

Trends within the Drug Delivery Sector

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Philip Brown (PhD) joined PharmaVentures in 2001 and since then has worked on a number of client-based consultancy projects involving aspects of strategy development, technical and commercial due diligence and licensing.

Introduction

As the pharmaceutical industry develops, it is clear that drug delivery technologies are of strategic importance and have become an integral part of the drug development process. Drug delivery technologies have enabled drugs to be launched that would otherwise have been terminated in development because they could not be delivered effectively. They have also helped in lowering the amount of drug that needs to be administered, thus giving improved safety profiles. Moreover, these technologies have been crucial to the life cycle management of therapies, prolonging key revenue streams. Therefore, drug delivery technologies have aided patients and pharmaceutical companies alike in delivering new and improved therapies to the market.

Trends within the Drug Delivery Sector

The aim of this article is to review past activity relating to drug delivery, to assess the trends and, finally, to analyse and discuss the possible reasons behind these trends. A broad analysis of the deals that have been recorded in PharmaDeals® Agreements reveals that the number of signed deals relating to drug delivery is generally on the increase, if the year 2000 is regarded as exceptional (*Figure 1a*).

The fact that there is a general increase in the absolute number of drug delivery deals that occur annually is not surprising. As the complexity of therapies increase, and the need to manage product life cycles becomes key, it must be expected that the number of deals would rise. However, if the number of drug delivery deals is considered as a percentage of the total number of deals that are recorded in PharmaDeals® Agreements, the trend is reversed and there is a slight decrease (*Figure 1b*).

Upon analysing the deals in more depth, it is possible to identify trends relating to the types of deals and types of companies involved in these deals. As with other pharmaceutical deals, there are a number of different types of deals that can relate to drug delivery, ranging from a fairly simple licensing agreement to complex collaborative R&D or co-development partnerships, to merger and acquisition (M&A) activity. The following sections of the article review these trends within the drug delivery sector, considering how they are changing and discussing the possible reasons underlying these changes.

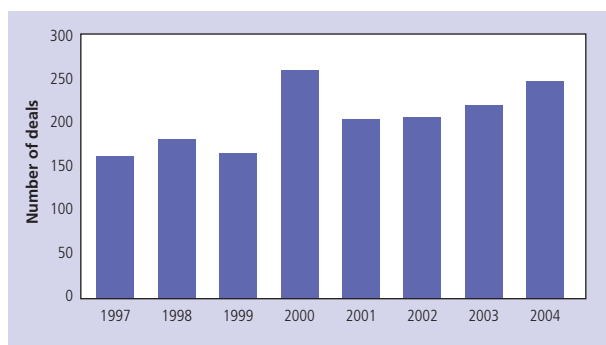


Figure 1a – Drug delivery deals.

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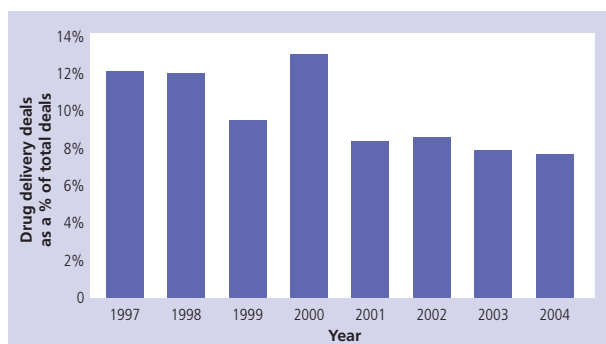


Figure 1b – Drug delivery deals as a % of total deals.

Licensing

A gradual increase in the volume of deals since 1997 becomes apparent when considering activities relating to licensing deals (*Figure 2*). This is a trend that could be predicted because these deals represent the simplest types of agreements, carrying the lowest risk and having the lowest commitment or involvement from either side. In addition, comparison with the number of partnerships involving collaborative R&D, co-development, joint ventures or M&As, reveals that there is greater activity relating to licensing.

