation of quality standards. Within a weak IPR regime, most Indian manufacturers have been surviving in the market by introducing new formulations with known (patented) molecules but based on non-infringing processes. Imposition of a strict IPR will severely limit the scope of this business and restrict the firm to the production of off-patented drugs only. To survive and maintain a steady growth path the firm will have to explore the growing international market for generic drugs, the US market in particular. Entry into this highly competitive market calls for stringent quality requirements. Indeed with the threat of ICH, not only US but the entire global market may be subjected to stricter quality norms.
In fact, recent World Trade Organisation (WTO) regulations have also paved the way for stricter product standards. WTO believes that product standard, technical regulations and certification systems are essential for effective functioning of modern economies.\(^\text{12}\) While standards are voluntary, and often specified by industry or other non-governmental organizations, regulations are mandatory and are believed to be imposed to safeguard "public, and animal health and environment".\(^\text{13}\) A transparent certification system should comprise of procedures to be followed by the producers in order to conform to the relevant standard or regulation. WTO does not specify any "standard", as it is believed to hamper free trade. But the use of the same has been justified on the above mentioned grounds. According to Hoekman (1995) "... central government bodies must follow MFN to all member countries in dealing with the adoption of technical regulations and standards and ensure that these are not more trade restrictive than necessary to fulfill a legitimate objective."\(^\text{14}\) However, sticking to its primary objectives of MFN, WTO directs to open local certification systems to foreign producers also. The government should also notify the regulatory norms used in domestic production to all its trading partners.

This has compelled Indian manufacturers to pay renewed and intensive attention to the concept of drug quality, which was hitherto largely ignored. To conform to international quality standards in its mutli-dimensional character, the following operational and organisational changes are taking place in the pharmaceutical sector:

(i) Quality control has been made much more rigorous with stricter parameters and sophisticated instrumentation. From the earlier concept of statistical quality

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\(^{11}\) Even the minimum quality standards specified by such loosely defined pharmacopoeia has often not been met in LDCs due to sub optimal vigilance and a lack of public awareness. Sub-optimal vigilance may often be a result of corruption.


\(^{13}\) See Hoekman (1995).

\(^{14}\) Emphasis own.
control of raw materials and final products, quality assurance has now become much more complex incorporating stringent *in-process checks* to maintain strict quality requirements throughout the production process continuously and minimise rejection or failure at the final stage.

(ii) To meet the high quality standards, production technology is being upgraded. Many erstwhile manual steps are being replaced mechanised processed. This has a three-fold objective of minimising “human touch” to avoid contamination, producing consistent batches without human errors, and enhancing compatibility of in-process testing equipment with production technology to facilitate sophisticated in-process quality checks.

(iii) The environmental dimensions of quality necessitate increased attention towards effluent treatment and proper waste management using modern methods and equipment.

(iv) Detailed documentation is becoming an important facet of production and quality control.

(v) Finally, quality has added a new dimension to their R&D thrust. Firms are now trying to develop new improved analytical methods for quality specification and control. Some Indian firms have already succeeded in developing superior methods, which have been incorporated in the global quality standards like USP and European Pharmacopoeia (EP). In a sense, Indian players have thus contributed to outward shifts in the global frontiers of drug quality.\(^\text{15}\)

The first four elements entail increased automation of the production process with its consequent implications for employment, factor prices, costs and market structure.

\(^{15}\) Grossman and helpman (1991) also consider such quality raising R&D in a growth theoretic model. They conclude that sustained growth requires continuous R&D to increase the average quality of industrial products.
Element (iv) has additional implications for costs of production. Element (v) will have implications for market structure and price.

8.4 QUALITY, EMPLOYMENT AND FACTOR PRICES

8.4.1 Quality, Automation and Employment

Automation has a direct impact on the level and composition of employment. Automation leads to replacement of labour by machine both in production and as well as in quality control.

In the production shop floor, automation will displace unskilled labour intensive processes. The task will be performed by sophisticated machines requiring one or two semi-skilled (trained) labour per machine at the supervisory level. This will perhaps result in a compositional shift in employment from unskilled to skilled or semi-skilled labour, although both are likely to reduce in absolute terms as a result of automation. In fact, if firms do not undertake training (or re-skilling) programmes, then automation might result in the replacement of the existing labour force by an altogether new one. Automation in quality control, however, might lead to displacement of skilled labour (scientific personnel) by sophisticated machinery operated by semi-skilled operators. In that case the skill composition will tilt in the opposite direction as suggested by Ure (1835). Gross employment of both categories will reduce nevertheless.

