Data Exclusivity

In Europe it is necessary to obtain a marketing authorisation from the appropriate regulatory authority to place a new medicinal product on the market. Depending on the situation, the marketing authorisation may be obtained Europe-wide or nationally. To obtain the authorisation, the innovator company wanting to market the medicinal product must file data indicating the product's efficacy and safety. This data includes the results of pre-clinical and clinical trials.

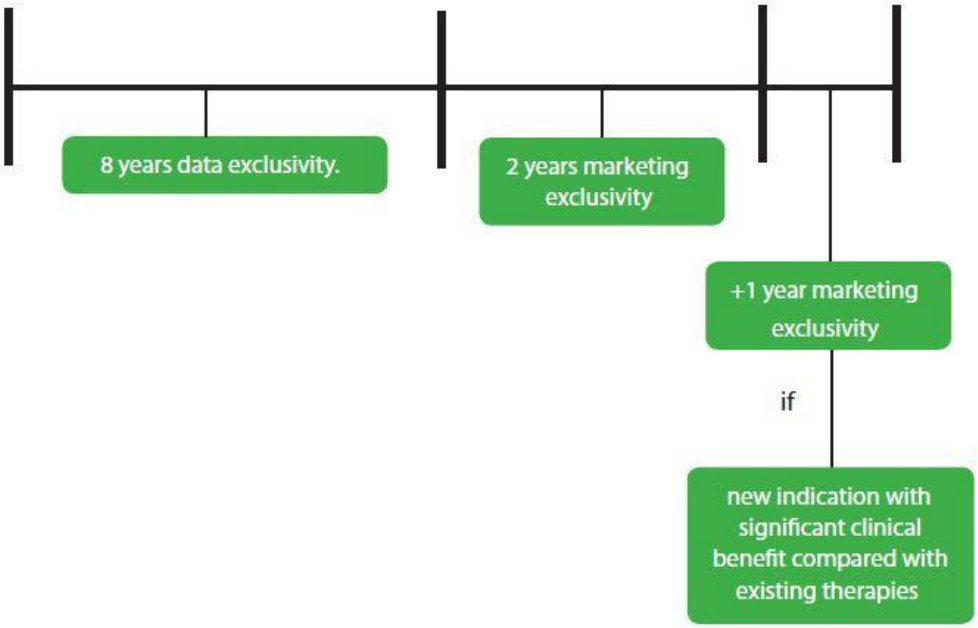
Filing this data provides the innovator company with two rights. These are: data exclusivity, a form of product exclusivity right for medicinal products in Europe; and marketing exclusivity, a related form of additional protection. These rights are intended to compensate the innovator company for their investment in developing the new medicinal product, and generating the required data to obtain the marketing authorisation.

Data exclusivity and marketing exclusivity are entirely different from, but exist in parallel to, patent rights, offering innovator companies different benefits, over different time periods, for their new medicinal products.

If a generics company wishes to market the same medicinal product, for example, upon expiry of the relevant patent and SPC rights, said company must also obtain a marketing authorisation. Generics companies do not wish to (and in many cases could not) provide the same level of data as was required by the innovator company. Instead, the generics company may wish to rely on the data filed by the innovator company in order to obtain their own marketing authorisation. This is done by filing an abridged application for a marketing authorisation, for which the generics company must show that their product has the same qualitative and quantitative composition as the innovator company's product and that it is bioequivalent. If the generics company can do this, they can then rely on the data filed by the innovator company, and obtain their own marketing authorisation.

However, data and marketing exclusivity ensure that the generics company cannot rely on the innovator company data until the innovator company has benefited from the high cost and effort it entailed in obtaining their own, first, marketing authorisation. Data exclusivity provides the innovator company with a time period during which their pre-clinical and clinical data may not be referenced in the regulatory filings of the generics company for the same medicinal product. For marketing authorisations made from November 2005, the period of data exclusivity in Europe is 8 years from the date of first marketing authorisation. The related marketing exclusivity provides an additional period of 2 years during which time a generics company can submit their own application for a marketing authorisation and have it processed; however, they cannot market their generic version of the medicinal product until the expiry of the 2 year period. This means that the generics company could be in a position to market their product 10 years (i.e. 8 years data exclusivity + 2 years marketing exclusivity) after the innovator company obtained their original marketing authorisation.

In some circumstances, the innovator company may qualify for an additional 1 year of exclusivity. These circumstances include where the innovator company is granted a further marketing authorisation for a significant new medical indication for the same medicinal product during the 8 year data exclusivity period. The product must be held to bring a significant clinical benefit in the second indication compared to existing therapies. In such a case, the generics company can only market their product after 11 years from the grant of the innovator company's marketing authorisation. This is known as the "8 + 2 + 1" approach, as shown below.



Data protection is an important barrier to market entry for generics companies. In some cases, for example, where the first marketing authorisation is issued late in the patent life of the medicinal product, data exclusivity may be the last right to expire, thus extending the period of exclusivity for the innovator company. Even when this is not the case, data exclusivity can be highly valuable, for example, when patent protection is weak or patents do not exist. Additionally, many generics companies will not challenge the validity of patents that expire before the expiry of the data exclusivity period.

We have explained the general principles of data exclusivity in this AL Factsheet but it is only an introduction, and any live situation will need individual assessment. Please contact us if you need more detailed information.