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> This article evaluates the post-discovery supply chain to determine whether it can be evaluated by conventional analytical methods and improved by the application of supply chain techniques. It considers the impact of factors, including changes in legislation and drug delivery methods.

A Holistic Analysis of Pharmaceutical Manufacturing and Distribution: Are Conventional Supply Chain Techniques Appropriate?

by Christopher J. Savage, Kevin J. Roberts, and Xue Z. Wang

Introduction

he pharmaceutical industry operates globally, generates a massive amount of revenue (Table A) and affects almost everyone in the developed world. Drug treatment is the most common form of healthcare intervention and represents the highest non-staff revenue cost in the UK's National Health Service (NHS) with estimates suggesting that 70% of the UK population are taking medication on any given day.¹¹ The industry traditionally enjoys high profits with finished product margins as high as 30%, notionally justified by the high R&D, drug development, and marketing costs estimated at US \$800 million to US \$1 billion per marketed Stock Keeping Unit (SKU).¹⁰

Recently, these profits have come under increasing scrutiny as a result of government

Country	US\$ billions
United States	177.40
Canada	10.43
Germany	25.70
Italy	14.50
France	21.70
United Kingdom	15.70
Spain	10.60
Japan	59.00
Mexico	6.60
Brazil	5.30
Argentina	1.80
Total	348.73

policies, generic competition, and wholesaler objectives. Logistics costs, as a percentage of sales revenue, tend to be lower than in other industries due to the high value of the goods.2 Nevertheless, pharmaceutical companies are becoming more interested in optimizing their supply chains to save costs and perhaps, more significantly, gain competitive advantage. This article focuses on adopting a holistic approach in order to try to identify problems that hinder optimization of the supply chain through a collaborative project involving the Institute of Particle Science and Engineering of the University of Leeds and the Division of Transport and Logistics of the University of Huddersfield. Data was collected through discussions and workshop sessions with a number of key UK pharmaceutical production companies as well as pharmacists from the UK, New Zealand, and the USA. The work summarized in this article provides the foundation for a larger project by examining the basic premise and potential future approaches.

Pharmaceutical Supply Chains: A Divided Structure

Overall, the pharmaceutical industry can be broadly divided into two market segments; ethical (prescription) and "over the counter" products. This work focused on the ethical segment, where two distinct supply chain components can be clearly identified, i.e., the pre-production (Discovery) chain and the post-development (Production) chain. Both components, while clearly different in their content and magnitude, form significant parts of the overall process responsible for converting an initial idea from discovery into a usable drug and delivering it to the patient (or rather to the retailer or dispensing pharmacist). These two components intertwine to form a lengthy and complex supply chain that

Table A. Retail pharmacy sales, 12 months to March 2005.⁴

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is difficult to consider holistically and can lead to a protracted "time to market" for the resultant product. In addition, the overall process could offer significant scope for improved efficiency and enhanced product profitability.

In the pre-production (Discovery) chain, the process of discovering and developing a compound to produce an ethical drug in an approved format to be used by the patient (Figure 1), can take as long as 15 years although a seven year development/approval time has been achieved for some markets. As product filing usually takes place five years into the development cycle, this leaves only 10 years from the 20 year patent protection limit for the company responsible for the research to enjoy "unshared" benefit of their discovery.

As the diagram shows, for each drug successfully approved, millions of potential compounds may be screened. Then typically, of those that enter the clinical stage, only one in 10 is eventually marketed. Further failures can occur after a product is launched, e.g., when longer term side effects become apparent. This can incur major expense or delay for reformulation/approval or in the worst case the abandonment of many years' work/cost. All of these trial products have high R&D costs that must be borne by those that are

brought successfully to market. Drug development also is made more difficult by the ever-increasing complexity of molecules required in drug compound formulation, which works against the need for a quicker route to market. In the post-development (production) chain, the more conventional procurement, production, delivery supply chain can range from nine to 24 months depending on the drug product form and the associated manufacturing complexity.

