AGENZIA ITALIANA DEL FARMACO

OSMED: presente e futuro

Nicola Magrini

Presentazione Rapporto OSMED – Uso dei farmaci in Italia

23 luglio 2021

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OSMED: presente e futuro

Dove vogliamo andare per migliorare l'accesso e gli usi ottimali dei farmaci

Nicola Magrini

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  - Mercato farmaceutico, andamenti e regole: un mercato molto regolato
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  - EMA-AIFA: maggiore attenzione aspetti usi ottimali, usi reali
  - Trasparenza: accesso ai dati degli studi clinici
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  - AIFA – all in one model
  - Cosa vogliamo fare meglio
- Conclusioni

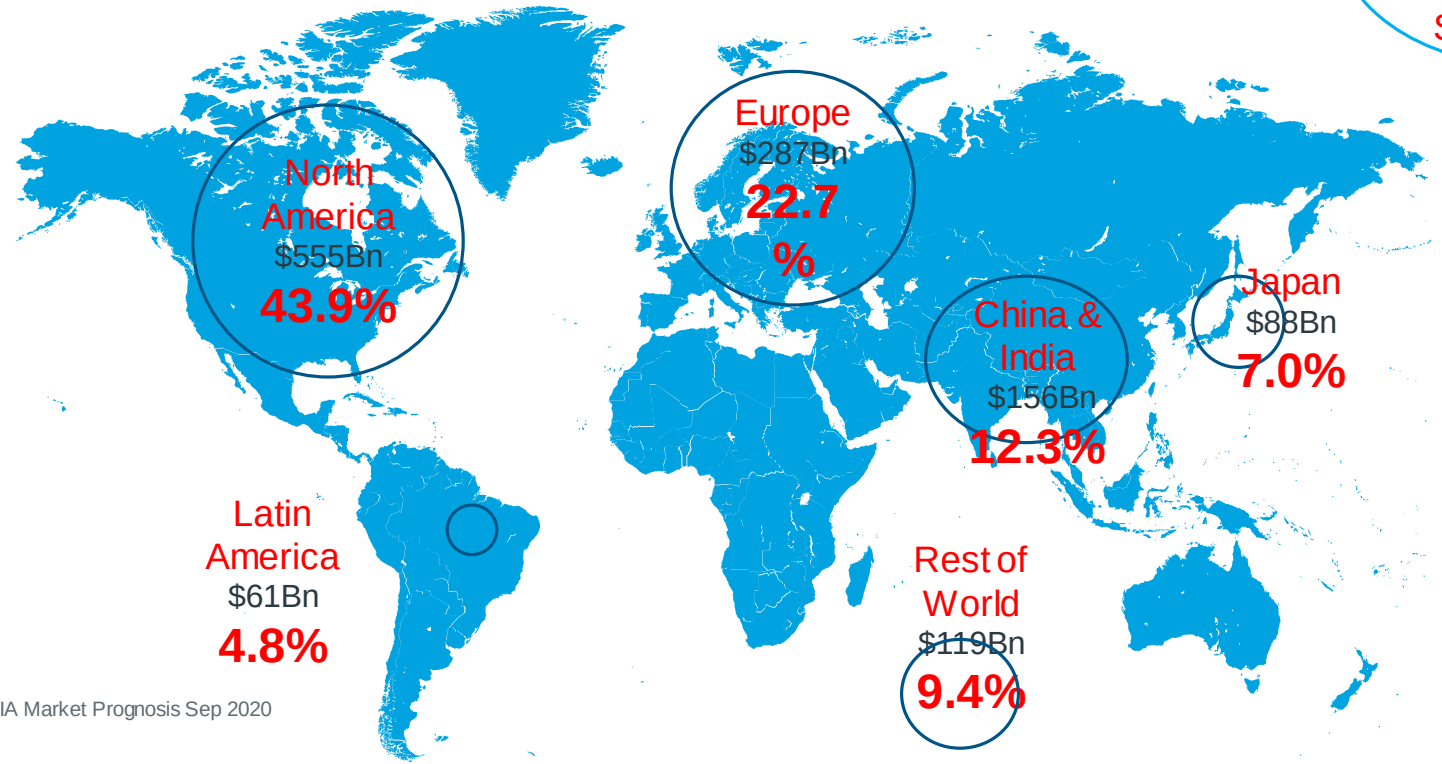
An overview of pharma market complexity

The long road to universal access

Global medicine spending in 2020

Spending in US$ Billions and % of Global Spending at List or Invoice Price Levels

