Preventing illicit markets of pharmaceutical and health products through regulatory best practice

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Minsk, 24th April 2018

Agenzia Italiana del Farmaco

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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 preavious years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	X	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	X	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	X	☐	☐	☐ optional
2. Consultancy for a company	X	☐	☐	☐ optional
3. Strategic advisory role for a company	X	☐	☐	☐ optional
4. Financial interests	X	☐	☐	☐ optional
5. Ownership of a patent	X	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	X	☐	☐	☐ optional
7. Investigator	X	☐	☐	☐ optional
8. Grant or other funding	X	☐	☐	☐ optional
9. Family members interests	X	☐	☐	☐ optional

*Lorenzo Montrasio, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts.

N.B. The compensation received is based on the collective bargaining agreement

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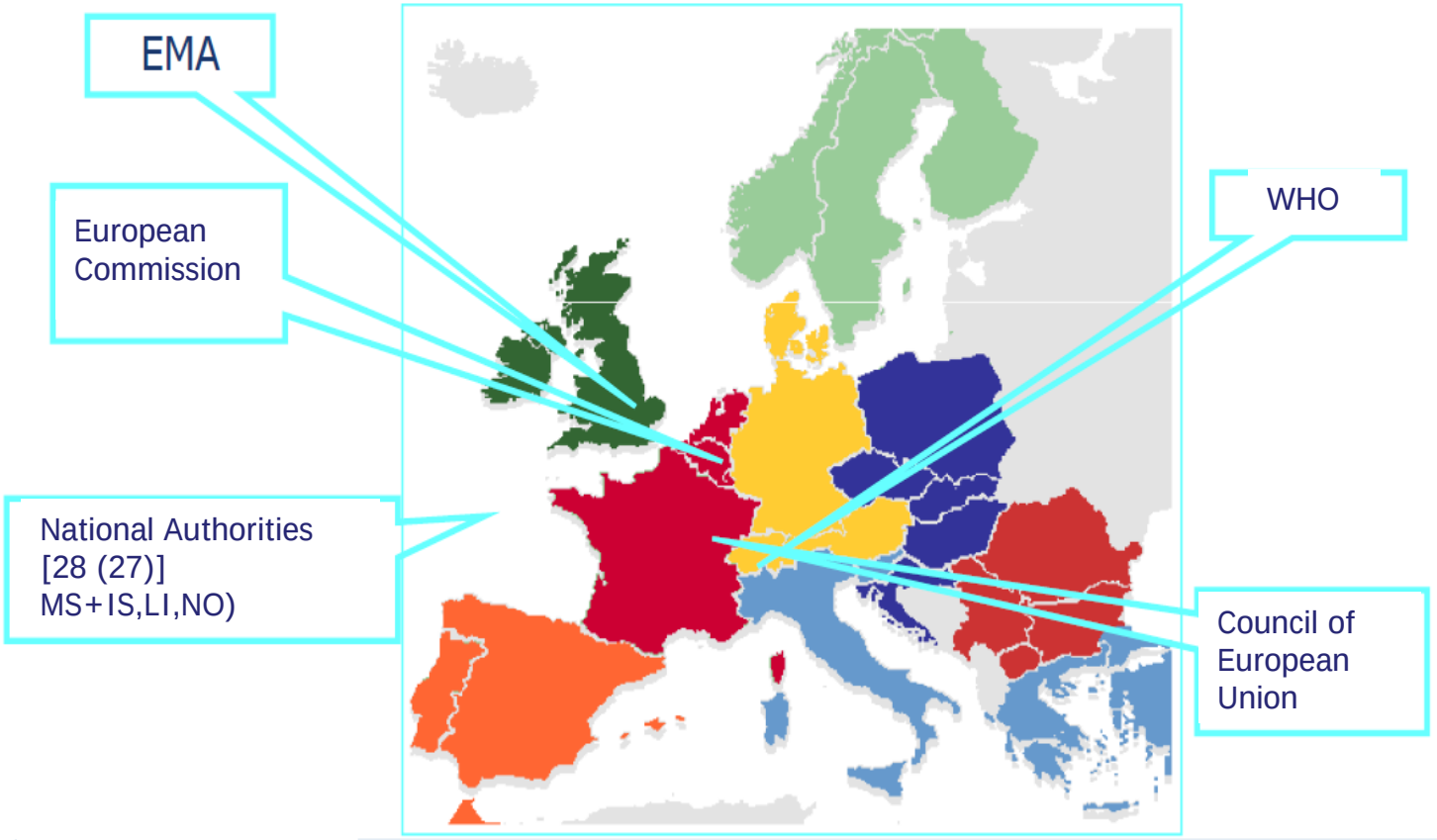
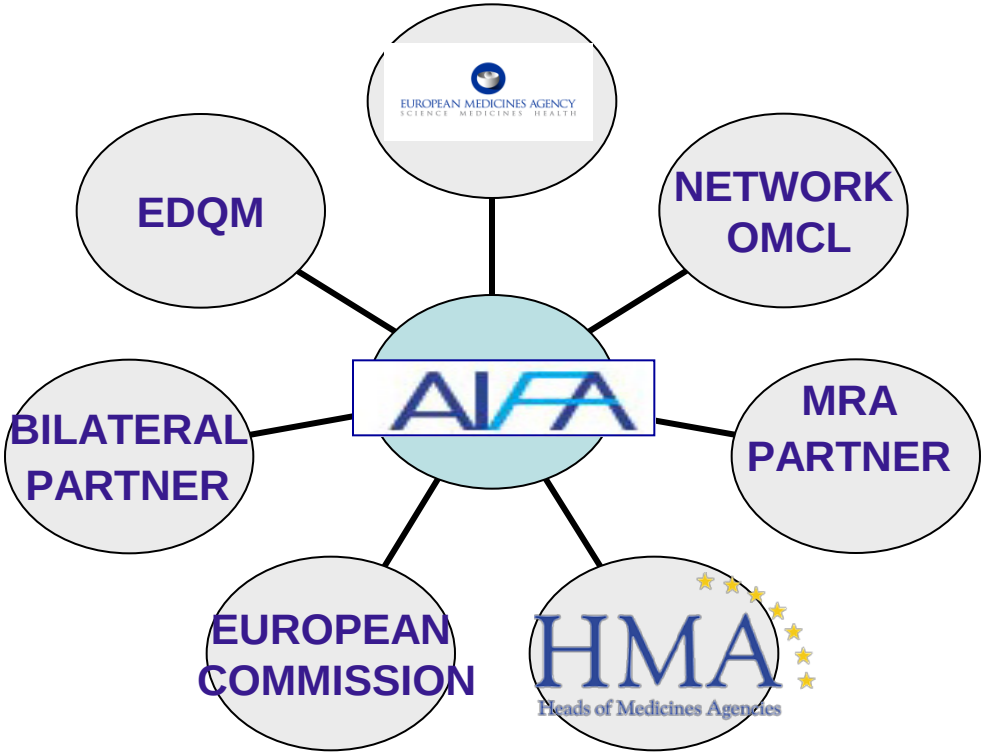
Europe: Competent Authorities for medicines



