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Bulletin

SEPTEMBER 2003

A different remedy

ASSESSING MERGERS IN THE PHARMACEUTICAL INDUSTRY

The UK competition authorities recently cleared a healthcare merger resulting in a combined market share in excess of 90% for one of the relevant products, merely imposing a temporary price cap. This seemed to mark a departure from the European Commission's approach to pharmaceutical merger cases, and its tendency to seek product divestments if market shares exceeded 40-50%. The explanation lies in the role of regulation and buyer power in the UK health service, which featured prominently in the UK decision. In this bulletin, Frontier Economics explores the implications.

Merger analysis typically starts by defining the relevant markets to be assessed. The European Commission's traditional approach involves identifying the set of substitute products available to the purchaser, taking into account product characteristics, intended use and price. In pharmaceutical markets the Commission has concentrated on therapeutic substitutability: i.e., the degree of similarity in the clinical effect of drugs. The Commission then undertakes a market assessment, to investigate whether sufficient competitive forces →

exist to constrain the firm's conduct. Possible constraints include:

- other competitors in the market, whose influence depends on whether they face barriers to expansion;
- potential competitors, which depends on the barriers to entry;
- buyers, whose influence depends on their number, size and alternative options; and
- other parties, such as regulators.

In the majority of EC merger cases involving pharmaceutical firms, the Commission has considered a wide range of such possible constraints – including the power of national authorities in negotiating prices, and the effect of hospital purchasing. The Commission has also considered such long-term issues as barriers to entry faced by possible future competitors. But its main focus has been on existing or near-term potential competitors, estimating the merging parties' combined market shares and considering in more detail those markets in which these exceeded a certain level. In many cases where combined market shares were at or above 40-50%, the Commission concluded that serious doubts existed, and required brand or product divestments.

DEFINING THE DEFINITION

Given the emphasis placed on market shares by the Commission, the approach to market definition clearly matters. While that taken for pharmaceuticals has been based on the demand-side or therapeutic substitutability of products, market definitions in other industries have increasingly focused directly on the constraints on price setting by the suppliers, using the "hypothetical monopolist" test. In most industries, these two approaches should lead to broadly similar conclusions, since the availability of substitutes typically provides the primary constraint on price setting. In this important respect, however, the pharmaceutical industry is different to most industries, as those who negotiate the prices of products are often not the people who decide which products to purchase.

In the UK, for example, the prices of branded pharmaceutical products sold to the National Health Service (NHS) result from negotiations between the pharmaceutical firms and the Department of Health (DH) and once prices are set, a firm's ability to raise them is extremely limited. However, purchasing decisions are made by individual GPs or hospital staff. Evidence suggests that doctors prescribe drugs on the basis of their clinical efficacy, safety, tolerability and convenience; price is only a secondary consideration[1].

In consequence, the demand-side or therapeutic substitution approach to market definition will not necessarily coincide with the results of the hypothetical monopolist test. So which is the most appropriate? That depends on the nature of the competition concern raised by a merger. If, for example, there is a concern that prices will rise following a merger, then an approach that focuses directly on the price setting constraints faced by the firms would seem the best investigative tool. Competition authorities will wish to consider not only therapeutic substitutability, but also regulation and the role of the state as a monopsony purchaser.

If, however, the concern is that a merger may result in certain products or brands being withdrawn and prescribing choices reduced, then the therapeutic substitutability approach to market definition may be more useful. However, in most cases this is unlikely to be an issue. The extent to which a merged firm will find it profitable to withdraw a product depends on the loss of sales revenue compared to the cost savings, and a high proportion of the costs associated with existing pharmaceutical products are likely to be already sunk.

ENTER THE STATE

Having defined the relevant markets, the European Commission has considered a range of possible constraints that may prevent pharmaceutical firms from profitably increasing their price. In the majority of cases, the Commission's focus has been on existing or near-term potential competitors, with an emphasis on market shares.

However, the state plays a particularly important role in the pricing of pharmaceuticals in most European countries, which may impose additional constraints. While the details vary

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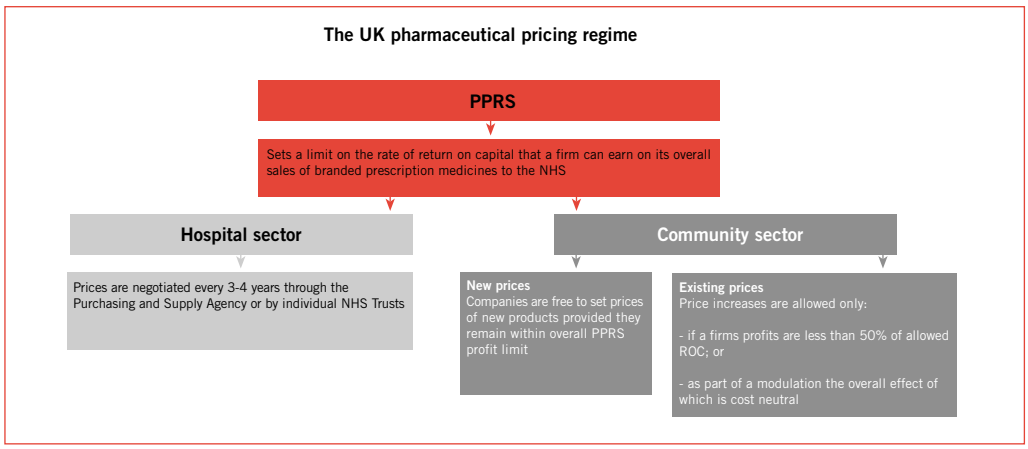
between countries, the UK system illustrates some factors common to may different national healthcare regimes.

