NEW RISK-SHARING AGREEMENTS FOR PHARMA INDUSTRY - ROCA JUNYENT

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A new medicaments purchase scheme between manufacturers and purchasers has been established, whereby both parties will share the risk of introducing a either new medicament, technology, procedure or medical device.

The scheme is designed according to a system of payment/reimbursement that is directly related to the effectiveness of the medicament and/or its cost-effectiveness. The scheme will be referred to by different names, such as risk-sharing agreements (RSA), patient access schemes (PAS), performance-based agreements (PBA) and managed entry agreements (MEA).

Initially used for the introduction of innovative products in the pharma industry, nowadays RSAs are also promoted for orphan medicaments and rare diseases, medical devices and other medicaments that – although not innovative – maximise their effectiveness if they are administrated according to some specific guidelines or patterns.

RSA may refer only to financial matters such as traditional price volume agreements or rebates, or more elaborate and real risk-sharing based on the outcomes guarantee (where the buyer/payer and the pharmaceutical company agree on the clinical outcomes expected, and the risk associated with them is reflected in the final price that the company will get for the product) or on the performance guarantee (because sometimes the effectiveness of a medicament is known, but the relationship between its costs and clinical benefits depends on its correct use).

An RSA, as a contract between parties, should include: the disease, care process or problem for which it is designed, well-specified and clearly identified, as well as the goals pursued (the obligations of all parties, definition of indicators, monitoring and evaluation should be in line with the goals pursued), patient eligibility criteria, monitoring requirements, evaluation process, pricing method and the guarantee that results will not be exclusively on the side of one of the parties and that there will be mutual benefits for all parties involved.

The terms of the RSA are a multidisciplinary product with the contributions of medical specialists in the disease or care process, pharmacologists, managers and lawyers. No one should write the whole terms of the agreement by themselves. It is not only a legal productbut neither is it exclusively medical/pharmaceutical. In fact, it should be both.

Most pharma buyers/payers in the EU are the member states or some other public bodies from their respective countries, with full submission to EU public market directives. In addition, pharma is a regulated area in all of these countries. If one asks whether those laws are impeditive for RSAs, the answer is no. On the contrary, Belgium, the Czech Republic, France, Lithuania, Norway, Portugal and Slovakia have specific RSA regulations, while some other countries like Cyprus, Italy, Malta, Sweden and the UK do not have specific legislation, although some of them, particularly the UK, Italy and Sweden, were pioneers and today they are benchmarks for this kind of agreement.

So, what is the situation in Spain? Public market laws do not ban this kind of contract, provided the principles and rules of procurement are respected. Neither does pharmaceutical law; article 90 of the Medicines Law 29/2006(Guarantees and Rational Use) rules that wholesale prices (industrial prices) are the maximum prices, so they may be reduced by this kind of agreement. The conclusion is that there is no legal impediment for RSAs in public markets in Spain, nor in the rest of the EU.

In the case of private markets, when buyers/payers are insurance companies, private health centres or companies, there is no legal limit beyond that of the principle of party autonomy.

In short, by using RSAs, parties can increase their knowledge about the real effectiveness of the product thanks to their accurate design, performance and evaluation, and the results can provide much more information than clinical trials for both parties. In addition, they are an opportunity for payers/buyers to include patients in new treatments without the risk of an uncontrolled cost increase.

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