Collaborative R&D/Co-development

Clear trends emerge when considering deals containing elements of collaborative R&D and co-development. These trends may reflect changing attitudes to the importance of the delivery method within the drug development process. Figures 3a and 3b show the number of deals recorded annually in PharmaDeals® Agreements relating to these areas. The general trends for both are clear: there has

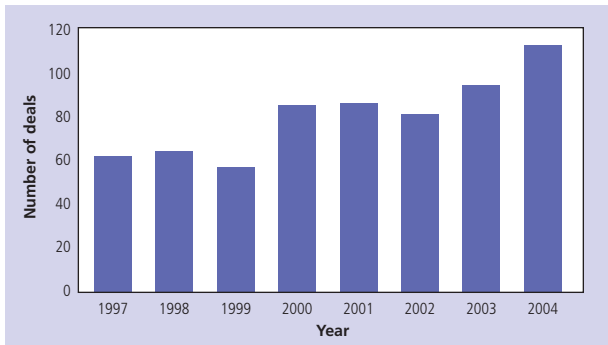


Figure 2 – Drug delivery deals involving licensing.

been a gradual increase in deals involving collaborative R&D, whereas the opposite is true for co-development. These trends indicate that the companies are beginning to consider the drug delivery technology within the development process at an earlier stage – the transactions involving collaborative R&D relate to deals prior to the initiation of clinical trials. The increase in drug delivery deals that relate to collaborative R&D is also likely to reflect the partner's need, and, perhaps, the realisation, that a high level of interaction with the technology company leads to greater development success.

Joint Ventures

This evidence of increased interaction might lead you to expect an increase in those deals that establish joint ventures; this was the case up to 2000 (*Figure 4a*). Although the actual number of deals was low from 1997 to 2000, there was a significant increase in the establishment of joint ventures relating to drug delivery during this time. However, after 2000 there was a sharp decline in the initiation of joint ventures. Therefore, even

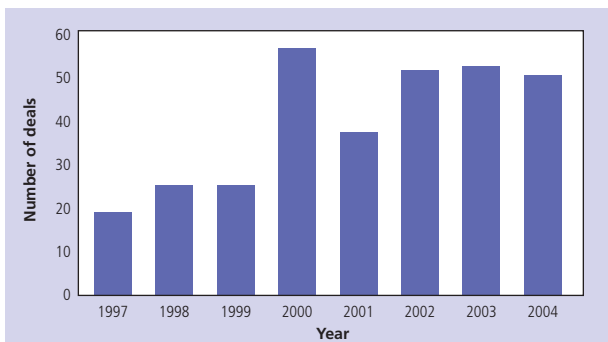


Figure 3a – Drug delivery deals involving collaborative R&D.

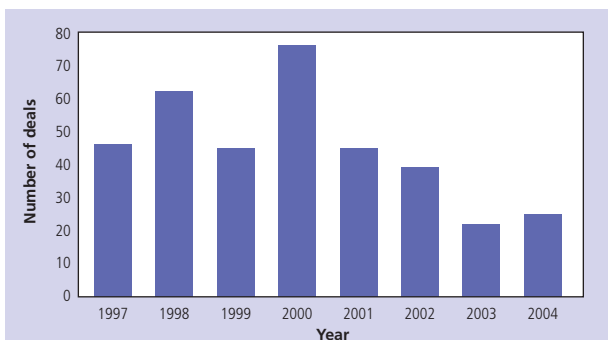


Figure 3b – Drug delivery deals involving co-development.

There are a number of well-publicised examples that stress the importance of drug delivery; among them are Vivitrex (naltrexone), Relenza (zanamivir) and Exubera (insulin).

- In June 2005, **Alkermes** and **Cephalon** announced that they had entered into an agreement to develop and commercialise Vivitrex, a monthly sustained release injectable version of ReVia. ReVia, a once daily, orally administered formulation of naltrexone was blighted by issues of patient compliance, but these issues should be overcome by Vivitrex.
- It was announced in August 2005 that **GSK** was considering the reformulation of Relenza (zanamivir) to help boost sales. Comparing Relenza with Tamiflu (oseltamivir), a similar treatment marketed by **Roche**, there is a vast difference in their respective success. Roche estimates sales of Tamiflu to be in the region of US\$800 M in 2005, whereas Relenza only managed sales of US\$3 M in 2004, although this is expected to be higher in 2005. The main difference between the two therapies is their delivery route: Tamiflu is an oral tablet, whereas Relenza is delivered via the lungs, making it more cumbersome.
- The big news relating to Exubera, the inhalable insulin of **Pfizer**, **Sanofi-Aventis** and **Nektar**, is that in September 2005 the US medicines regulatory advisory panel recommended approval. The FDA is likely to follow this recommendation and give marketing approval. Exubera would be the first inhalable formulation of insulin to reach the market, which should be welcome news to diabetics.

though there is a clear need for therapy and drug delivery companies to work closely together, they are not choosing to enter into joint ventures.

