# SCAN: AN INTEGRATED SYSTEM FOR MARKET ACCESS OF NEW DRUGS IN ITALY

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## BACKGROUND

Italy is a very challenging country for market access (MA) of drugs, due to the dominance of cost-containment objectives, the extensive use of comparative analysis and therapeutic equivalency [(1)] and fragmentation of pharmaceutical policies at the regional level [(2)]. This has turned into drug prices that are generally below major EU countries, both for retail [(3)] and hospital [(4)] markets, important market access delays at national and regional levels [(5)], and market penetration that is well below the European level for some diseases [(6)]. This multilevel and complex environment requires an integrated approach to market access actions by the pharmaceutical companies. Market Access Provider (MAP) is a privately owned consultancy, born in 2010, by winning on SCAN project the FISMER funding from Regione Lombardia for innovative start up projects.

### Figure 1. MA Provider activities


## OBJECTIVES

Purpose of the SCAN project is to support the industry in managing value proposition for market access, integrating national and regional issues and different functions in the companies (Pricing and reimbursement, Outcome research, Health economics, Public affairs, and Marketing), usually involved into market access actions.

## METHODS

Value-based pricing is the key feature of SCAN. Prices are determined according to added value in terms of efficacy, safety, compliance, compared to the standard of care (SOC) for the relevant indication. Added value measurement is validated by a multi-stakeholder panel of Opinion Leaders from different fields: pharmacologists, pharmacoeconomists, and clinicians.
The integrated platform is open to all functions involved in MA (marketing, health economics and outcome research, P&R…) that could contribute, populating the model, with the relevan data. The model should be implemented at least 18-24 months before the expected launch date of the product.

## HOW SCAN WORKS

The SCAN software is divided into different chapters (Figure 2):

1. **Main drugs info:** includes the therapeutic scheme of the new drug and the comparators chosen, in order to calculate the number of packs used per year and also the annual cost of the already marketed therapies;
2. **Epidemiology:** the target population is calculated starting from the whole population and the epidemiological data available (prevalence, incidence, mortality rate, eligible population, expected treatment rate…) (figure 2);
3. **Assessment of clinical and pharmacoeconomic studies** of the drugs vs the chosen comparators. The analyst needs to choose comparable clinical data in terms of efficacy, safety, compliance endpoints using the Jadad scale. [(7)] The core output of this phase is the calculation of the difference between the new drug and its comparator,which are summed up in a comparative table. These data are necessary to estimate the relative value of the new drug vs the comparators. .

### Figure 2. The different sections of SCAN software (left) and the calculation of the target population (right)

COMPARATORS
KEY ASSUMPTION
CLINICAL DATA
MARKET
BRAND FORECAST
PRICING
NATIONAL PATIENT PATHWAY
VALUE BASED PRICE
REIMBURSMENT MODELS
P&L
REGIONAL MARKET ACCESS
NATIONAL BIA INPUT
NATIONAL BIA
NATIONAL SUMMARY
REGIONAL MARKET
REGIONAL PATIENT PATHWAY
REGIONAL BIA INPUT
REGIONAL BIA
REGIONAL SUMMARY
REGIONAL & NTL COMPARISON

| | Y01 | Y02 | Y03 | Y04 | Y05 |
|---|---|---|---|---|---|
| Whole population | 60.340.328 | 60.479.111 | 60.618.213 | 60.757.635 | 60.897.378 |
| est.population growth (%) | 0,00 | 0,23 | 0,23 | 0,23 | 0,23 |
| prevalence (x/100.000) | 2.049,20 | 2.049,20 | 2.049,20 | 2.049,20 | 2.049,20 |
| # prevalent patiens | 1.236.494,00 | 1.239.338,00 | 1.242.188,00 | 1.245.045,00 | 1.247.909,00 |
| incidence (x/100.000) | 125,00 | 125,00 | 125,00 | 125,00 | 125,00 |
| # incident patients | 75.425,40 | 75.598,90 | 75,772,80 | 75.947,00 | 76.121,70 |
| diagnosis rate% | 90,00 | 90,00 | 90,00 | 90,00 | 90,00 |
| N. diagnosed | 67.882,90 | 68.039,00 | 68.195,50 | 68.352,30 | 68.509,50 |
| mortality rate (x/100.000) | 31,40 | 31,40 | 31,40 | 31,40 | 31,40 |
| N. of deaths | 18.947 | 18.990 | 19.034 | 19.078 | 19.122 |
| **Disease population** | **1.285.430** | **1.288.387** | **1.291.349** | **1.294.319** | **1.297.297** |
| **SUB POPULATION:** | | | | | |
| Her-2 neg. | 80,00% | 80,00% | 80,00% | 80,00% | 80,00% |
| Her-2 pos. | 20,00% | 20,00% | 20,00% | 20,00% | 20,00% |
| **TREATMENT RATE:** | | | | | |
| TR Her-2 neg. | 95,00% | 95,00% | 95,00% | 95,00% | 95,00% |
| TR Her-2 pos. | 95,00% | 95,00% | 95,00% | 95,00% | 95,00% |
| **TOTALS:** | | | | | |
| | **Y01** | **Y02** | **Y03** | **Y04** | **Y05** |
| Her-2 neg. | 1.028.344,0 | 1.030.709,6 | 1.033.079,2 | 1.035.455,2 | 1.037.837,6 |
| Her-2 pos. | 257.086,0 | 257.677,4 | 258.269,8 | 258.863,8 | 259.459,4 |
| **Disease population** | **1.285.430** | **1.288.387** | **1.291.349** | **1.294.319** | **1.297.297** |
| Target Her-2 neg. | 976.926,8 | 979.174,1 | 981.425,2 | 983.682,4 | 985.945,7 |
| Target Her-2 pos. | 244.231,7 | 244.793,5 | 245.356,3 | 245.920,6 | 246.486,4 |
| **Target population** | **1.221.158,5** | **1.223.967,7** | **1.226.781.6** | **1.229.603,1** | **1.232.432,2** |

