



INTEXO

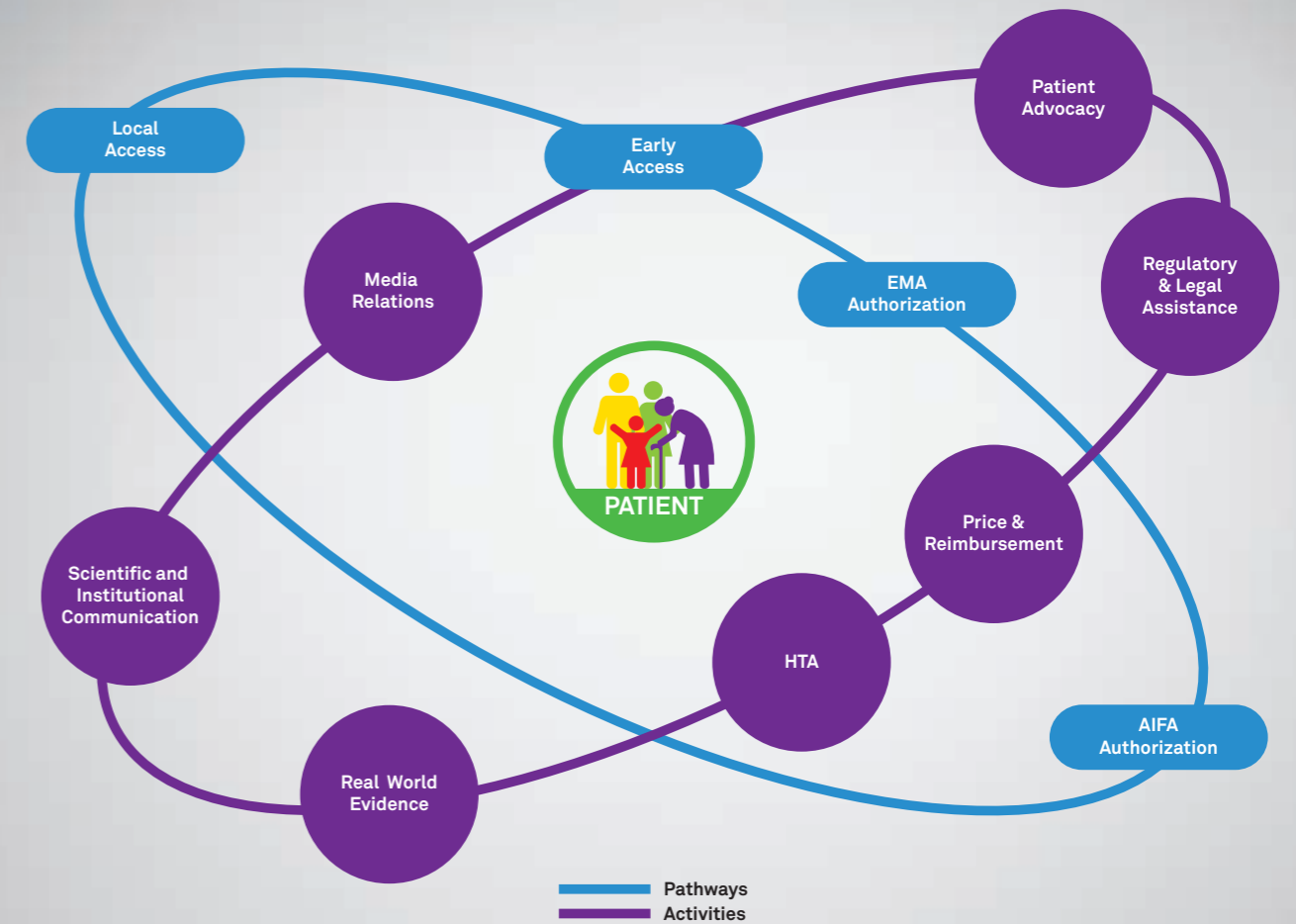
Doorways to the Italian Market

A **change** of perspective  
from **market** access  
to **patient** access

L'accesso ad un farmaco o ad una cura è il risultato di un complesso di attività e procedure che coinvolgono soggetti diversi (Comunità scientifica, Regolatori Pubblici, Imprese, Pazienti) ed integrano procedure regolatorie, valutazioni scientifiche e farmaco-economiche, analisi dei dati, comunicazione ed informazione al paziente. Mentre questo flusso ha come unico fine la cura del paziente, i singoli attori sono portatori di interessi che talvolta possono divenire confliggenti tra loro. Quando prevalgono le divergenze, l'obiettivo della «miglior cura» fallisce.



*Access to a drug or treatments depends on a complex set of activities and procedures involving a number of different players (scientists, official Regulators, Companies, patients) and combining regulatory procedures, scientific and pharma-economic assessments, data analysis, communication and patient information. Though the process as a whole has just one purpose – patient protection – these individual players are stakeholders whose different interests can sometimes come into conflict. When such differences become paramount the goal of “best treatment” is missed.*



Il nostro obiettivo è **ridare centralità al paziente** lavorando per garantire un accesso precoce, appropriato e sostenibile, al farmaco o alla terapia. Per raggiungere questo obiettivo promuoviamo una nuova forma di dialogo tra imprese, regolatori, medici e pazienti, per definire un nuovo paradigma di accesso alla cura.

*Our objective is to **give back centrality to patient** by working to ensure an early access, appropriate and sustainable, to drugs or therapies. To achieve this we promote a new kind of dialogue among companies, Regulators, clinicians and patients, with a view to drawing up a new paradigm for access to treatment.*



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- Global and local Regulatory Affairs
- Advice on regulatory strategies
- Due diligence and gap analysis
- Pharmacovigilance
- CTD and regulatory procedures management
- Scientific Advice with Regulatory Authorities
- Life cycle management
- Training and Education
- Reference market
- Critical analysis of clinical trials data
- Local Guidelines and their translation into the clinical practice
- Place in Therapy
- Early access strategies
- Price and Reimbursement Dossier
- Management Entry Agreement
- Regional Market Access

- HTA models
- Business Impact
- Models/Analysis
- Registries
- Patient data analysis
- Innovative integrated systems for data management
- Collection and real world data analysis
- Company reputation and institutional accreditation
- Media accreditation
- Press conference/media tutorial
- Communication projects
- Cooperation with Italian patients associations
- Cooperation with Italian stakeholders, both at national and regional level
- Integrated communication plans
- Strategic analysis of politics and decisional networks

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## Intexo Srl

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### **Spreading the culture of Quality and Compliance:**

Model of organization, management and control as referred in **DLgs231/01** and related provisions.  
Ethical and behavioral principles as described in the Intexo Ethics Code.



Ref. RT1382 dated 02/12/2015