Global Estimated Spending 2020 $1,265 Bn



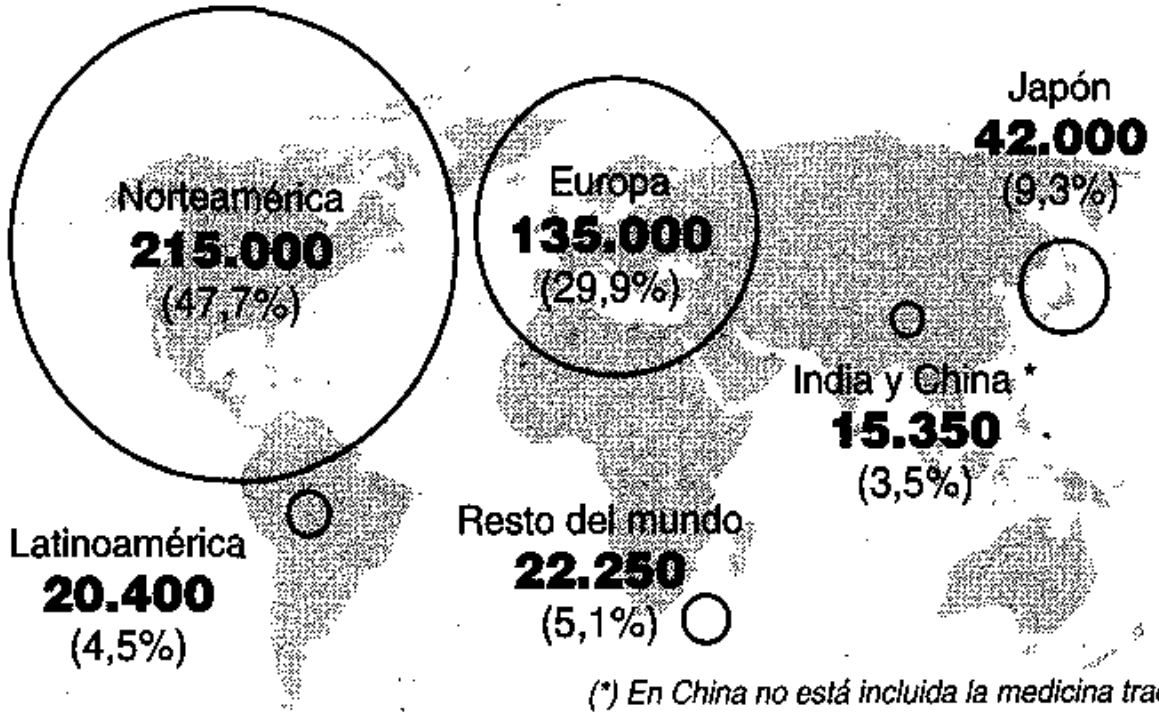
Source: IQVIA Market Prognosis Sep 2020

In the last 15 years pharma market has not changed much globally

Contrary to the predictions of 20 years ago

Ventas mundiales de fármacos en 2006

En millones de euros. Entre paréntesis, el porcentaje sobre el total mundial.