The network concept



Medicines Regulatory Agencies

Protect the health and safety of the population ensuring the safety, quality, and efficacy of medicines.

Global level

Safety, quality, and efficacy of medicines.

Local level

intellectual property issues

Interchangeability and substitution

Labelling and prescribing information

Regulatory Framework for Marketing Authorization of Medicinal Products

Legislations

Good Manufacturing Practice (GMP)

The European Pharmacopoeia

Guidelines

Scientific Advice

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

No medicinal product can be placed on the market in EU without having obtained a marketing authorization by NCAs (Directive 2001/83/EC) or a Community authorization under Regulation (EC) no. 726/2004.

A medicinal products, in order to obtain a marketing authorization, must meet the EU standard and requirements for Quality, Safety and Effectiveness.

Transparency

EU Agencies strives towards being as open as possible about how it works and how it comes to its decisions.

- Information released proactively
- Information documents under the rules on access to documents and information

Transparency:
The medicine authorisation process

Evaluation

Opinion

Authorization or Refusal

Post authorization

[Information available on the Agency's website]

Evaluation phase

List of the international non-proprietary names (INNs) and therapeutic areas for all human medicines under evaluation by the Committee for Medicinal Products for Human Use .

Agendas and minutes of EMA scientific committee meetings, which contain information on the medicines discussed at each meeting.

Withdraw of application during the procedure

Opinion, Authorization/Refusal

Summary of the committee's opinion: explaining the reasons for the decision.

European Public Assessment Report (EPAR): describing the evaluation of a medicine and including the product information.

Refusal European public assessment report, including a question-and-answer document and an assessment report

Post Authorization

Updated EPAR for each medicine while it is on the market, including information on the approved changes to the marketing authorisation.

Press releases and question-and-answer documents summarising the major changes.

Refusal of changes including applications for extensions of the indication (minutes of the Pharmacovigilance Risk Assessment Committee (PRAC).

Other outcomes

Publication of clinical data submitted by industry to support their marketing applications

Rare disease (orphan) designations

Paediatric investigation plans

Conflicts of interests of staff and experts
(CV, DoI, Risk level)

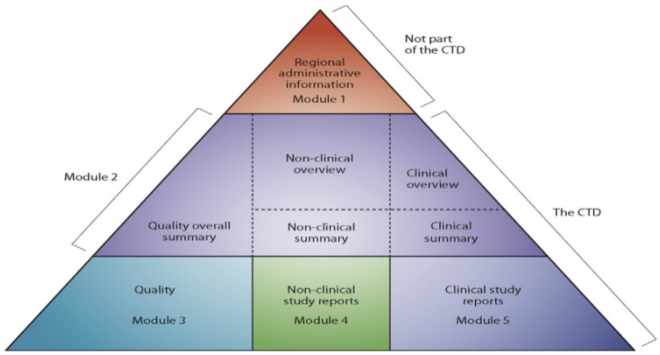
Side effects of medicines

Information on suspected side effect reports are available on EudraVigilance database.

Manufacturing inspections

Information on inspections of the manufacturing sites for medicines performed by regulatory authorities in the EU, Iceland, Liechtenstein and Norway are available in a public database called EudraGMP.

Common Technical Document (CTD)



Module 1: *Administrative and prescribing Information*
Module 2 *Summaries*
Module 3 *Quality (Drug substance and Drug product)*
Module 4 *Nonclinical Study Reports*
Module 5 *Clinical Study Reports*