Overall, there may be scope for time reduction in both of these supply chain components with the concomitant potential for significant cost savings and possibly earlier relief from sickness or even prevention of death. Although both are important, this article will concentrate on the more conventional, post-development supply chain. As this project develops, a parallel article will address the drug discovery chain itself leading to integration of the two components with the aim to examine their design interdependence and give an holistic view.

Methodology

Initial work has concentrated on gathering data on specific as well as generalized pharmaceutical supply chains in order to



Figure 1. Schematic representation of the timescale for drug development to the marketplace with drug filing after five years into a 15 year drug development cycle.³

determine whether conventional logistics analysis techniques and tools can be used to evaluate them and by doing so, identify the critical points for further, more detailed investigation. In addition, an evaluation has been made as to whether manufacturers of similar products structure their supply chains and respond to challenges in a similar manner. The method adopted was to gather data from a series of face to face interviews and brainstorming workshop sessions, and by telephone and e-mail with a sample population of manufacturers, intermediaries, and dispensing pharmacists. The output from these¹¹ was then combined, compared, and analyzed.

Results and Discussion An Examination of the Post-Development Supply Chain

The first task was to try to determine whether pharmaceutical supply chains are "different" to such an extent that conventional techniques cannot be used. The initial response from the group of interviewees was usually that "pharmaceuticals are different; they cannot be treated as normal commodities." The most frequently stated reasons for this were the high cost and long duration for the R&D process and the possible impact on life should a drug not be available on time.

There was also a commonly held belief that the production cycle time is very short and highly reactive, a view that would be contested by many supply chain professionals from other fields. When challenged over these statements, their promulgators were unable to substantiate them convincingly. This suggests that they are perceptions rather than facts and that pharmaceutical supply chains could be modelled and optimized like any other. If one concludes that a pharmaceutical supply chain may be treated in a conventional manner, it is nevertheless important to acknowledge some factors that do make it more difficult to change existing methods or at least to do so "quickly." These include:

- a high degree of regulation at all stages of manufacture and distribution, this is arguably greater than any other industrial sector (including the aeronautical industry)
- In the case of ethical (prescribed) medicines, one must be aware that in most cases, the end user (patient) does not choose the product, and that although the patient makes a contribution (e.g., prescription charge), it is the government of the country concerned that is the main financial customer.¹⁴
- complexity of regulatory environment where for example, changing any manufacturing facility, even something as apparently simple as a packaging site, will require multiple approvals for each SKU for each sales territory. This can take different lengths of time for the same product, e.g., Europe three months, Middle East three years
- the complex extended supply chain with its simultaneous, interwoven discovery, and production components

• supply chain integrity, i.e., a reflection of "life impact" view mentioned above, but not an insurmountable one

The combination of these features may apply significant constraints on strategic supply chain development, often exacerbated by "within company" conflict of interest (e.g., R&D or marketing vs. manufacturing) over issues such as standardization. Similar difficulties result from the proliferation of drug and packaging variants, which some writers ascribe to pharmaceutical companies' desire to differentiate themselves.⁵ It is acknowledged that proliferation takes place, but the apportionment of "blame" is disputed by the industry feeling that is frequently caused by customer and/or legal demands and not the manufacturer's whim.

A number of examples have been cited in support of the above view, notably:

Country specific regulations which are very explicit and often subtly different, e.g., packaging has to have details of the product licence holder printed on each inner carton and some regulations require that the foil portion of a blister pack covering each tablet or capsule has a small red box with warnings printed on it.

Fraud prevention where manufacturers may create artificial differences in the physical product to identify it with a specific country, e.g., GSK produce HIV drugs and sell them into African countries on a marginal cost basis. The difference between that price and the selling price in (say) the UK is so great that it is worthwhile for unscrupulous people to buy the tablets in Africa manually open them and repack the product in blister packs or jars for reselling. To prevent this, "Africa specific" SKUs of a different color to mainstream ones are produced. This is similar to the counterfeiting problem discussed by Lewis.²

Personalization where conventional dosages are calculated to give the statistical "best fit." This may produce a tablet of 50mgs when the patients need is for 25 or 45mgs. Modern thinking suggests that the correct dosage should be available on an individual basis (without cutting tablets). In due course, the medical practitioner may be able to prescribe an exact dose to match the patient genotype and metabolism. This will require significant legislative changes, but should be possible in the UK within 20 years and will clearly have significant implications for pharmaceutical supply chains.