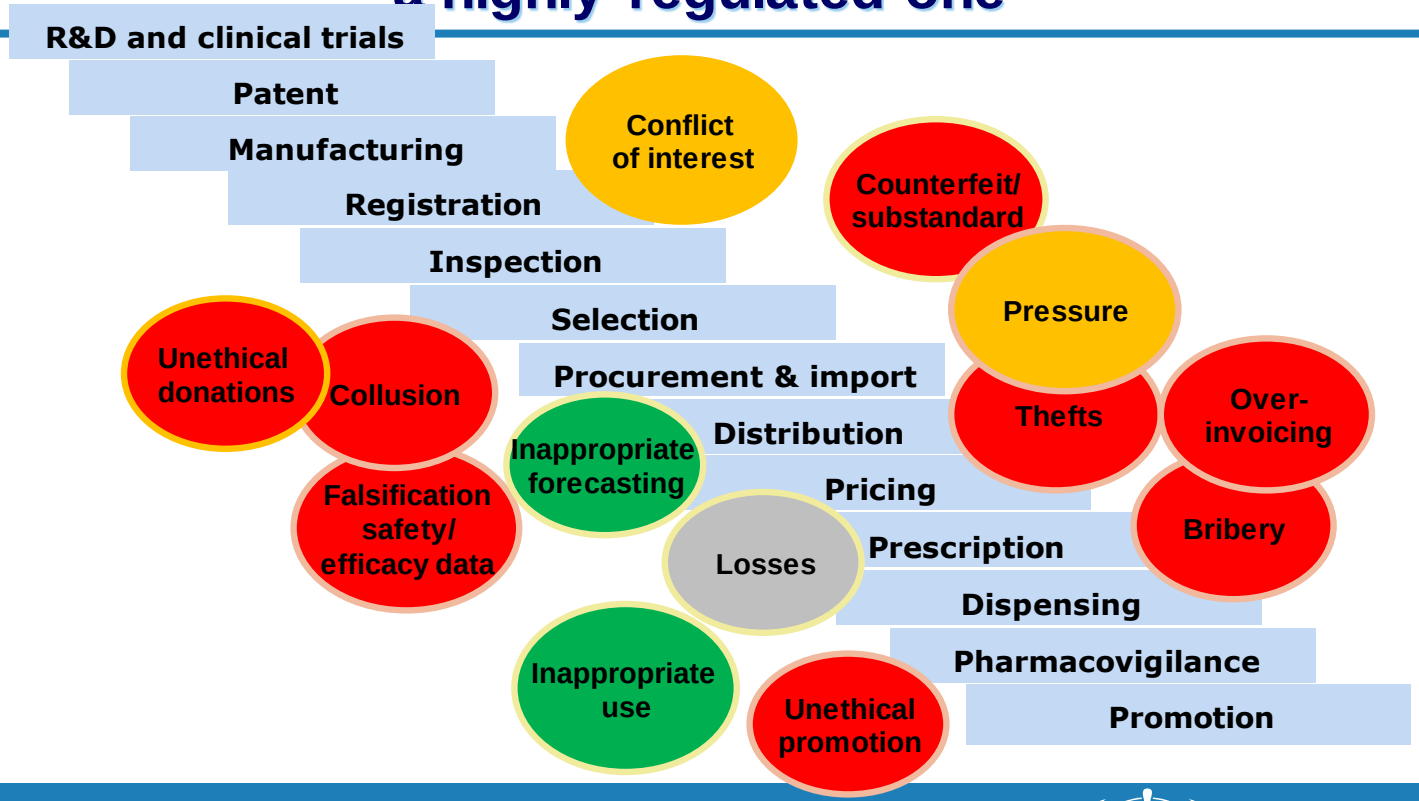


(*) En China no está incluida la medicina tradicional

Fuente: IMS Health.

EL PAÍS

The pharmaceutical market:
a highly regulated one



World Health Organization

Accesso globale ai vaccini/farmaci

AIFA AGENZIA ITALIANA DEL FARMACO
Tutela Ricerca e Sviluppo per la Salute

Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment

Olivier J Wouters, Kenneth C Shadlen, Maximilian Salcher-Konrad, Andrew J Pollard, Heidi J Larson, Yot Teerawattananon, Mark Jit

