



Market Definition in the Pharmaceutical Sector

Introduction

Defining relevant product markets in the pharmaceutical sector is not straightforward.¹ Many of the assumptions that implicitly underpin the conventional SSNIP test do not apply; as we explain below, prices in European markets are commonly subject to regulation by buyers with monopsony power and ultimate consumer (i.e. patient) preferences frequently do not determine substitutability. In the light of these industry characteristics, applying the SSNIP test in a competition case involving pharmaceuticals is unlikely to provide much insight into the competitive dynamics of the market in question.

The role of market definition, as defined by the European Commission, is to “identify in a systematic way the competitive constraints that the undertakings involved face”.² This memo sets out a framework for identifying competitive constraints that takes into account the idiosyncrasies of the pharmaceutical sector. Although it is based on our experience of defining markets in dominance cases involving pharmaceutical companies, the framework could be readily adapted for merger analysis.

Why pharmaceutical markets are different

European pharmaceutical markets have two key characteristics that need to be taken into account when approaching market definition.

- First, the price of patented (and innovative) drugs tends to be regulated. This is because in many national markets pharmaceutical firms face the Government as a single monopsony buyer. This regulation means that firms cannot freely set prices, and in particular cannot increase prices over time even if it is otherwise profitable to do so. On the other hand, firms are usually free to *decrease* prices when facing stronger competition.
- Second, these markets are characterised by an unusual structure whereby the ultimate consumer (patient) differs from the decision maker (doctor) and very often from the payer (national insurance service or private health insurance). Because of this peculiar structure, there is usually very limited price sensitivity on the part of the decision makers.

These characteristics combine to create a market environment in which pharmaceutical companies compete

mainly through non-price means. These include: detailing activity to doctors (where a sales representative visits a doctor to discuss the characteristics of a specific drug); advertising in medical journals; funding clinical studies; mailing doctors; introducing new presentation forms (e.g. tablets, capsules); and widening the indications for which products can be prescribed.

In most other markets in which non-price competition is important, there is also price competition. This means that own-price and cross-price elasticities of demand can still be estimated (provided there are controls for non-price factors).³ The situation in the EU pharmaceutical sector is different. First, because competition in this sector is essentially on non-price grounds, it makes more sense to investigate the nature of this non-price competition directly. Second, restrictions on the freedom to price mean that there will be very limited price variation over time. The limited price variation will undermine any simplistic efforts to econometrically estimate demand elasticities. Taken together, these considerations mean that pricing analyses of the type normally undertaken for the purpose of market definition are generally unlikely to be very informative in defining markets in the EU pharmaceutical sector.

Key results from the economic literature

In the light of these considerations, how should the conventional approach be refined in order to ensure that the analysis of market definition is sensitive to the drivers of demand in the pharmaceutical sector? A survey of the economic literature in this area suggests a market definition assessment should include the following three aspects.

First, evidence on therapeutic substitution should be used to restrict the “choice set” to the group of molecules that are regarded by doctors as therapeutically substitutable for treating a specific condition (or a set of related conditions). This should be based on information from the medical literature, labelling information and expert witness statements. All the products that are not generally perceived by doctors as appropriate to treat the specific condition(s) should be excluded from the relevant market at this stage. This criterion should not, however, be viewed as sufficiently stringent. Further work should be undertaken to define the markets because (for example) different products might have similar indications but might not be regarded as interchangeable by the majority of doctors.

¹ The recent decision by the European Commission in the AstraZeneca Art.82 case discusses in detail the main relevant issues (see Commission Decision of 15 June 2005 in Case COMP/A.37.507/F3). The authors are ongoing advisors to AstraZeneca in this case. The views expressed in this Competition Memo are those of the authors and do not purport to be the views of CRA International.

² See the Commission Notice on the definition of the relevant market for the purposes of Community competition law, OJ C 372 on 9/12/1997, Section I.

³ The own-price elasticity of demand of a product or group of products measures the extent to which volume is lost when price is increased. The cross-price elasticity between two products measures the extent to which the volume of sales of one responds to changes in the price of the other.

Second, evidence on prescribing patterns needs to be incorporated into the assessment when available. This can provide very useful information as it tracks exactly how different prescription drugs are used over time to address specific diagnoses. It also provides an insight into the most common indications for which specific drugs are prescribed. Evidence which suggests that two products (or two classes of products) are prescribed for the same specific conditions over time would constitute strong evidence that the two products (or two classes of drugs) should be included in the same product market.