The above suggests that, while pharmaceutical supply chains can be broadly regarded as "conventional" in terms of their potential for evaluation, there are indications that special circumstances may modify the way in which such tools are applied to develop workable operational solutions.

Application of "Tools" to Pharmaceutical Supply Chains

During discussions, most of the population agreed that the application of supply chain tools was possible, but research to date has failed to uncover much noteworthy, documented, supporting evidence. One published example is the case of Boehringer Ingelheim's Roxane Laboratories (Columbus, Ohio) where a Supply Chain Operations Reference Model



Figure 2. Schematic representation of a generic ethical pharmaceutical manufacturing network.

(SCOR) was said to be used in conjunction with a system of benchmarks to improve customer service level and improve inventory turn by 44%.⁸

The apparent lack of evidence may not be significant as such work is regarded as highly commercially sensitive, often kept "in house" and not published. Therefore, as the contributors were not able to provide conclusive confirmation, it was decided to seek corroboration by treating the use of a particular logistics technique within the supply chains of contributors' companies as an "indicator." In order to decide which indicator might be appropriate, it is necessary to understand the nature of modern pharmaceutical supply chains, their structure, and what drives them. There are many variants even within a given company; therefore to make a selection and illustrate the reasons for the choice, the artificial "generic" shown in Figure 2 has been derived from discussions/ correspondence with members of the sample group.

Examination of the typical network structure used by a generic ethical manufacturer, e.g., for the production of tablets and capsules, reveals that three major "stages" or "levels" in the production process or network are clearly recognized.

Primary Stage

This concerns the manufacture of the Active Pharmaceutical Ingredient (API). It is technology driven, usually taking place in "focused factories" that tend to operate globally, producing material for many countries and is often outsourced ~ frequently dual sourced. The processes are multi-staged, usually with stages occurring on different sites depending on the APIs concerned. Process control is often weak, which combined with scheduling issues, leads to proliferation of safety stock, poor asset utilization, and high levels of Work In Progress (WIP) capital.

Secondary Stage

This is where the intermediate formulation processes such as blending, granulation, drying, compaction, and coating leading up to and including the production of the "tablet" take place. These factories also may be considered as focused in that they tend to specialize by physical product type, e.g., sterile, topical, tablet, or capsule. The preferred location would be physically near to the market to serve regions consisting of one or more countries that are close to one another, but this may be overridden by political and/or economic factors. Units tend to be global, where the technology is difficult, but regional where the technology is less critical or well established. Products may be moved from global to regional factories as they mature (i.e., later in their life cycle) or when some specific "local formulation variants" can be produced. Localized secondary manufacture may tend to increase should personalized prescribing become a reality.

Tertiary Stage

This is where packaging takes place and is divided into three significant component types each of which may entail different manufacturing sub-stages, including:

• Drug product environment, i.e., packaging closest to the tablet (the blister pack or bottle) which is often critical as it provides immediate protection for the product and helps maintain its stability.

- Drug packaging, i.e., the carton that holds the blister packs or bottle together with the associated leaflet.
- Product identification, i.e., printing or labeling of a carton with specific information such as date, price, and license holder. It is also where customer (retailer) specific additions are made, e.g., the addition of Radio Frequency Identification (RFID) tags to packs.

In general terms, the shape of the bigger companies' networks are influenced by the principle of continuous improvement and a continual tension between the desire to have common global supply and the need to satisfy specific local needs. Networks are evolving and simplifying by reducing the number of nodes, e.g., GSK reduced from 120 manufacturing sites worldwide four years ago to current 80 (as of May 2005).

