

ITALIAN HORIZON SCANNING PROJECT

Concept Document

May 2008



Preliminary remarks

This document aims to illustrate the goals and the roadmap of the Italian Horizon Scanning Project (IHSP).

1. Background

Demographic changes, increased life expectancies and the accelerated development of new health technologies have a great impact on the National Health Services world-wide¹. According to the Pharmaceutical Research and Manufacturers of America (PhRMA) 2000 new molecules are currently in development². However the modest therapeutic value the great uncertainty on the innovation grade and the high cost of new medicines^{3,4,5,6,7} suggest that early evaluation of emerging pharmaceuticals should be introduced.

Health Technology Assessment (HTA) is a form of policy research that studies the short- and long-term consequences of the introduction of health technologies in a healthcare system in terms of safety, clinical benefit, and social-economic aspects, providing important information to decision makers⁸. This kind of evaluation is performed only after launch of new technologies. However to react to technological developments only when confronted with their consequences is not satisfactory because management strategies implementation is not possible. Thus, methods for identifying and timely assessing new technologies coming through are necessary to support decision makers in planning the appropriate use of new technologies to optimise resources^{9,10,11,12,13}

On the basis of these considerations an early warning system for identification and assessment of emerging technologies has been implemented in Italy¹³.

2. General purpose

IHSP aims to collect, organize and evaluate information on emerging medicines and medical devices with medicated coating.

3. Specific purposes

IHSP specific aims are the following:

- to produce periodical lists of emerging medicines for which an European Marketing Authorization will be expected within 12-36 months (see paragraphs 6.1 and 6.2)
- to evaluate potential clinical and economic impact of emerging medicines on the Italian National Health Service (see paragraph 6.4)
- to provide timely information to the Italian NHS stakeholders based on available information on emerging medicines
- to identify research needs.

4. Project organization structure

The main IHSP infrastructures are the following:

- the Scientific Committee
- the Database Team
- the Evaluation Team of emerging pharmaceuticals

4.1 Scientific Committee

The IHSP Scientific Committee (IHSP-SC) includes 15 members: three representatives of the Italian Medicines Agency, two representatives of the Veneto Region, two representatives of the Verona's Pharmaceutical Department, seven experts in medicine evaluation.

The IHSP-SC tasks are the following:

- to establish the Standard Operating Procedures to handle the collected information
- to establish report templates assessing the clinical and economic value of emerging medicines
- to prioritise medicines
- to identify experts to be involved in the assessment of prioritised medicines
- to review the New Product Information Report, of each prioritised medicine (see paragraph 6.4)
- to decide on the possible publication of the evaluation reports and/or other material produced by IHSP.
- to identify possible therapeutic needs and priority research areas interesting for the Italian National Health Service
- to establish connections with other NHS institutions, with scientific associations and international partners.

4.2 Database Team

The IHSP Database Team (IHSP-DT) includes three part-time and three full time pharmacists, three part-time IT people, one part-time administrative employee.