The COVID-19 pandemic is unlikely to end until there is global roll-out of vaccines that protect against severe disease and preferably drive herd immunity. Regulators in numerous countries have authorised or approved COVID-19 vaccines for human use, with more expected to be licensed in 2021. Yet having licensed vaccines is not enough to achieve global control of COVID-19: they also need to be produced at scale, priced affordably, allocated globally so that they are available where needed, and widely deployed in local communities. In this Health Policy paper, we review potential challenges to success in each of these dimensions and discuss policy implications. To guide our review, we developed a dashboard to highlight key characteristics of 26 leading vaccine candidates, including efficacy levels, dosing regimens, storage requirements, prices, production capacities in 2021, and stocks reserved for low-income and middle-income countries. We use a traffic-light system to signal the potential contributions of each candidate to achieving global vaccine immunity, highlighting important trade-offs that policy makers need to consider when developing and implementing vaccination programmes. Although specific datapoints are subject to change as the pandemic response progresses, the dashboard will continue to provide a useful lens through which to analyse the key issues affecting the use of COVID-19 vaccines. We also present original data from a 32-country survey (n=26 758) on potential acceptance of COVID-19 vaccines, conducted from October to December, 2020. Vaccine acceptance was highest in Vietnam (98%), India (91%), China (91%), Denmark (87%), and South Korea (87%), and lowest in Serbia (38%), Croatia (41%), France (44%), Lebanon (44%), and Paraguay (51%).

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Department of Health Policy (O J Wouters PhD, M Salcher-Konrad MSc) **and Department of International Development** (Prof K C Shadlen PhD), **London School of Economics and Political Science, London, UK; Oxford Vaccine Group, Department of Paediatrics, University of Oxford, Oxford, UK** (Prof A J Pollard FMedSci); **NIHR Oxford Biomedical Research Centre, Oxford, UK** (Prof A J Pollard); **Department of Infectious Disease Epidemiology, London School of Hygiene & Tropical Medicine,**

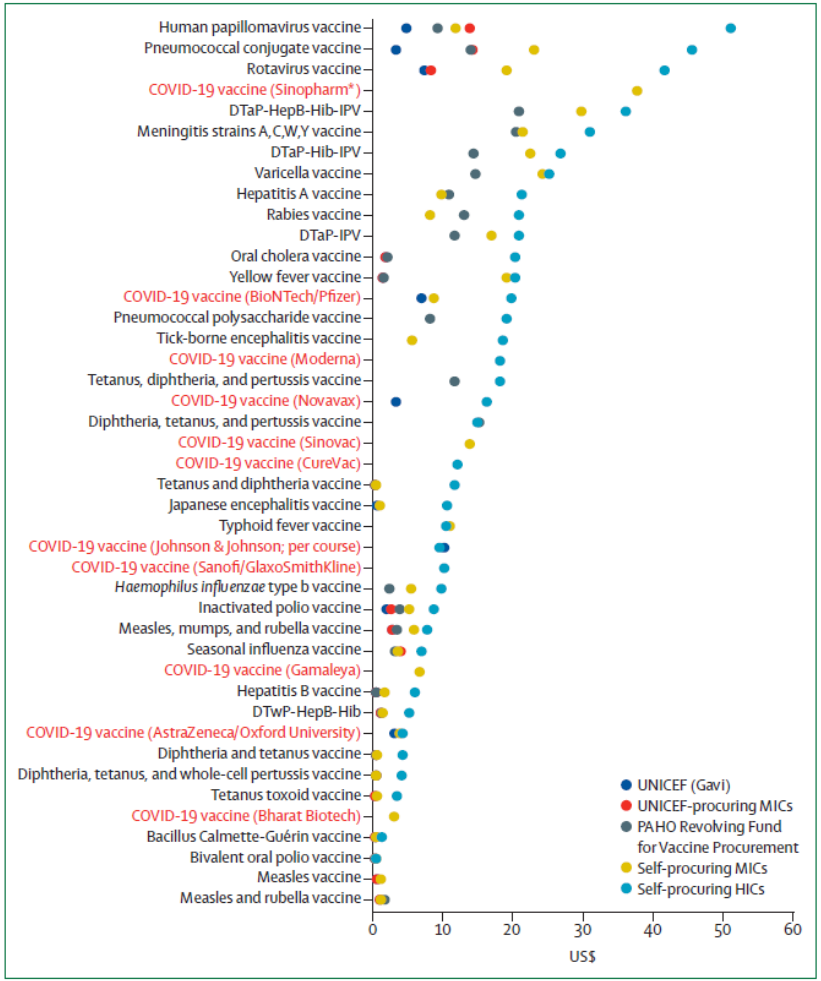

Figure 3: **Median price per dose for existing vaccines and for leading COVID-19 vaccine candidates by procurement or country income group**

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> In this Health Policy paper, we have stressed the interactions among the four dimensions involved in the global COVID-19 vaccination challenge. It is not enough to have new vaccines developed; they must be affordable, accessible, trusted, and, to maximise impact, used efficiently.