4. **SCAN algorithm** to define the price at national level. The value-based price algorithm is the core application of the SCAN platform. In this session all available data are summed up to determine a fair price for the new drug. For each chosen endpoint, a panel of expert gives a relative percentage score according to their importance (Figure 3). The weighted ratio of the endpoints is used to calculate the real value of the drug/comparator considered.

### Figure 3. Value-based price algorithm, an application

| Value attribute | Endpoint | Weight | Trastuzumab | Lapatinib |
|---|---|---|---|---|
| Efficacy | CR | | | |
| | PR | | | |
| | OR | 25% | 100% | 56% |
| | PFS (m) | | | |
| | MDR (m) | 20% | 100% | 172% |
| | TTP (m) | | | |
| | OS (m) | 25% | 100% | 46% |
| Safety | Neutropenia | | | |
| | Cardiac Events | | | |
| | **Rash** | 15% | 100% | **108%** |
| | Nausea | 15% | 100% | 123% |
| **Value ratio vs comparator (%)** | | | 100% | 95% |
| **drug value/patient per year (€) (ex factory)** | | | € 28.808 | € 27.256 |
| **drug value per pack (ex factory)** | | | € 640 | € 1.514 |

## CASE HISTORY RESULTS

To validate the methodology, the authors have applied SCAN to some drugs recently approved in Europe and Italy. One of them is Lapatinib, that has recently got the price for metastatic breast cancer, vs trastuzumab, bevacizumab and docetaxel.
Twelve clinical trials have been found, verified / selected according to Jadad scale, and subsequently considered in the value-based price algorithm. Actually, the simulated price id close to 1,500 € vs the approved by AIFA 1,225 € approved.

## CONCLUSIONS

The simulations show that SCAN is a useful tool to get a value-based price which takes into account all aspects of a new drug, compared to SOC. The model could be further developed to include assessment of new indications and new drugs with no available SOC. In addition, even if it has been tailored for the industry, it could be used also by third party payers to understand whether they are actually using a value-based approach.

For further information visit us at www.maprovider.com or contact lanati@maprovider.com

Bibliografia
(1) Fattore G., Jommi C. (2008), "The last decade of Italian Pharmaceutical Policy: Instability or Consolidation?, Pharmacoeconomics, 26, 5-15.
(2) Jommi C., Armeni P., De Luca C. et al , Il governo regionale dell'assistenza farmaceutica e il suo impatto sulla spesa. In Anessi Pessina E. and Cantù E. Rapporto OASI 2010 (in press).
(3) De Rosa M, Messori A, Scroccaro G, Il sistema dei prontuari in Italia. Aboutpharma. 2010
(4) Jommi C, Aguzzi G, Otto M (2008). Il confronto internazionale tra prezzi dei farmaci: aspetti metodologici, principali risultati in letteratura e studio sui farmaci con obbligo di prescrizione. In: Giorgio Macciotta. La Salute e il mercato. La ricerca farmaceutica tra Stato, industria e cittadini, 19-47, Il Sole 24 Ore, Milano.
(5) Jommi C. Confronto internazionale tra prezzi unitari dei farmaci ospedalieri nei principali Paesi UE. Available on URL: www.farmindustria.it, last access 31° of October.
(6) Russo P, Mennini FS, Siviero PD, Rasi G, Time to market and patient access to new oncology products in Italy: a multistep pathway from European context to regional health care providers. Ann Oncol. 2010 Oct;21(10):2081-7.
(7) Jadad scale for reporting randomized controlled trials. Appendix to Evidence-based Obstetric Anesthesia. 2007

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