The process of automation will lead to alienation of labour from the entire production process as postulated by Marx. The labour force would be confined to less technical departments like packaging and will no longer be able to relate to the production process in totality. The Marxian alienation will contribute to the erosion of labour’s bargaining power and control of the production process in favour of the entrepreneurial class. This process will be reinforced with the reduction and fragmentation of the labour

\[16\] In his opinion mechanisation reduces the requirement of ‘skill’ (journeymen of experience) in favour of ‘unskilled labour’ (children).
force coupled with a threat of increasing automation even in the labour intensive less technical segments. Therefore, it will be difficult to protect labour's interest in terms of employment (preventing redundancies) and real wages with rising automation in the pharmaceutical industry.

The excess supply of unskilled labour created by automation in this pharmaceutical, ceteris paribus, will perhaps create a Lewis process at the macro level. The precise macro impact on labour supply is, however, difficult to predict as it will depend on the growth of the economy and the capacity to absorb this excess labour by other industries.

8.4.2 Quality-driven Exports and Factor Prices

International trade is expected to lower the real wage of the scarce factor of production according to the Stolper-Samuelson process.\(^{17}\) This, of course, presupposes the validity of the Heckscher-Ohlin (H/O) theorem. For a labour abundant country like India, this would imply a rise in the relative factor rewards to labour. Proponents of globalisation and trade liberalisation have often put forward this neoclassical argument to highlight the welfare effects of export expansion in a labour abundant LDC.

In the Indian pharmaceutical sector, we have already argued how the new global order of the 1990s characterised by a strict IPR regime and stringent quality norms has prompted the manufacturers to enter into the global generic market as a strategic response. Prima-facie, this move might appear to lead to an expansion of India’s exports with all its desired welfare effects. However, as we shall examine, such a process of export expansion subject to stringent quality constraints will initiate an anti-H/O process resulting in a fall in the real wage of labour. Our arguments are presented below.

\(^{17}\) See Stolper and Samuelson (1941), pp 66.
As discussed, conformation to new stringent norms of quality standards results in higher level of automation of the production technology. This entails a change in the production function (the isoquant) itself. Rise in automation implies a more capital intensive production structure at all factor price ratios. Moreover, the new production technology will perhaps be represented by a Leontief (L-shaped) production function as capital-labour substitutability disappears. Since this change in technology is driven not by factor price movement but by “quality norms”, the specialised machinery becomes “essential” for meeting the standards and therefore can not be substituted for by labour of any skill.\textsuperscript{18}

One should then ideally consider the high quality and low quality segments of the pharmaceutical industry as into two sub-sectors with distinct production functions. While the high quality sector (H) is highly capital intensive, the low quality sector (L) is labour intensive. As per the factor endowment consideration of the H/O theorem, India will enjoy comparative cost advantage in the production and export of L under free H/O-trade. But the emerging political economy of quality under the new global order alters this scenario by affecting the demand structures for quality medicines. The international market is becoming increasingly quality sensitive with the emergence of ICH and as a result the relative price of H is shooting up in the international market. Whereas the Indian consumer, in the absence of strict quality norms, remains largely indifferent towards H. This international demand bias in favor of H outweighs the India’s cost disadvantage due to factor proportions in producing H and results in a lower relative autarkic price of H in India. With the opening up of trade, the Indian manufacturers will therefore specialise (not completely) in the production and export of H in an anti-H/O

\textsuperscript{18} We further assume that successive addition of machines does not raise the level of automation any further: an operator is always needed to run the machine.
direction. This will lead to reallocation of resources from subsector L to H within the pharmaceutical industry.

Effectively, as the production technology becomes more automated in the face of quality-driven exports, the old labour intensive industry is replaced by a capital intensive industrial structure characterised by a Leontief production function. In this process of reallocation of resources, relatively more labour will be released from the older outfit (L) compared to capital, while the new setup (H) will absorb relatively more capital than labour. This would lead to an excess demand for capital and excess supply of labour resulting in a decline in the wage-rental ratio. This is exactly the converse of what the proponents of free trade would claim in a pure Heckscher-Ohlin-Samuelson (H-O-S) framework, namely, a rise in the returns to labour (the abundant factor) in the face of trade liberalisation and export expansion by LDCs.