Third, evidence on the impact of different competitive factors on sales of a specific product (or class of products) is critical. Whenever data are available, an econometric estimation of the impact of specific competitive variables (such as detailing and advertising activity, entry of competing products, introduction of new presentation forms, and output of clinical studies) holding everything else constant may be extremely useful in understanding the patterns of substitution among different prescription drugs. Such an econometric study would generate a robust and economically sound assessment of the degree of competition between different prescription drugs in a specific country over time.

A proposed framework

A hypothetical example can be used to demonstrate how this methodology can be applied. The example involves two products: Drug A, a well established “incumbent” product used to treat a variety of symptoms; and Drug B, a recently introduced new molecule which is possibly superior to Drug A for the treatment of certain conditions. In this example, it is conceivable that Drug B’s superiority may raise dominance issues at some point, so the question of whether the two drugs are in the same relevant market could be pivotal to the outcome of a dominance investigation. Our proposed framework, drawing on the economic literature, involves a four-pillared assessment covering the three areas discussed above.

The first pillar involves a review of medical evidence. The views of doctors, as decision-makers, are important as they provide a key insight into the potential functional substitutability between Drug A and Drug B. This would involve an assessment of issues such as (i) the extent to which uncertainty and safety fears impeded the acceptance of the new product (Drug B); (ii) the degree to which there was inertia in prescribing practice, possibly due to the slow dissemination and acceptance of the medical literature relating to Drug B; (iii) the extent to which this inertia was overcome by detailing and advertising activity by the makers of Drug B.

The second pillar entails an assessment of commercial evidence. Internal documents and the views of third party commentators (including rivals) can also provide useful evidence on substitutability. For example, do the internal documents of the manufacturer of Drug B show that its marketing and research were concentrated on stressing the benefits of Drug B over Drug A? How did the manufacturer of Drug A respond when Drug B was introduced? Did it, for example, launch an aggressive marketing campaign to counter the perceived threat to its business? Similarly, what did independent third parties (such as the financial press and medical commentators) say about the likely impact of Drug B on the sales and profits of Drug A?

The third pillar involves a detailed analysis of prescribing patterns. If data permits, this analysis can be used to investigate a range of questions relevant to the issue of market definition. For example, to what extent have Drug A and Drug B been prescribed for the same specific diagnosis? If the two products are not in the same relevant market, we would not expect them to be prescribed for the same conditions. Similarly, are there any specific diagnoses for which Drug B is unambiguously preferred over Drug A? If so, how significant are these specific diagnoses as a proportion of the full range of diagnoses for which the drugs are prescribed? Prescribing patterns can also assess the extent to which Drug B is indeed the superior treatment; a rapid shift from Drug A to Drug B across a range of diagnoses would be indicative of a perceived superiority of treatment.

The final pillar involves econometric analysis. Econometrics can play a key role in identifying patterns of substitution among prescription drugs. It allows the impact of each of a range of competitive variables to be isolated. In the example used above, these variables would include: the pricing, detailing and advertising activity of both products; entry of other competing products; the approval of new indications; and the introduction of new presentational forms. This allows for the quantification of competitive interaction. It could identify, for example, the relative importance of detailing activity in explaining the demand for Drug B. Similarly, it could quantify the extent to which one product constrains the demand for a rival product (therefore identifying the closeness of competition between Drug A and Drug B).

Conclusion

In this memo, we propose a methodology to define markets in the pharmaceutical sector that takes into account the specific features of the industry. There are a number of attractions to this proposed approach.

First, it takes into account the dynamic nature of pharmaceutical markets. Even when a new molecule is unambiguously superior to previous treatments, it cannot be assumed that this superiority is recognised immediately in prescribing practice. In dominance cases, the framework set out above would provide a robust insight into exactly when – if at all – a particular drug attained a dominant position.

Second, the four pillars identified are complementary and provide a range of information to assess the question of market definition. For example, we would expect statements made by medical experts about which products are functional substitutes to be consistent with the results of the analysis of prescribing patterns, which in turn should tie in with the results of the econometric analysis and the commercial evidence. A more robust market definition is likely to be achieved if consistent results are attained from a diversity of sources.

Third, it takes into account the specific characteristics of pharmaceutical markets identified at the start of this memo. It avoids an over-reliance on pricing analysis in a market in which pricing is artificially constrained. It also takes into account the importance of non-price factors in determining the nature of competition among pharmaceutical products.

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