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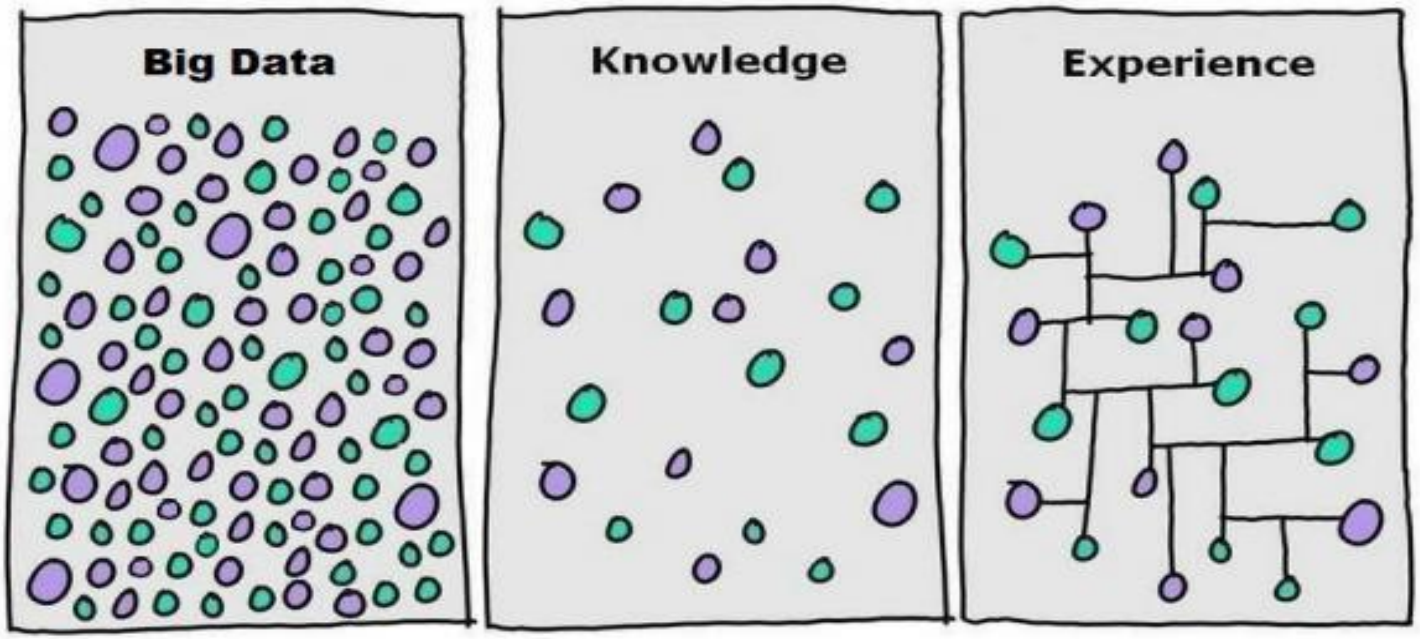
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/b/update_200805/ctd_05-2008_en.pdf



R&D CTD

Guidelines and Standars for assessment

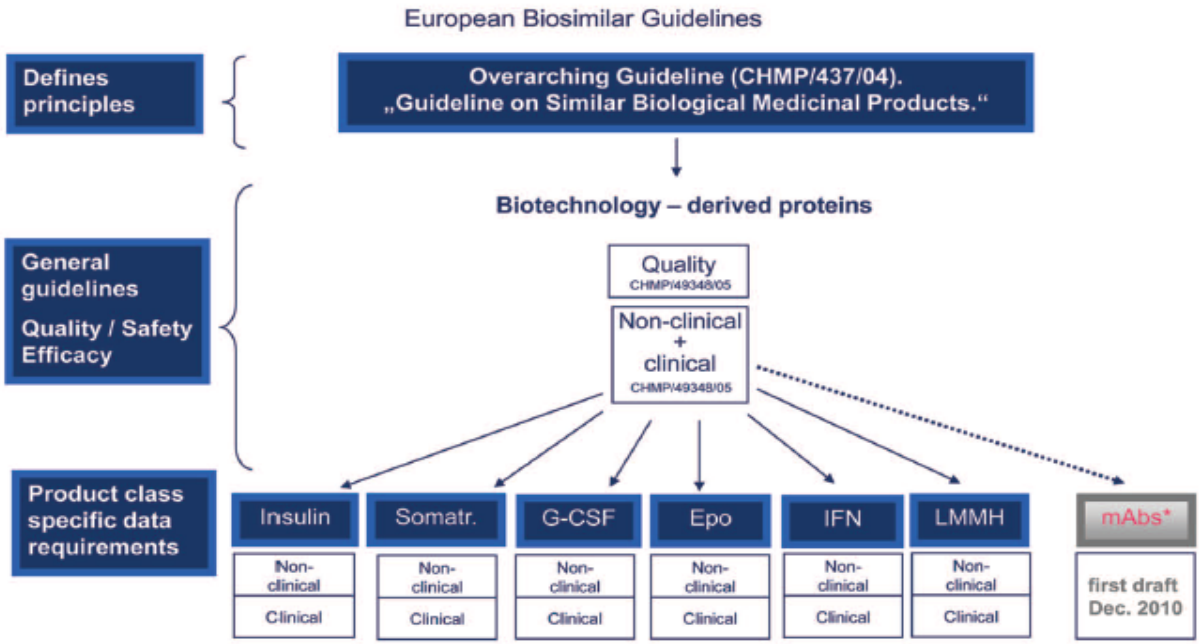


Figure 1. European biosimilar guidelines. The EMA began with an overarching guideline on biosimilars and then general guidelines, before issuing product class specific data requirements. The EU Guidelines that have been finalized are indicated in blue. A draft guideline for mAbs is currently available for public comment.[25]