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  - Cosa vogliamo fare meglio
- Conclusioni

OSMED/AIFA: EU/Europa

AIFA partecipa in EMA/EU a:

- EMA approva i farmaci (con rapporto benefici-rischi favoevole)
- EU Joint procurement per tutti i farmaci emergenza COVID19
- , …

ON THE COVID-19 JPAs

- Did the JPAs adopted during the Covid-19 follow the previously mentioned 'golden rules'? Not always, to say the least, first of all because of the emergency-driven extraordinary conditions faced by whose negotiating on behalf of the public side.

- In fact, the way procedures – and, more than all, negotiation rounds with pharmaceutical companies – have been designed, from a public interest viewpoint clearly suffered of deep asymmetries as regards both information availability and bargaining power.

- The EC recognizes that the JPA has limitations, and is considering new streamlined solutions: this will involve increasing speed and flexibility in the current legal framework. Such statement comes from a very recent document, issued on 6 May 2021, the *EU Strategy on COVID-19 Therapeutics.* (https://ec.europa.eu/info/sites/default/files/communication-strategy-covid-19-therapeutics_en.pdf)

- The *EU Pharmaceutical Strategy* (November 2020) refers to new «*smart*» public procurement procedures as a way to address the issue of sustainable access to medicines and devices.

OSMED/AIFA: EU/Europa

AIFA partecipa in EMA/EU a:

- EMA approva i farmaci
- EU Joint procurement per tutti i farmaci emergenza COVID19
- …
- NB: Valutazioni comparative lasciate agli Stati Membri cosi come il valore terapeutico aggiunto, il role in therapy, gli usi ottimali, prezzi e rimborsabilità, etc

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AIFA: all-in-one model

AIFA concentra/raggruppa diverse funzioni:

- Approvazione / registrazione
- Giudizio innovatività e Usi ottimali (Note AIFA)
- Informazione indipendente

ON THERAPEUTIC EQUIVALENCE (WHO EML)

- The square box symbol is primarily intended to indicate similar clinical performance within a pharmacological class.
- The listed medicine should be the example of the class for which there is the best evidence for effectiveness and safety. In some cases, this may be the first medicine that is licensed for marketing; in other instances, subsequently licensed compounds may be safer or more effective.
- Where there is no difference in terms of efficacy and safety data, the listed medicine should be the one that is generally available at the lowest price, based on international drug price information sources.
- Therapeutic equivalence is only indicated on the basis of reviews of efficacy and safety and when consistent with WHO clinical guidelines.

frontiers in Pharmacology

POLICY AND PRACTICE REVIEWS
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The "Square Box": Therapeutic Equivalence as a Foundation of the WHO Model List of Essential Medicines

Bernadette Cappello[1]*, *Lorenzo Moja*[1], *Albert Figueras*[1,2] and *Nicola Magrini*[3]

[1] Department of Health Products Policy and Standards, World Health Organization, Geneva, Switzerland, [2] Department of Pharmacology, Therapeutics and Toxicology, Universitat Autònoma de Barcelona, Barcelona, Spain, [3] Italian Medicines Agency, Rome, Italy

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Edited by:
Susan Leigh Craddock,
University of Minnesota Twin Cities, United States

Reviewed by:
Muhammad Usman,
University of Veterinary and Animal Sciences, Pakistan
Tanja Mueller,
University of Strathclyde, United Kingdom