- **One large buyer.** The vast majority of the sales are to the NHS, which therefore has considerable influence over prices.

- **Regulation.** In the UK, the most obvious example is the Pharmaceutical Price Regulation Scheme (PPRS), a voluntary scheme agreed between Whitehall and the industry.

The PPRS sets a limit on the rate of return that a company can earn on its overall sales of branded prescription medicines to the NHS, which includes sales to hospitals and to the



community sector (i.e., prescribing by GPs). Although there are different price-setting arrangements for these two groups, the overall profit restriction imposed by the PPRS applies to both. The diagram illustrates this arrangement.
As the diagram shows, the PPRS restricts a firm's ability to increase the prices of its existing products sold in the community. This is particularly relevant to merger analysis, which is concerned about future price increases from today's levels. To give some idea of the significance of these restrictions, sales in the community account for about 80% of total UK sales of branded pharmaceutical products. Moreover, the regulatory framework makes it more likely that behavioural remedies, such as a commitment not to raise prices post-merger, can be policed.

While the restrictions imposed by the PPRS apply equally to sales of branded medicines to the hospital sector, such sales are frequently made at a discount to NHS list prices. Competitive tenders are often introduced in an attempt to obtain lower prices, even when there are only a few suppliers; so a merger could lead to a loss of competition in the hospital sector. This will not necessarily be reflected in an analysis of market shares; but the existence of close substitutes, whose producers could enter the competition, will be important.

Other countries have different regulatory regimes for pharmaceuticals. For example, Austria, Belgium, Canada, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal and Spain have reference pricing regimes. Under such regimes, the price of a pharmaceutical product is a weighted average of the prices charged in a specified group of other countries. Reference pricing limits a firm's ability to raise prices post-merger, since it can only achieve higher prices if it can increase prices in the other countries that form the reference pricing basket. Such regimes therefore also give rise to a need for detailed consideration of the role of the state in merger analysis.

PRESCRIPTION FOR THE FUTURE?

A recent UK merger in the healthcare sector between Coloplast A/S and SSL International (see box) indicates that comprehensive analysis of the workings of the regulatory regime and the power of large buyers can lead to apparently unconventional solutions to competition concerns[2]. While this case related to healthcare appliances, for which the regulatory regime

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in the UK is not quite the same as for drugs, much of the analysis would be equally applicable to mergers amongst pharmaceutical companies. Similar issues are also likely to arise in other EU countries, although differences in the regulatory regime and role of buyers mean that the analysis would need to be conducted at the national level. The moral of the Coloplast story is that in markets of this type, comprehensive analysis of the competitive condition is essential and can show that the most obvious remedies to competition problems may not be the most appropriate.

THE COLOPLAST STORY

The Competition Commission's (CC) recent investigation into the Coloplast/SSL merger provides an interesting example of the effect of taking buyer power and regulation into account. Both businesses were engaged in the manufacture and sale of continence care products. In one of the relevant markets, the merger resulted in an estimated increase in market share from 34% to 92%. On top of this, the CC found no evidence to suggest that other suppliers would become large players, and concluded that new entrants would face manufacturing, marketing and regulatory barriers to entry.

Nonetheless, the CC concluded that for community sales, which accounted for around 90% of the total, no detriment to the public interest was to be expected, and accordingly no remedy was required. For sales to hospitals (the remaining 10%), a four-year price cap was sufficient to allay its concerns. At first glance, this seems a surprising result.

The CC did find that, in the absence of effective price control, prices for supplies to the community would be higher as a result of the merger. However, the price at which manufacturers can introduce new products on to the Drug Tariff is controlled, while their ability to increase the community sector prices of existing products is limited by a formula. So the CC did not expect the price for the products in question to be higher in practice. It also investigated the effects on innovation incentives, quality and service and product rationalisation and did not expect adverse effects.

On prices for supplies to hospitals, the CC found that the Purchasing and Supply Agency (PASA), an executive agent of the NHS, has some purchasing power, but – critically - that the exercise of this power is dependent upon the availability of substitutes from alternative suppliers. The merged company had a market share of over 90% for one product, with control over the two leading brands. There would be no practical alternative to including one of these on the hospital list for the next buying round. So prices were expected to be higher as a result of the merger. Coloplast faced a recommendation that it should be required to divest one of these key brands. However, the CC also suggested that a behavioural remedy, in the form of a price cap, would provide an acceptable alternative. The final outcome was a price control on this product in the hospital sector, to run until 2007.

Since sales in the hospital sector are made to a small number of centralised buyers, monitoring prices is quite feasible and there was not thought to be any need to introduce any form of "market manager". Moreover, Coloplast supplies the key brand under a licence that expires in 2007. Temporary price control represented a practical way of ensuring that prices did not increase as a result of the merger, in advance of the development of competition in the medium term.

Frontier Economics provided economic advice to Coloplast A/S throughout the merger inquiry.

SOURCE	1. *Department of Health and the Association of the British Pharmaceutical Industry (2002), "PPRS: The Study into the Extent of Competition in the Supply of Branded Medicines to the NHS".* 2. *See Competition Commission (2002), "Coloplast A/S and SSL International plc, A report on the merger situation".*
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