Import Authorizations

	Italian Medicines Agency		Ministry of Health	
	Product Quality and Pharmaceutical Crime Counteracting Office	Certification and Parallel Import Procedures Office	Central Office for Narcotic Drugs	Maritime, Aviation and Border Health Office (USMAF)
Medicinal products registered in Italy and temporarily lacking	●			
Plasma and blood or plasma derivatives registered in Italy and abroad	●			
Medicinal products containing narcotic substances			●	
Medicinal products undergoing clinical trials/compassionate use				●
Medicinal registered abroad (EU or third country)				●
Medicines under the full charge of the NHS pursuant to Law n. 648/1996				●
"Parallel Import" medicinal products		●		

Import authorization

Parallel Import

Import of medicines authorized abroad

Parallel Import

Example: Parallel import medicine, repackaged, from Greece

Italian product

Greek product

Repackaged product
For the Italian Market

Import of medicines authorized abroad

- Ministerial Decree of 11 February 1997: justified by objective reasons of exceptionality need; absence of a valid therapeutic alternative (under physician responsibility). The product should be regularly authorized in a foreign country.

- Memorandum of 23 March 2017: different dosage of active ingredient, different route of administration, different excipients, different formulation of active ingredients, or when access to the medicinal product available in Italy is not possible due to its excessive cost.

“Health Products”

Knowledge of the different types of "health products" and the differences that characterize them regarding the use, the mechanism of action, the system of authorization and post marketing controls.

- » Medicine
- » Active ingredients [(INN): Paracetamol; IUPAC: N-(4-hydroxyphenyl)acetamide]
- » Excipient
- » Medical devices
- » Cosmetic
- » Food supplements

Conclusion

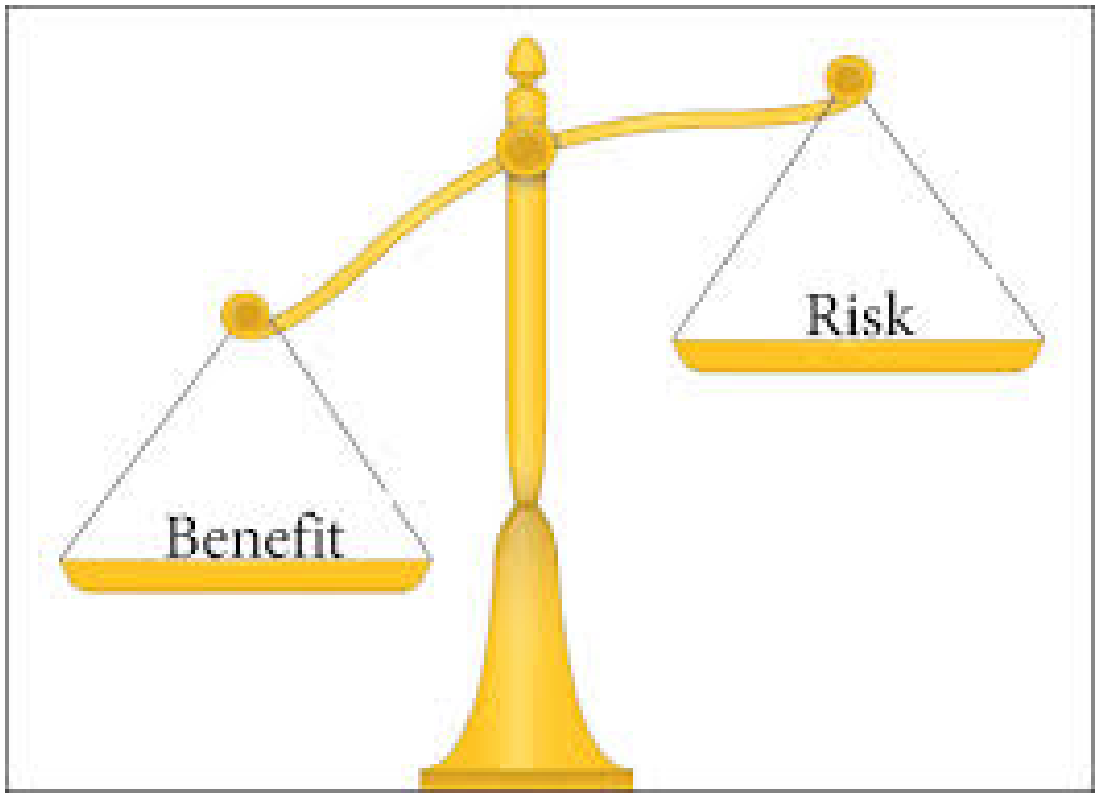
Accepted norms and standards for the evaluation