The reasons for this sharp decline are probably linked to issues with funding and the level of risk companies and investors are prepared to take. Prior to 2000, the availability of funding within the pharmaceutical industry was high. However, after 2000 a number of changes occurred that made funding much harder to secure. The commitment to develop therapies has not diminished but it appears that the commitment to enter into a joint venture has dwindled (*Figure 4a*). This reluctance to form a joint venture is not limited to the drug delivery sector; it is also seen throughout the wider industry (*Figure 4b*). The drop is not as marked but there is a considerable lowering in the number of joint ventures entered into. Again, this is likely to be due to cost containment issues and an attempt to lower the risks associated with deal making.

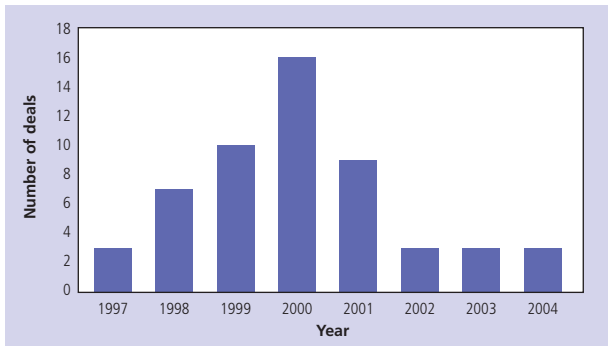


Figure 4a – Drug delivery deals involving joint ventures.

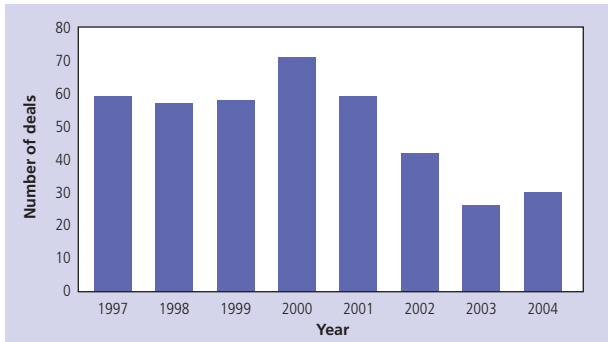


Figure 4b – Industry deals involving joint ventures.

Merger and Acquisition (M&A)

A possible way of lowering risk within drug delivery is to merge with, or acquire, another company. There are a number of reasons why a drug delivery company would choose to, or would need to, merge with another company. These can range from forming an alliance to combining a therapy with a technology, thereby giving the company exclusive access to a new technology. This allows a company to build a suite of technologies. Another reason may simply be the survival of the company.

The number of drug delivery companies that undertake M&A activity has been increasing over recent years (Figure 5a). An increase also emerges when considering the M&A activity within the entire pharmaceutical industry (Figures 5a and 5b). However, if the percentage of drug delivery M&A deals is considered as a proportion of the overall industry M&A activity, there is a much faster increase within the drug delivery sector (Figure 5c). This rapid increase in drug delivery M&A activity relative to the industry as a whole indicates yet again the increasing interest and importance in drug delivery technologies.

Types of Companies Involved in the Deals

In addition to assessing the trends that relate to the types of deals that are occurring in the drug delivery sector, it is also possible to analyse the trends relating to the types of companies involved. The strongest trend relates to alliances formed between two emerging companies; these types of deals have increased considerably since 1997 (Figure 6a). When the deals involve a start-up/emerging company as the principle company and an established or global

A recent and well publicised alliance that combines elements of licensing, collaborative R&D and co-development are the agreements between **Vectura, Arakis and Novartis**. Initially, Arakis and Vectura entered into a collaborative R&D/co-development agreement in 2000 for AD 237 (NVA 237). This agreement was for the two companies to develop an inhaled treatment for chronic obstructive pulmonary disease (COPD). The two companies agreed to fund the development of the product jointly and to share the commercial returns. This agreement was followed by a licensing deal between Vectura, Arakis and Novartis in April 2005. At this point the product was in Phase II development and Novartis agreed a global development and commercialisation deal. Novartis is responsible for developing the product as a monotherapy and as a combination with one of its own development products.

