Description: Managed entry agreements apply to an increasing number of new, innovative drugs in a growing number of markets. They are designed to share the risk between the manufacturer and the payer, consequent on uncertainties - usually at launch - about the product's value (clinical- and cost-effectiveness), budget impact and/or utilisation to optimise performance, whilst at the same time allowing patient access. For many products considered costly they are almost essential to achieve reimbursement where health technology assessment is applied.

Risk Sharing and Other Forms of Managed Entry Agreements for Medicines, Worldwide covers all the main types of agreements (finance-based, outcome- or performance-based, and compliance-based) and their many variants in all countries that employ them. The confusing taxonomy associated with the topic (e.g. price/volume deals, budget impact schemes, cost capping, cost sharing, coverage with evidence development, money back guarantees, conditional reimbursement, listing agreements, payment for performance, payment by results) is clearly explained.

Find out from a manufacturer's perspective:

- Which party should first propose an agreement and at what stage?
- What types of agreements are possible and where?
- Which therapeutic classes are most affected?
- Can an agreement accepted in one country be rolled out to another?
- Is standardisation of design likely?
- How is monitoring conducted?
- What types of outcome are measurable in performance-based schemes?
- How much confidentiality surrounds finance-based deals?
- What are the benefits of risk sharing, what are the concerns?
- How much do schemes burden the health service?
- Have past agreements delivered on expectations?
- Is more of the same the way forward?

Focussing on markets with the most experience of risk sharing – Australia, Belgium, Canada, France, Italy, Portugal, Sweden and the UK – the report in total covers 24 countries across Europe, North America and Asia-Pacific. Deals where the payer is an insurer/health system at the national or local level, or an individual patient are included. Numerous brand name examples are cited by country/agreement type with 12 case studies in more detail.

A good risk-sharing agreement will create a win-win situation all around. Take the first step to resolving uncertainties with your key launches by purchasing or ordering your copy of this essential new report.
Belgium
Czech Republic
Denmark
France
ATUs
Price-volume agreements
Performance-based agreements
Requests by Transparency Commission
Requests by CEPS
Germany
Non-tender discount agreements
Cost-capping agreements
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Coverage with evidence development agreements
Serbia
Slovenia
Spain
Sweden
Case studies
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Acomplia
Risperdal Consta
Role of county councils
Switzerland
United Kingdom
Multiple sclerosis scheme
Principle and design of a patient access scheme
Results of patient access schemes
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Scotland
Wales
Case studies
Velcade
Lucentis
Issues arising from national patient access schemes
Local patient access schemes
Prospects
EU managed entry agreements project

3. North America

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Industry initiatives
Provincial product listing agreements
United States
Pay for performance
Cost capping
Coverage with evidence development
Patient assistance programmes

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Other early examples
Case study: Tracleer
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Managed entry schemes
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For providers
For payers
For patients/society
Concerns
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For providers
For payers
For patients/society
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Does it add a bureaucratic burden?
Can one scheme be applied in several countries?
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