The neoclassical arguments favouring liberalisation and free trade in LDCs based on enhanced labour welfare becomes weaker in the face of the new global order of drug quality. Trade, in this case, is not guided by the H/O theory and hence it produces a factor price effect resulting in a decline in the reward of its abundant factor labour.

8.5 QUALITY AND MARKET STRUCTURE

Conventional industrial organisation theory recognises potential economies-of-scale in production as a credible entry deterrent. In the presence of scale economies, the incumbent might prefer to install excess capacity, which can be utilised to expand output in the face of entry-threat. This would lower unit costs of the incumbent and enable him to reduce price. The fear of price cut by the incumbent deters the potential entrant. In the absence of scale economies as in the pharmaceutical industry, a powerful brand name

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may also act as an entry-deterrent. In case of pharmaceuticals this would be possible only with strong marketing skills to build up goodwill among physicians and patients. However, this may prove to be very difficult in case of off-patent old drugs with numerous players in the market.

In the post 1990s, 'quality' emerges as a new entry deterrent in the Indian pharmaceutical industry. We have already argued that quality demands sophisticated (automated) equipment, skilled manpower and detailed documentation, thereby raising both sunk cost as well as variable costs of production. With market imperfections and rationed access to finance and technology, quality could act as an entry-deterrent in LDCs. Its implications for market structure will depend on whether or not strict quality standards are imposed as a norm by regulatory authorities. Under such a norm, all producers who can not conform to the stipulated quality will be weeded out, resulting in an oligopolistic market structure with a limited number of large players having easy access to finance and technology.

Even in the absence of a regulatory quality-norm, the same outcome would follow if all consumers are highly quality conscious rejecting drugs below a stipulated quality. This, of course, is rather unlikely in India with consumers coming from diverse socio-economic backgrounds. The perception of medicinal quality varies with the levels of income and enlightenment. Unenlightened people belonging to economically and socially underprivileged groups (for instance, wage labour and landless farmers) are concerned with immediate (perhaps, short-term) cure to avoid being grounded and loose their daily wage. To them, medicinal quality is reflected only in its immediate effectiveness, rather than other parameters like toxicity, safety or impurity. These parameters become increasingly important with rising levels of income and enlightenment of the consumer. It

20 See Ray (2001b) for detail.
is perhaps the most affluent and enlightened consumer, prone to demonstration effect of
global drug quality specifications, who is concerned with stringent impurity profile and
other safety parameters.

In the face of such a varied perception of drug quality among consumers
determined by diverse socio-economic factors, the imposition of stringent quality norms
by a regulatory authority (representing a democratically elected government) becomes a
complex political-economic process. If the issue of consumer welfare is a predominant
concern of the government, then the political and economic costs of imposing stringent
drug quality norms could prove to be prohibitively high.

In the absence of a stringent quality norm of international standards, the producers
will try to cater to the demands for both high as well as low quality drugs. But with
problems of asymmetric information about drug quality and associated moral hazards, the
standard lemon market phenomenon might emerge whereby low quality drugs will tend to
drive out high quality drugs and could eventually lead to complete collapse of the high
quality market.

However, if the quality sensitive segment of the market comprises of the educated
and enlightened consumers consulting specialist (and highly qualified) physicians, the
producers will perhaps find it less difficult to communicate a-priori information about
drug quality. The problem of asymmetric information and moral hazards will thus be
minimised enabling the producers to charge a premium for quality in this restricted high
quality market segment.

Consequently, we may expect a market-structure with two (or may be more) non-
overlapping segments. One segment will be characterised by high quality medicines of
changing international standards. In the other segment low quality will tend to drive out
high quality medicines. The first will be an oligopolistic market with few large producers, while the second will perhaps remain perfectly competitive.

Accordingly, price of medicines will also diverge. The price in the high quality market will be high reflecting premiums for quality and oligopoly. The price elasticity of demand will be low reflecting insensitivity of quality conscious consumers to changing prices. The price prevailing in the second (low quality) market will be much less due to competitive pressures. Here the price elasticity of demand will be higher.