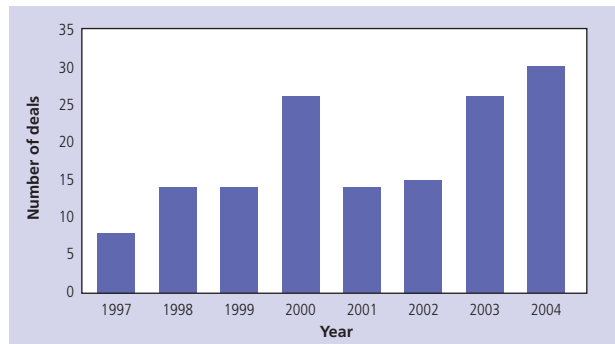


Figure 5a – Drug delivery deals involving M&A.

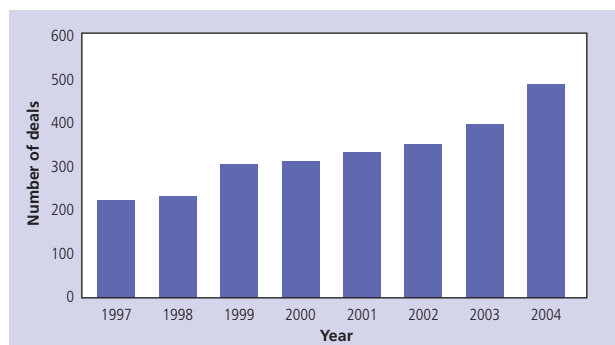


Figure 5b – Industry deals involving M&A.

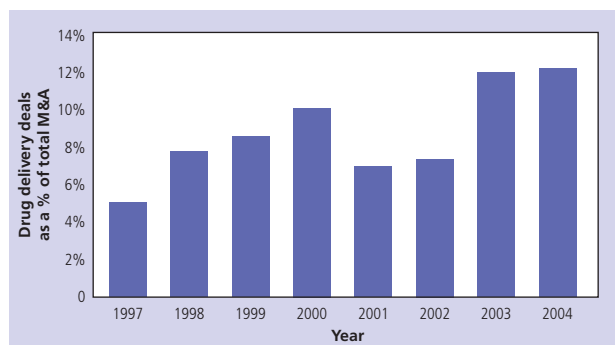


Figure 5c – Drug delivery deals as a percentage of industry M&A activity.

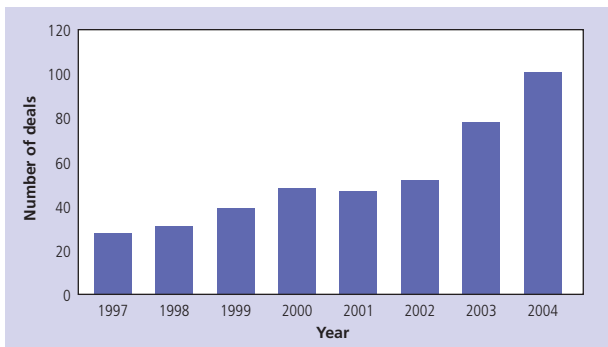


Figure 6a – Emerging companies involved in drug delivery.

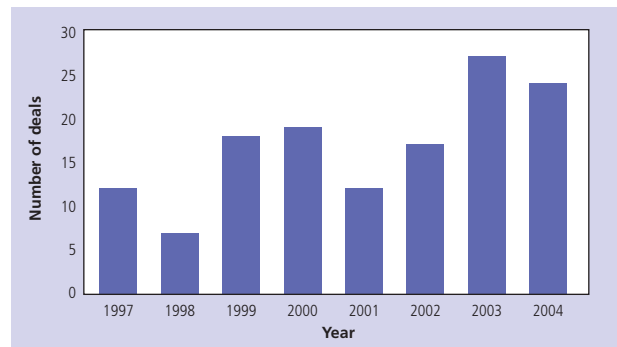


Figure 7a – Established/start-up companies involved in drug delivery.

