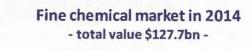


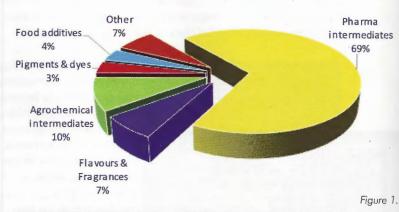
How much of the fine chemicals market can pharma lay claim to today – and in the future? Jan Ramakers, Jan Ramakers Fine Chemical Consulting Group writes

ine chemicals, speciality chemicals, and performance chemicals are some of the various names used to describe products in the high-value end of the chemical market. In order to avoid any confusion, it is good to keep in mind that fine chemicals are defined as (high value) chemical products that are sold for what they are, ie for their precise chemical structure. Speciality chemicals, often also referred to as performance chemicals, are (high value) chemical products that are sold for what they do. So an intermediate used in the manufacture of a specific API is a fine chemical as it needs to have a very specific chemical structure; a different chemical structure cannot be used. Fine chemicals are used across a wide range of market segments, and it is easy enough to make a list that features 40-50 different application areas.

The products end up in speciality chemicals markets, for instance as active ingredients in biocide formulations, as additives for plastics and coatings, or as active ingredients in cosmetics and toiletries. Some are used as intermediates in the manufacture of liquid crystal displays, and so on. Many of those end markets are quite large, but most of them are fairly small as an outlet for fine chemicals.

Larger markets for fine chemicals include agrochemicals, flavours & fragrances, and dyes. Together, agrochemicals and flavours and fragrances represent some 17% of the value of the total fine chemicals market. The pharmaceutical industry has been the largest market for fine chemicals for a long time. In the late 1990s the pharmaceutical industry was responsible for just over half of the fine chemicals market. As a result of the fact that the pharma market has enjoyed significantly higher annual growth rates than the other segments of the fine chemical market for many years, the market share of the pharmaceutical industry increased to 69% in 2014 (figure 1).



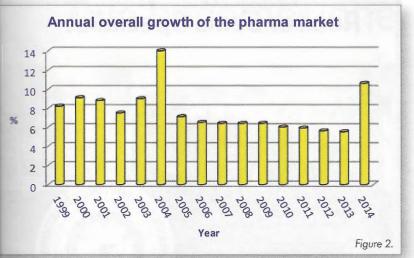


Fine chemical market split. Source: Jan Ramakers Fine Chemical Consulting Group

In view of the anticipated market developments of the various segments in the coming years, it is likely that the pharma market will account for some 73% of the fine chemical market by 2020. By that time the life science sector – human and veterinary pharma and agrochemicals – will use more than 80% of all fine chemicals (by value).

The massive market share of pharma means that the trends and developments in the pharma market largely determine what is happening in the fine chemical industry. In the remainder of this article we will look at the main trends in pharma and what they could mean for fine chemicals.

In the nineties the annual growth of the pharma market was often in the double digit figures. Gradually however the overall growth figures came down to the current level of about 6% per year (figure 2).



Growth of the pharma market. Source: Jan Ramakers Fine Chemical Consulting Group

It is interesting to note that the effects of the credit crunch on the global pharma market appear to have been limited, as the overall market growth did not drop off. It is fair to say however, that there have been some effects of the credit crunch on the R&D side of the pharma market. Some segments of the pharmaceutical market are showing annual growth rates that are well above the average for the whole market.

One of those segments is high potency drugs. Currently drugs with a high potency API are estimated to represent more than 14% of the total market value. During the next few years the annual growth of this segment is estimated to be well above overall market growth. The manufacture of high potency compounds requires specialised production equipment and because of the very low exposure limits of the compounds manufactured the barrier requirements to prevent anybody from coming into contact with the products are very strict. Needless to say that the right equipment and physical barriers alone are not enough; training and attitude of the people running and operating the plant are even more important here than in other areas. So far the number of fine chemical companies involved in the manufacture of high potency products is limited. Because of the higher growth rates the segment does attract a lot of interest from companies that consider entering this market.

Another segment with a significantly higher growth than average is biopharmaceuticals, where the manufacture of the APIs requires at least one biotechnological step. That can be anything between a fermentation and mammalian cell technology. Currently the market

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for biotechnology drugs is estimated to be similar in size to the market for high potency drugs. The growth of this segment is estimated to be in the 10-12% range for the coming years, giving a market value of around \$260-280 billion in 2020. A lot of these biologicals are developed by specialist biotech companies. After initial development, such companies often license out their new products to the big pharma companies for further development, making use of the economies of scale that their partners

can offer. Many of the larger fine chemical companies have invested in biotechnology (mostly fermentation), either through acquisitions or self-funded R&D and commercial plants. The relatively high investment needed to be able to use mammalian cell technology has kept all but a very few of them away from that technology.

Together the markets for high potency drugs and biotechnology drugs are set to grow to just over one third of the pharma market value in 2020.

Generics is the third segment of the pharma market that has shown above average recently, due to the large number of blockbuster drugs that lost patent protection in recent years (the patent cliff). The peak of the patent cliff is well behind us. In spite of that the share of generics will continue to grow, fuelled by regulations in countries around the world that promote the use of generics instead of originator drugs where possible, as part of the effort to keep the cost of health care under control.

During the past decades an increasing number of large pharma companies have chosen to outsource more of their manufacturing to the fine chemical industry. With the increasing complexity of the chemistry and technology involved in the manufacture of the newest generations of APIs it makes sense to source those products from the

specialists: the fine chemical industry. The increased outsourcing obviously creates opportunities for the fine chemical industry because it increases the merchant market for pharmaceutical fine chemicals. This should not be confused with additional overall market growth however. The additional products that are going to be outsourced because of the increased outsourcing level of the pharma industry used to be made in-house by them. Therefore, the increase of the merchant market is compensated by an equal



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decrease in the captive market. Because of the increased outsourcing, in-house fine chemical equipment will be freed up and often the pharma companies will try and divest the plants to the fine chemical industry too. In that case both the merchant market and the merchant capacity will grow at the same time and overall capacity utilisation across the industry will remain more or less unchanged. Looking at the overall picture, certainly in the mid-term future more outsourcing should benefit the fine chemical industry.

The fine chemical industry remains as fragmented as it has always been, and even the leading fine chemical producers have a market share of only about 3%. M&A activity has been low during the economic downturn but during the last few years the number of fine chemical businesses (companies or parts of larger companies) involved in M&A has increased significantly. It is interesting to note that the interest of private equity companies in acquiring businesses in the fine chemical segment is growing.

As always there are threats for the industry, such as the growing number of new fine chemical suppliers from non-traditional areas like India and China. More recently, however an increasing number of Chinese and Indian producers of pharma intermediates, drug substances, and drug products have been facing significant quality and compliance issues. As a result of that some have been (temporarily) banned from supplying their products to Western markets. At the same time their domestic markets are growing rapidly, which means ever larger quantities of drug products can be sold locally. As a result of those developments a new trend emerged, called 're-shoring'. Western pharma companies are increasingly bringing (custom) manufacturing back to Europe and North America.

Going forward the fine chemical industry should be able to benefit from the developments in the pharma industry, especially those fine chemical companies that are working in close partnerships with their customers, to provide high quality products as well as high quality service. That is what the pharma industry is looking for, now more than ever.