**Vertical Integration**

Large firms in the Indian pharmaceutical industry have often opted for vertical backward integration with smaller firms, particularly producing bulk drug, to reduce the agency problem regarding uncertainty of raw material quality as small firms may follow less stringent quality control norms.²¹ The tendency of vertical integration is especially pronounced among domestic enterprises. Vertical integration reveals the willingness of these firms to increase their production commitments and thereby giving a signal to the consumers and shareholders (both nationally and internationally) about their true-motive of being a long term player in the market. Vertical integration may also reduce transaction costs by eliminating (or reducing) arm's length transactions with external parties. As we have argued in chapter 7, development of a product or process requires high degree of inter-departmental flow of information. A non-integrated firm therefore has to rely on market transaction of this information and suffers from problems of transaction costs. However, vertical integration is not costless. As we have already argued in chapter 2 that a vertically integrated firm narrows down its interaction with others as the integration reduces inter-firm interaction due to self-sufficiency and fear of leakage by the competing non-integrated firms. In case of the Indian pharmaceutical industry, however, inter-firm

²¹ Kathuria (1996) argues in the context of automobile industry that quality consideration of raw materials was the driving force behind the TELCO's increasing vertical integration at the initial period.
interaction is anyway minimal and therefore the opportunity cost of losing information may be insignificant. It is also argued that excessive vertical integration may reduce the scope of organisational specialisation in any particular area, and thereby limit the growth in efficiency and productivity.

8.6 QUALITY, EXPORTS AND DOMESTIC OUTPUT

As stated earlier the high quality producers will enter the export market in generic drugs raising the level of competition in the exporting countries and driving down prices there in turn.

However, increased competition in the international market may induce incumbent firms to invent ways and means to make quality standards more stringent and thereby prevent entry. This would require investment by the firm in quality related analytical R&D to come up with new dimensions and methods of quality analysis. If the regulatory authorities (the relevant Pharmacopoeia) can be convinced to incorporate these changes as part of minimum quality requirements, then the firm in question might gain monopoly power (may be of transient nature a la Schumpeter). 22

We study a case where a domestic Indian firm enters the global market by developing a new analytical method which gives it a monopoly position in a particular product segment both in the domestic as well as in the export market. Assuming the two markets to be non-overlapping, we can analyse the effect of this firm’s entry into the high quality export market on its equilibrium output for the domestic market in the framework of a price discriminating monopolist. The issue of price discrimination arises because of the difference in the demand elasticity of two markets. Since, export market is assumed to

22 Indeed, the final pharmacopoeial consent may be contingent upon the applicant’s capacity to meet the total demand for the specific drug in question in the eventuality of the applicant becoming a monopolist supplier due to the imposition of this new quality standard. The large firms may enjoy an advantage over smaller ones on this count. Accordingly such R&D thrust is likely to rise with firm-size.
be more quality sensitive than the domestic market, its demand should be less price elastic for a given quality.

The Model:

Let the demand functions in the domestic and the export market be

\[ Q_1 = a_1 - b_1 P_1 \]  
(1)

(for the domestic market);

\[ Q_2 = (1 - a_1) - (1 - b_1) P_2 \]  
(2)

(for the export market)

The total demand, after the trade opening up, is therefore:

\[ Q = Q_1 + Q_2 = 1 - P \]  
(3)

We now derive the equilibrium domestic output both before and after the opening up of the international market.

Case I: Before the opening up

\[ P_1 = \frac{a_1}{b_1} - \frac{1}{b_1} Q_1, \quad TR_1 = \frac{a_1}{b_1} Q_1 - \frac{1}{b_1} Q_1^2 \]

The marginal revenue is therefore:

\[ MR_1 = \frac{a_1}{b_1} - \frac{2}{b_1} Q_1 \]  
(4)

Let the marginal cost curve be \( MC = dQ_1 \).

The profit maximising output will be given by \( MR_1 = MC \)

\[ Q_1^* = \frac{a_1}{(2 + b_1)d}. \]  
(5)

Case II: after the opening up

After the opening up, the firm will operate on the aggregate demand curve given by (3)

\[ Q = 1 - P, \quad \text{or,} \quad P = 1 - Q. \]

The marginal revenue curve is \( MR_{agg} = 1 - 2Q \)  
(6)

The profit maximisation (\( MR_{agg} = MC \)) implies aggregate output will be
\[ Q = \frac{1}{2 + d} \]  

(7)

The equilibrium MR_{agg} is therefore equal to \( \frac{d}{2 + d} \) [putting \( Q \) in the equation (6)]

The new price discriminating output is governed by \( MR_1 = MR_2 = \frac{d}{2 + d} = MC \).

The domestic output will be

\[ Q_t^- = \frac{a_1 - b_1 MR_1}{2} \]

\[ = \frac{2a_1 - b_1 d + a_1 d}{2(d + 2)} \]  

(8)

\( Q_t^- \) is positive as long as \( d < \frac{2a_1}{b_1 - a_1} \).