***Correspondence:**

Every two years, the World Health Organization (WHO) updates its Model List of Essential Medicines, intended as a guide for countries to adopt or adapt in accordance with local priorities and treatment guidelines, for the development of national essential medicines lists. When more than one therapeutic option is available for a given indication, the WHO Model List often includes a single medicine as representative of a group of equivalent and interchangeable medicines. The representative medicine of that group is listed with an accompanying 'square box' symbol. The intended purpose of the square box is to highlight pharmacological classes or groups of medicines for which countries, institutions and health professionals can assume homogeneous therapeutic efficacy and safety and select the most appropriate single medicine based on price, local availability, and acceptability. Though this concept of therapeutic equivalence within a therapeutic class has been endorsed by most authoritative textbooks of pharmacology since *Goodman & Gilman's The Pharmacological Basis of Therapeutics* and evidence-based guidelines,

PUBLIC PROCUREMENT: OPEN ISSUES

- How many drug categories for therapeutic equivalence … a definite list
- Ideal size of tenders: largely unknown and probably not true that the larger the better
- What is preferable for competition and lower prices: multiple tenders vs national one with multiple winners.
- There is a need to review best practices to support the Italian NHS in becoming a more informed purchaser
- Finally, there is not a one size fits all solution/approach to improve access … we need multiple and highly differentiated approaches

AIFA: all-in-one model

AIFA concentra/raggruppa diverse funzioni:

- Approvazione / registrazione
- Usi ottimali (Note AIFA) e informazione indipendente
- Prezzi e rimborso
- Ricerca indipendente
- Monitoraggio usi, variabilità regionale, …

ON MEAs: WIDER DEBATE EXPECTED

- MEAs promised to address some uncertainty issues related to both public expenditures and cost-benefit assessment. Italy has been at the forefront of this contractual approach, linked to the experience gained on the use of "registries".

- However, from the public side, the administrative burden to manage MEAs is high, and the impact on NHS savings seems to be limited/poor. This is a clear indication for a serious reassessment of this approach in the near future.
  - Please note, there is a shared feeling among various EU important countries about the need of such a reconsideration. According to a recent survey, «"*Pay for performance is like warm beer - nobody wants that in Germany. These schemes are really difficult to administer. We just want lower prices, and this is easiest to achieve via list price reductions or a mandatory discount.*" (Budget holder, SHI, Germany)» (see Anhert et al., *European Drug Pricing and Market Access in a COVID-19 World*, L.E.K. Executive Insights, October 2020)

AIFA: migliorare trasparenza

AIFA si concentra su:

- Accesso ai dati di tutti gli studi clinici

- Transparency is a fundamental issue – but a mean to an end: wider access.

Methods/approach

- Democracy
- Transparency

Objectives

- Common good, fair society, better lives
- Access for all those in need, universal access, full coverage

&

- Sustainability of health systems

AIFA: cosa vogliamo fare meglio

Nuovi gruppi di lavoro (2021):

1. Antibiotici/AMR – da trattare come «emergenza»
2. Oncologia ed ematologia
3. Terapie avanzate e geniche
4. Cronicità/MMG/ continuità terapeutica
5. … altre aree terapeutiche

AIFA/NHS: progetti infrastrutturali

Tre nuovi progetti nazionali:

1. Necessità di un dataset nazionale a partire dai DB regionali che comprenda: farmaci, ricoveri, altre info sanitarie, etc
2. Programma di informazione indipendente (Network 5-6 regioni: adulto e paed)
3. Programma di formazione per Alta Scuola di Formazione in Esperto di Drug Evaluation (biennale): template per biennio

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The young physician starts life with 20 drugs for each disease,
and the old physician ends life with one drug for 20 diseases.

Sir William Osler (1849 - 1919)

Covid19: cosa abbiamo imparato

1. Ruolo fondamentale SSN e della ricerca clinica (studi randomizzati, RCT)
2. Standard of care – cambiato rapidamente ogni 3-4 mesi (grazie agli RCTs e RWE)
3. Ci vogliono meno studi clinici e più coordinati a livello internazionale, possibilmente piattaforme multiarm per confronti multipli
4. Sentirsi/essere parte di una *research community* globale
5. Emergenze sono realtà complesse e la complessità va affrontata
   - Senza paura (*freedom from fear*, Gandhi)
   - Condividendo e discutendo le migliori evidenze e la loro qualità/affidabilità
   - Comunicazione istituzionale (less is more)

GRAZIE | THANK YOU

n.magrini@aifa.gov.it