



EDQM Network on Borderline Products

Plenary meeting

Rome, Italy

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Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 previous years
<i>DIRECT INTERESTS:</i>				
1.1 Employment with a company: pharmaceutical company in an executive role	X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.3 Employment with a company: other activities	X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
2. Consultancy for a company	X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
3. Strategic advisory role for a company	X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
4. Financial interests	X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
5. Ownership of a patent	X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
<i>INDIRECT INTERESTS:</i>				
6. Principal investigator	X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
7. Investigator	X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
8. Grant or other funding	X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
9. Family members interests	X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
10. Serious reasons of convenience	X	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional

***Isabella Marta**, in accordance with the Regulation for the prevention and handling of conflicts of interest of the Italian Medicines Agency, approved by AIFA Board of Directors (Resolution no. 9 - 12 February 2025).

N.B. < I am not receiving any compensation >

Italian Medicines Agency (AIFA)

- Responsibilities:**
- Marketing authorisation of medicines for human use
 - Pharmacovigilance
 - GMP/GCP/GVP inspections
 - Shortages and market surveillance
 - Clinical trials
 - HTA
 - Price and reimbursement

Medicinal products can only be marketed after obtaining a marketing authorisation from AIFA or through the European centralised procedure

AIFA Organization

President (legal representative) BOD

Administrative Directorate

Digitalization, Procurement and
Asset Management Division

Staff and Budget
management Division

Technical-Scientific
Directorate *

Pre-Authiorization and
Research Division

Medicinal Products
Authorization Division

Post Marketing Surveillance
Division

Market Access and HTA
Division

AIFA Organization

President (legal representative) BOD

Administrative Directorate
(AD)

Digitalization, Procurement and
Asset Management Division

Staff and Budget management
Division

Technical-Scientific
Directorate (TSD) *

Pre-Authiorization and
Research Division

Medicinal Products
Authorization Division

Post Marketing Surveillance
Division

Market Access and HTA
Division

* Medicinal shortages, product quality and pharmaceutical crime/ counterfeiting Office refers directly to the TSD

Medicinal Products Authorization Division

Is composed of six Offices:

- European and national procedures
- Post-Authorization procedures
- Centralized procedures
- Certification and parallel import
- GMP inspections and manufacturing authorization of medicinal products
- GMP inspections and manufacturing authorization of APIs

Borderline products

- Can involve in the evaluation and management of borderline products, on a case by case, approach:
 - The Medicinal products authorization Division
 - The Medicinal shortages, product quality and pharmaceutical crime/counterfeiting Office
 - The internal representatives of Carabinieri health protection (NAS)
 - Legal and legislative Affairs Office
 - Disputes Resolution Office

Competent Authorities for health-related products in Italy

Authority	Main responsibilities
Ministry of Health	Food supplements, cosmetics, medical devices, narcotics, others
AIFA	Medicinal products for human use
ISS	Scientific and technical support
Regions	GDP Inspections and local surveillance

Ministry of Health

<https://www.salute.gov.it/new/it/ministero/direzione-generale-dei-dispositivi-medici-e-del-farmaco>

<https://www.salute.gov.it/new/it/ministero/direzione-generale-delligiene-e-della-sicurezza-alimentare>

- In charge for:
- Food supplements
 - Cosmetics
 - Narcotics
 - Medical devices

Food supplements must be notified to the Ministry of Health before being marketed and must comply with the national rules implementing EU legislation

Istituto Superiore di Sanità (ISS) Italian National Institute of Health

- Key roles:
- Research
 - Scientific assessment on public health matters
 - Official Medicines Control Laboratory
 - Scientific support for the Ministry and AIFA

The ISS provides scientific and technical support to the Ministry of Health and other Authorities, including risk assessment and laboratory analysis.

Management of borderline cases in Italy

Handled through cooperation between: **Ministry of Health, AIFA** and **ISS** (If necessary NAS)

Key criteria for classification:

- composition
- mechanism of action
- intended use

The classification is performed case-by-case to ensure consistent application of EU legislation and protection of public health.

Conclusion

The classification of health-related products in Italy depends:

- on their legal status and intended use
- several Authorities may be involved in the assessment of borderline products
- inter-institutional cooperation is essential to ensure a consistent application of EU legislation

Thank you for your attention!