Tables 1: CIRR update of July 31

Figure 4. The data undergo an initial aggregation within an intermediate table of the dashboard. After the coding of all data, the system via a second data aggregation creates the final table.

Figure 2. Risk sharing procedures: an innovative drug should be reimbursed only if effective; the welfare systems can’t bear the costs of new drugs. One mechanism that can contain the costs of new drugs is shared risk, which is defined as the proportion of the costs that are borne by the manufacturer and the health system. The shareable costs are those associated with the introduction of the drug, including clinical trials and the costs of monitoring the drug post-market. The shareable costs are then divided into two categories: the risk-bearing period and the risk-sharing period.

Figure 1. Tomino C. Balance between new treatment opportunities and public health expenditure control: The Regulatory Agency role. Pharmaceutical Policy Law. Volume 12, number 1-2/ 2010

With the experience of more than six years of monitoring (profiled access to the projects over 90,000,000, public access to all those involved in the authorization mechanism, production, prescription and administration of drugs monitored has reached a high level of completeness and accuracy and has been integrated into a database that can be accessed by all the actors involved. The mechanisms of monitoring by registries, the MEAs schemes and the information of regional dashboards are all intended to ensure that the data collected is accurate, complete, and up-to-date. Access to the data is restricted to those with a legitimate interest in the information provided.

The benefits of all the actors involved:
- To customize and save research criteria.
- To have an overview of data recorded in all Registers of Monitored Drugs (since 2006 over 400,000 cases);
- Economic/Administrative: dispensed drugs per marketing authorisation, expenditure (per treated patient, pathology, difference among prescription sites), expenditure reimbursed by Risk Sharing and/or PbR (Payment by Result).
- Clinical: eligible patients, treated patients, duration of treatment, end of therapy, ADR, per drug or therapeutic indication;
- Static reports: tabular listing synthetic indicators (rates, percentages, ratios, medians, etc.) From a technical viewpoint, the data is presented as:

THE REGIONAL DASHBOARD

Several quality and consistency controls are implemented during the data entry.

- In case of "hospital pharmacy": the data must be validated by the pharmacist and the pharmacy must indicate the dispensing reference pharmacy. If the pharmacy is a hospital pharmacy, the system may automatically generate the dispensing form. The correct completion of the dispensing form is a crucial and important step: it provides valuable data that allows the system to track the use of the drug and to detect any anomalies. The data is then fed into the database, which is then used by the system to generate reports.

THE APPLICATION OF MANAGED ENTRY AGREEMENTS

The parties involved may enter into a Managed Entry Agreement (MEA) as a mechanism to manage the risks associated with the introduction of a new drug. The MEA is a legal agreement between the manufacturer and the health system that specifies the terms and conditions of the introduction and use of the drug. The MEA may include provisions for the sharing of risks between the manufacturer and the health system, including the costs associated with the introduction and use of the drug.

The formulas are:

- PbR: Payment by Result (or performance) as total refund applied to the initial cycles for non-responder patients after re-evaluation.
- Risk Share: as special discount applied to the initial cycles for non-responder patients after re-evaluation.

PROTECTED CONTENT

The data is protected by copyright, trademarks, and/or other intellectual property laws and rights. Any use of the data must be in accordance with the terms and conditions set forth by the data owners. Any unauthorized use of the data may result in legal action.

THE REGISTRIES OF ITALIAN MEDICINES AGENCY

The Italian post-marketing registries are the database for the monitoring of new drugs. They are accessible to the public and provide information on the safety and efficacy of new drugs. The registries are maintained by the Italian Medicines Agency (AIFA) and are accessible to the public via the website: http://monitoraggio-farmaci.agenziafarmaco.it. The registries are updated on an annual basis and include data on the safety and efficacy of new drugs, as well as information on the cost-effectiveness of new drugs.

The benefits of using the registries include:
- Access to new drugs, supported by the National Health Service (NHS) and again, new sources of relevant clinical data.
- Access to market for the new drugs, supported by the NHS and again, new sources of relevant clinical data.

THE WEB-BASED REIMBURSEMENT PROCEDURES

The web-based reimbursement procedures are used to manage the risks associated with the introduction of new drugs. The procedures are designed to ensure that the costs associated with the introduction and use of new drugs are managed effectively. The procedures are designed to ensure that the costs associated with the introduction and use of new drugs are managed effectively. The procedures are designed to ensure that the costs associated with the introduction and use of new drugs are managed effectively. The procedures are designed to ensure that the costs associated with the introduction and use of new drugs are managed effectively. The procedures are designed to ensure that the costs associated with the introduction and use of new drugs are managed effectively.