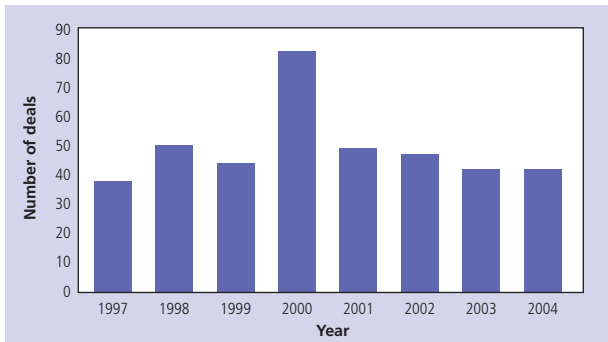


Figure 6b – Emerging/established companies involved in drug delivery.

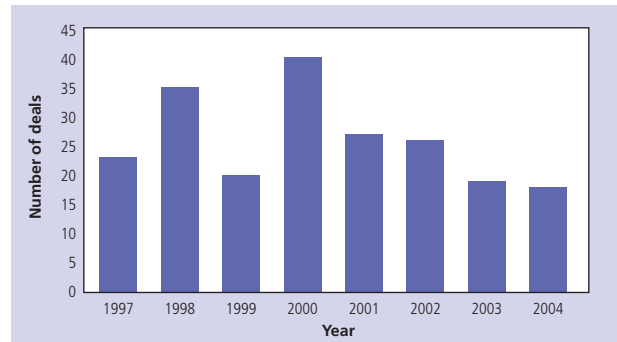


Figure 7b – Established companies involved in drug delivery.

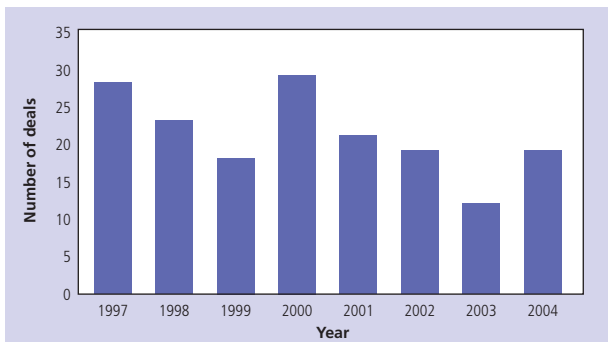


Figure 6c – Emerging/global companies involved in drug delivery.



Figure 7c – Established/global companies involved in drug delivery.

A recently announced acquisition relates to **Nektar Therapeutics and Aerogen**. Through this acquisition, Nektar is able to broaden its pulmonary technology base and strengthen its capabilities for treatment within the acute care setting. It already has a strong portfolio of inhalable drugs, most notably its inhaled insulin product Exubera for diabetes. In recent years, Nektar has followed an acquisition strategy and this deal is one of a number of deals that Nektar has entered into, enabling it to build significant capabilities. In 2001, it acquired both **Bradford Particle Design** and **Shearwater Polymers**; Bradford gave Nektar access to supercritical fluid drug formulation technology and Shearwater gave it access to PEGylation technology, which Nektar has used to great effect.

company as the partnering organisation, the trend is fairly static, with little sign of growth or decline (Figures 6b and 6c).

This analysis demonstrates that there has been a slight move by emerging companies away from forming alliances with established or global companies and a significant increase in the number of deals that they sign with other emerging companies.

A similar trend is seen when the principle company in the alliance is an established company; the number of deals formed with a start-up company has generally increased (Figure 7a) but alliances with other established companies or with global organisations have decreased (Figures 7b and 7c). This decrease is more marked for global organisations.

An analysis of the types of companies that are involved in drug delivery deals indicates that the majority of the agreements that occur are between emerging companies.

These are small, new companies that are more likely to merge to build critical mass, thereby allowing them access to a suite of technologies. Other motivations are likely to be related to the survival of the company, especially because raising investment is currently difficult.

Future Trends

When considering drug delivery deal activity in the recent past it becomes clear that a number of trends are emerging and it is likely that these trends will continue:

- The number of licensing agreements occurring within the industry is increasing and can be expected to continue to increase
- The trend of drug delivery alliances occurring earlier in the development process, where collaborative R&D is increasing and co-development is decreasing, is also expected to continue as the delivery technology becomes more integral in company strategy and the development process
- The establishment of joint ventures takes a high level of commitment and investment and, therefore, until investor confidence returns to the industry the level of joint ventures is expected to stay low
- The trends associated with deals relating to M&As are also expected to continue. Currently, the percentage of drug delivery M&As compared with the rest of the healthcare industry is increasing and, as companies try to gain exclusive access to technologies, this trend can be expected to continue.

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