The traditional manufacturing approach has been that of a "push" of production against forecast. This is changing and companies are moving towards more "leagile" networks where lean and agile paradigms are combined within a total supply chain strategy to respond to volatile demand downstream while providing level scheduling upstream.9 This is usually accomplished by means of a de-coupling point so that the later (secondary and tertiary manufacturing stages) are made to order (pull) while the primary (API) manufacture is effected via a controlled push to meet forecast. This push process is often managed using Kanban. The latter is a Japanese term used to signal a cycle of replenishment for production and materials to maintain an orderly and efficient flow of materials throughout the manufacturing process with low inventory and work in process. The key to successful "leagility" may be said to be "decoupling" the supply chain by making use of postponement where possible.¹³ Although postponement has been proposed as a logistics and manufacturing concept for a long time,¹ and its use has led to improved supply chain performance,15 its use in the ethical pharmaceutical area is less and documented. Therefore, the use of postponement was selected as a specific indicator of the application of a conventional logistics tool to pharmaceutical supply chains.

Current Application of Postponement in Current Pharmaceutical Supply Chains

When asked about the concept of postponement (or late stage customization as it is sometimes referred to in the industry), the response was often positive but varied. The degree to which it has been adopted or is perceived to be able to be used differed greatly across countries and companies as well as within them. The restriction often cited was legislation, but it appears that the degrees of inventiveness and/or risktaking that management were prepared to utilize were also major factors.

The following responses to the question "Do you use postponement?" give an indication of the range of reaction:

- Very positive: we are trying to make as much use of postponement as possible to decouple the supply chain, reduce stock holding/costs, while maintaining/improving customer service.
- **Positive (conditional):** the simple answer is yes, we would like to meet specific customer needs as late in the supply chain as possible because we would consider that there is more mileage in demand driven supply. It is easily dismissed and while patient specific supplies, personalized medicines or 'lot size 1' are often discussed as concepts, the traditional methods of manufacture (big, push driven, batch sizes) are often used to block changes.
- Neutral (or confused?): there are two basic inventory management approaches more pharmaceutical companies are moving toward to demand forecasting.
- **Negative:** "this might happen somewhere in industry, but I doubt it."

To seek clarification, more positive respondents were asked to give some examples of postponement as used in their company. The following is a sample of the responses:

- **Common cartons:** facilitated by attaching the leaflet to the outside of the carton rather than inserting it.
- White box printing technology: by using high quality, limited color printing, "vanilla" cartons can be used for a number of lower demand countries.
- **Blister pack customization:** is possible using "on-line" foil printing, but is much more difficult due to technical issues, country specific variations, and the associated cost. It is probable that pre-printed foils will continue to be preferred, and that manufacturers will concentrate on developing packaging lines with faster changeover times. Thus, trading-off line-operating speed (less important as batch sizes reduce) against set up/changeover time (becoming more important as batch sizes become smaller and changeovers more frequent)
- **Two stage packing:** one factory would pack bulk blister strips or bottles of tablets/capsules. These would be printed only with common data, such as the brand, generic name, strength, batch number, expiry date. This factory could utilize efficient high speed packaging equipment as it would be packing for several markets. At a later date, the same factory (or a different one) would complete the packaging by printing any market specific data onto the pack using on line printing equipment and would add a market specific leaflet to the pack. Typically, these packaging runs would be smaller and utilize semi-automated equipment again this is "under development."

Future Scope for Application of Postponement in Pharmaceutical Supply Chains

It must be noted that most examples given above are of possibilities or developments rather than "current practice." Therefore, respondents were asked what their views of the future scope for postponement were and whether they were aware of any likely constraints.

Technology Developments

There are a number of technology developments that will have a significant impact on the supply chain and could lead to a need for decoupling much closer to the end-user. For example, the possibility of remote prescribing by medical or nursing practitioners via internet or sophisticated computer enabled telephones. In addition, developments in knowledge based systems combined with the availability of genotype and complimentary information will enable greater tailoring of drugs, and combined with the above technology, will permit remote diagnosis and prescribing. Note, currently, all new UK-issued prescriptions (excluding repeat prescriptions) should be issued "face to face." Although not yet legal in the UK, the use of such approaches would enable patient specific prescriptions to be sent directly to the dispensing pharmacists who are already assuming a greater role in the management of drug treatment. This would have a significant impact on the supply chain and could even lead to in-pharmacy formulation. In general larger companies will listen to customer requirements and try to meet them where appropriate. Specific requirements may increase supply chain complexity so they need to be evaluated (usually against a two-year development/approval horizon) to decide if they add sufficient value.