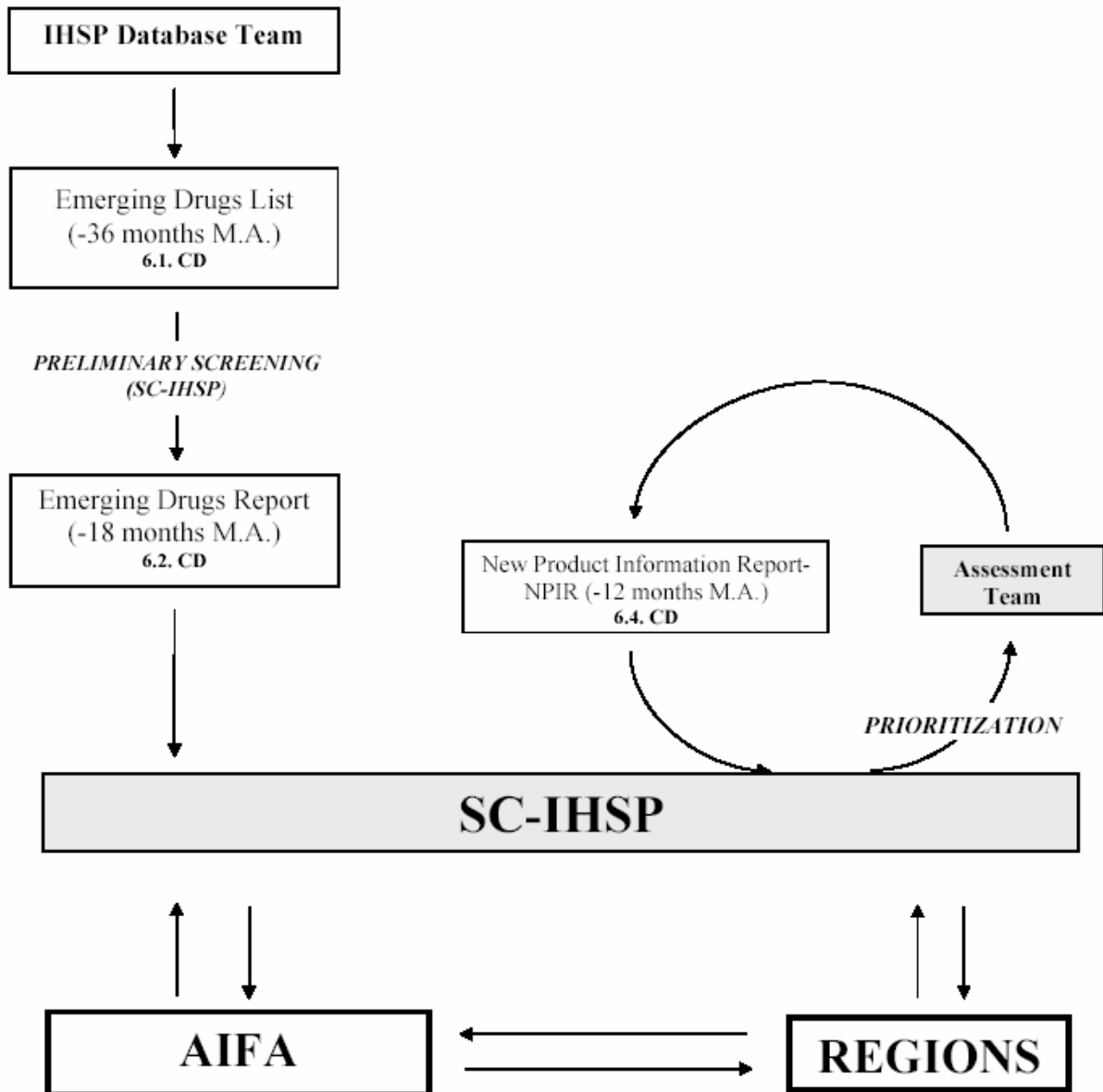
The IHSP-DT tasks are the following:

- to set up, maintain and update the database
- to guarantee the confidentiality of the stored data
- to collect information
- to produce the - 36 months lists and -18/ -12 months reports of emerging medicines
- to produce any possible additional document useful to the IHSP-SC and/or to the Evaluation Team.

4.3 Evaluation Team

The IHSP Evaluation Team (IHSP-ET) for emerging medicines includes a panel of 50 clinicians, with expertise in different medical and surgical fields, and a Scientific Secretary with six pharmacists (three part-time and three full-time people) and a part-time administrative. The IHSP-ET produces the New Product Information Report (see paragraph 6.4).

IHSP Flow Chart



Legend

SC-IHSP: Italian Horizon Scanning Project - Scientific Committee

M.A.: EU Marketing Authorization

AIFA: Italian Medicines Agency

5. Methods

5.1 Data sources

IHSP collects information on emerging medicines from the following sources:

- Websites (pharmaceutical companies; financial analysis companies; international scientific societies; international regulatory authorities; health information websites; others)
- Medical-scientific literature
- Pharmaceutical Companies press releases
- Reports from the EuroScan network

All the data are recorded in an ad hoc database.

5.2 Italian Horizon Scanning Database

IHSP is supported by a technological infrastructure for data collection, check, monitoring and analysis. The database is available, by a restricted access, at the following: <http://horizon.cineca.it/>

The IHSP database (IHSP-DB) main features are the following:

- Centralized database with different access profile according to different kind of users (SC-IHSP; Database Team; Assessment Team; others)
- Historical file and data finding tools
- On line predefined reports and possibility of self-making specific reports
- Horizon Community with private web area for documents and data sharing, and discussion forum.

http and SSL protocols with username and password access are in place to assure high security and secrecy of the recorded data. Data transmission is achieved by a protected and cipher channel.

