PROFARMA

Based on excerpts from the "Evaluation Guide of PROFARMA 2013-2016", the PROFARMA project appeared to be a success with respect to:

"Making Spanish (pharma) industry more competitive and

- for local companies: expand their reach through internationalisation, on the back of innovation in both research and manufacturing
- for multinationals: expand their commitment to invest in the national industrial structure as well as R&D, and improve the commercial balance

Impact of this program:

- increase of investment by those companies participating in this program
- increase of spending on R&D in general
- increase in employment, especially in R&D, related activities and manufacturing
- turnaround of commercial balance deficit
- increase of share of R&D spending as a % of total spend on reimbursed pharmaceutical drugs"

"This is a tool developed by the ministry of industry, energy and tourism, with the specific goal of being able to classify companies on how they contribute to the objectives of PROFARMA. Companies can request evaluation by a committee of experts on a voluntary basis. **Being classified as a company that contributes in a substantial way to innovation and industrialisation can translate into lower taxes and/or favourable treatment in either access or pricing."**

The criteria taken into account in Spain with diversified weights embrace the following:

"Evaluation of R&D activities

- Projects of basic and pre-clinical research
- Projects of clinical research
- Projects of research into galenic research and development of new technologies
- Centres of basic and/or pre-clinical research either owned by a company or through public-private partnerships

- R&D history, i.e. relevance and continuity of effort in this area by the company (local and global)
- Patents registered by company (local and global)
- Creation of consortia with local partners aimed at promoting and doing R&D

Evaluation of industrialization process

- Industrial activity in Spain => manufacturing either by a company or contracted third parties, with a distinction between active pharmaceutical ingredients vs others and number of different products or AE produced
- Concession for licenses to either produce or commercialise

Investment in production and others

- Level of sophistication of the manufacturing facility
- Total investment

Information regarding team and human resources of company

- Number of employees in R&D
- Number of employees in manufacturing and control
- Number of new employment (positions) created or destroyed

Information regarding commercial activity

- Commercial balance and its trend
- Export volume and trends

It is applicable to the entire pharmaceutical industry."

The system in Spain assumes parallel evaluation by two parts of the project committee apprising data provided by industry according to two sets of criteria, which overlap only partially. It seems RTR designed in Poland is more repeatable, based on highly verifiable data provided by the pharma industry under criminal liability and therefore requires no appraisal by any committee – that translates to high level of automation. It should be noted that the Spanish system was proven to be operational and seen as a success, while RTR is still pending.