Inventory Policy

This factor may be seen to override postponement benefits for which a number of key reasons emerged. First, medical criticality, i.e., the failure of drug availability, could cause patient harm and damage to the company's image. Second, the balance of business financial risk reflecting the fact that the cost of the API is frequently much less than 25% of the final price and so the risk of revenue loss through failure to supply, a "stock out" situation, is perceived as outweighing the cost of stockholding. Finally, there is a clear need to maintain safety stocks:

- Normal: to cover minor "blips" and irregularities in production or the supply chain
- Strategic: to cover a major disaster such as a factory fire or raw material supplier failure

Parallel Importing Issues

Common pricing across Europe does not apply to pharmaceutical products; which means that customers may import at lower prices from non-manufacturing countries, which, in turn, frustrates the manufacturer's inventory stock holding, production, and packaging plans making postponement more difficult.

Drug Delivery Change Constraints

Most companies are aware of the possibility (probability) of changes in methods of drug delivery (i.e., moving away from tablets); therefore, current supply chains could become obsolete in time. This means that any significant change to the supply chain has to be assessed for potential advantages against a possible relatively short time-frame (say 10 years?). Active companies are conducting research into methods to suit alternatives. This is ongoing, but confidential.

Conclusions and Forward Look

The observations discussed in this article are from a small, sample population intended as a pilot for the extended project. Any findings based on them will require confirmation, but they do suggest that conventional supply chain analysis methods can be used to evaluate ethical pharmaceutical chains with a view to moving them toward optimum performance, despite perceptions of "difference." There are factors that may restrict developments based on such evaluations and there are also valid differences between countries due to legislative and valid cultural issues. Additionally, there seems to be a general move from the traditional "push" operations to more of a demand-led market-pull response model often leading to attempts to decouple the supply chain to create "leagility." Some companies are aware of shortcomings in their supply chains and are actively trying to improve them, and of these, some understand and already try to use techniques such as postponement. There is a clear awareness of possible developments in alternative methods of prescription and of drug administration that both stimulate and restrict willingness to invest in supply chain development. However, the innate conservatism of the drug companies causes apparently unnecessary proliferation of inventory to avoid stocking out and being "beaten to a market" even though such stock can and does degrade over time. Overall, differences between the manufacturing companies suggest that analysis to date requires development. Further, conclusions on the feasibility of the "holistic approach" can only be safely drawn when the above findings on the "Post-Development" supply chain are combined with the output from similar and related studies on the "Discovery Chain" component.

For the future, it will be important to investigate the scope for applying supply chain strategic philosophy in an integrated manner covering both up and down stream process sectors to bring efficiency to the whole discovery and production supply chain. It also may be useful to compare pharmaceutical supply chains with those of commercial products with a high Intellectual Property Rights (IPR) product such as the semi-conductor industry. The first steps in this process should be to map in detail a significant number of supply chains for similar products in different companies. These can then be used as a basis for more detailed analysis and comparison including determining a method of measuring the effectiveness of these chains, as well as the impact of any changes that might be suggested. The present work looked at ethical products that are in patent. In the future, once a viable methodology has been established, it would be interesting and useful to look at other aspects such as:

- ethical products in different stages of their life cycle (e.g., after patent expires)
- generic ethical products
- non-prescription pharmaceutical products (e.g., aspirin). Interestingly, these are often subject to more frequent changes in pack style, etc., than ethical products. They are subject to less stringent regulations, but all changes still need approval.
- the downstream part of the delivery chain, including the role of wholesalers, hospitals, and governments
- what impact alternative drug delivery methods (e.g., patches, inhalation, parenteral) would have on supply chain design
- the potential for remote and "personalized" prescribing, especially following individual genomic profiling
- how the design of individual supply chains could be influenced by and/or influence the drug development process

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