To help applicants obtaining marketing authorisation

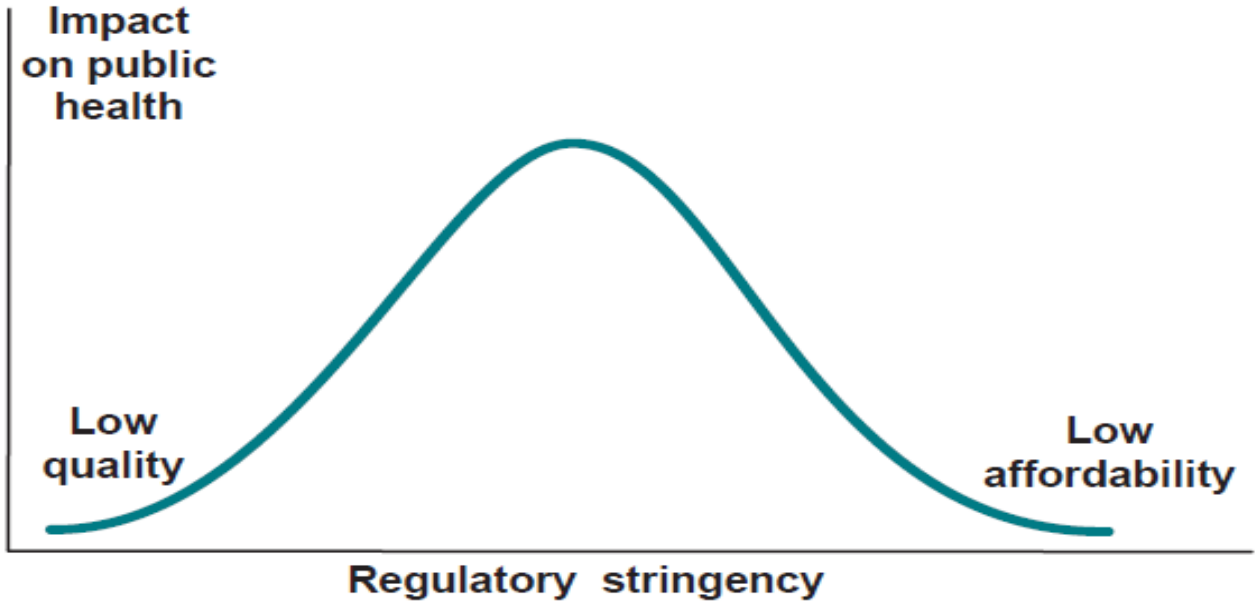
To guarantee a harmonised approach of assessment and to support the decision process

Written standards (i.e. legislation and guidelines)
Laboratory standard (i.e. Harmonised Methods; I.S.)

Conclusion



Conclusions



Public health requires quality and coverage

Conclusion

The evaluation process of medicines is based both on trust and detailed controls

Conclusion

Regulatory best practice contribute effectively preventing illicit markets of pharmaceutical and health products

- Protection of public health

- Legislation
- Network
- Guidelines
- Standards

- Transparency
- Knowledge
- Competence

Thank you for your attention!

CONTATTI

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