The change in domestic output:

\[ Q_t^- - Q_t^* = \left\{ \frac{(2a_1 - b_1 d + a_1 d)}{2(d + 2)} - \frac{a_1}{2 + b_1 d} \right\} \]

\[ = d \left\{ \frac{2b_1(a_1 - 1) + b_1 d (a_1 - b_1)}{2(2 + d)(2 + b_1 d)} \right\} \]

(9).

Thus the change in domestic output depends on the values of the parameters of the demand and cost functions. If either \( d < 0 \), or the bracketed term in the numerator is negative, the domestic output may actually reduce. Since \( d \) itself is always positive the necessary condition for a negative change in the domestic output is

\[ d < 2(1 - a_1)/(a_1 - b_1) \]  

(\#*)

To find out the implication of the inequality we find the equilibrium output in the export market after price discrimination.

The demand function for the export market is:

\[ Q_2 = (1 - a_1) - (1 - b_1)P_2 \]

or, \( P_2 = \frac{(1 - a_1)/(1 - b_1) - 1/(1 - b_1)}{Q_2} \)

The marginal revenue function is therefore

\[ MR_2 = \frac{(1 - a_1)/(1 - b_1) - 2/(1 - b_1)}{Q_2} \]

(10)

Since in the price discriminatory framework, the firm will operate on the basis of \( MR_1 = MR_2 = \frac{d}{2 + d} = MC \)

The equilibrium output is given by
\[ Q_2^- = \frac{[(1 - a_1) - (1 - b_1)MR_{agg}] - 2}{2}. \] Now for \( MR_{agg} = \frac{d}{d+2} \), we get

\[ Q_2^- = \frac{[2(1 - a_1) - d (a_1 - b_1)]}{2(d+2)} \]  

(11)

We know that export market did not exist earlier. Thus an effective price discrimination implies a value of \( Q_2^- > 0 \).

Thus

\[ d < 2(1 - a_1)/(a_1 - b_1) \]  

(**)

Thus (*) and (**) are the same. Therefore if the parameters of demand functions and the cost function are such that output in the export market is positive after opening up of trade, then domestic output will decrease if the monopolist firm can exercise price discrimination between the two markets after opening up. Note that we have assumed unchanged marginal cost for simplicity. However, analytical R&D may also lead to an increase in the MC.\(^{23}\) If MC rises, the fall in domestic output will be unambiguous even in the absence of price discrimination. This result reinforces the argument presented in chapter 4 that Indian domestic firms are diverting their business away from the domestic market towards a more lucrative but quality sensitive export market.

8.7 CONCLUSION

In this chapter, we have shown how the political-economy forces have shaped the concept of drug quality over time and how the Indian pharmaceutical industry has responded to this dynamic process of quality construction. Its R&D thrust, production organisation, domestic market structure, factor rewards and employment, export portfolio and destinations all have undergone a sea change with the newly emerging construction of drug quality. We have attempted to capture some of these in this chapter.

\(^{23}\) Grossman and Helpman (1991) assume that R&D costs may increase for incremental quality upgradation.
In the absence of a very stringent domestic quality norm, two sets of non-overlapping market structure may emerge depending on the demand parameters like income and quality-awareness of consumers. The low quality segment of the market will be more of a perfectly competitive nature, while the high quality segment will be served by a few large firms in an oligopolistic market structure. Consequently, the price will also be higher in the latter segment. The new form of production structure with increasing automation would favour the employment of skilled labour at the expense of unskilled labour. This would perhaps cause a rise in the supply of unskilled labour, reinforcing a Lewis process in the context of a labour surplus (unskilled) less developed economy. Moreover, quality led exports in this environment will not be dictated by the theoretical premises of the H-O-S framework and is likely to produce an anti Stolper-Samuelson effect resulting in a decline in the reward of abundant factor, labour.

We have postulated a case where domestic output falls due to export. However, in this case, export competitiveness is a reflection of increased capability in analytical R&D, which gives the firm a monopoly power to discriminate prices between domestic and export market in a particular product segment. This is a typical Schumpeterian case, where innovating firm enjoys a transient monopoly in the product market. Moreover, it is possible to relate the few successful cases of analytical innovation by Indian firms with the so-called technological catch-up processes in LDCs. These success stories reveal that some of these Indian firms are moving along the international frontiers of analytical research, perhaps indicating a successful catch-up process.