Daily data backup and disaster recovery procedures are in place along with the ISO 9001:2000 quality management system, and the ISO 27001:2005 (BS 7799) security management system.

5.3 Priority-setting process

The IHSP-SC selects the emerging medicines for assessing their clinical and economical value according to the following priority criteria:

- possible marketing authorization date
- possible innovation grade^{14,15}, therapeutic and economic impact
- possible price and NHS sustainability
- other relevant considerations pointed out by the Regulatory Authority or the IHSP-SC itself.

5.4 Assessment of the clinical and economical value of emerging medicines and their sustainability for the NHS.

The IHSP-SC charges the Evaluation Team (including different clinical experts according to the medicine to be assessed, see paragraph 4.3) with the evaluation of the potential clinical and economical impact of the prioritised emerging pharmaceuticals: the “New Product Information Report”.

6. Expected results

6.1 Emerging medicines: - 36 months report

IHSP annually produces a report on the pharmaceuticals possibly being authorized by the European Medicines Agency (EMA) in the subsequent 36 months.

This report includes the following:

- medicine name
- licensee
- stage of development
- possible submission date of the marketing authorization dossier to the EMA
- main proposed indication(s)
- ongoing studies

6.2 Emerging medicines: - 18 months report

Every six months IHSP produces a report on the pharmaceuticals possibly being authorized by the EMA in the subsequent 18 months.

This report includes the following:

- general information (active ingredient(s), brand name, licensee, ATC code, administration route, strength, international authorisation state, possible launch date)
- proposed indication(s)
- burden of disease
- summary of the available data on clinical efficacy and safety
- possible price and economic impact (if available)
- probability of success
- alternative(s) already on the market
- possible competitors in development

6.3 Prioritized medicines

The SC-IHSP commits the Assessment Team with the production of the New Product Information Report of prioritised medicines (see paragraph 5.3 Priority Setting Process) among those listed in the “-18 months report”.

6.4 New Product Information Report (- 12 months report)

The New Product Information Report (NPIR) concerning the prioritized medicines possibly being authorized by the EMA in the subsequent 12 months includes:

- general information (active ingredient(s), brand name, licensee, ATC code, route of administration, strength, international authorisation state, possible launch date)
- clinical need and burden of disease
- therapeutic alternative(s) already available
- summary of the available data on clinical efficacy and safety
- quality evaluation of the studies
- ongoing studies for the same or other indication(s)
- evaluation of the innovation grade and possible place in therapy of the emerging medicine
- NHS and financial impact
- clinical and patients impact

7. National collaborations

The Italian Horizon Scanning Project cooperates with the Italian Drug Assessment Units already existing or in progress (Italian Drug Assessment Network – IDAN)

8. Relations with the Institutions of the National Health Service.

The Italian National Health Service has established in its Concept Map 2006-2008 to promote Health Technology Assessment (HTA) activities establishing a national network. IHSP aims to become partner of this network providing information to be used in the assessment of new pharmaceuticals.

The Italian HTA network aims to strengthen the relationship between the Italian regions and the Italian Medicines Agency, integrating the different institutional levels with their specific responsibility.

Involving numerous Italian clinical experts (see paragraph 4.3) in evaluating the possible impact of emerging medicines, IHSP gives the opportunity to the final users to share the whole assessment process and promotes the dissemination of an evidence based information.

9. International collaborations

IHSP plans to cooperate with the most important organizations involved in early warning activities, giving the opportunity to Italy to collaborate in international activities related to drug policy^{16,17,18}.

9.1 UK NHS

IHSP has currently a partnership with the National Prescribing Centre in Liverpool with the following aims:

- to access information on emerging medicines (12-18 months before the European Marketing Authorisation) that can be adapted and utilized in the Italian context;
- to share with English colleagues methods for identification and early assessment of emerging pharmaceuticals.

9.2 EUROSCAN

IHSP intends to become a member of the international network EuroScan (<http://www.euroscan.bham.ac.uk>), a collaborative network of Early Warning Units for the identification and assessment of emerging new technologies, working 2 to 5 years before EU approval. The network currently consists of thirteen representatives located in twelve countries: Canada, Denmark, Norway, Sweden, Australia, and New Zealand (collaborating in one centre), The Netherlands, The United Kingdom, Israel, Spain, France, and Switzerland.

9.3 MEDEV

The Medicine Evaluation Committee (MEDEV) is an official committee of the European Social Health Insurance Forum. It was established as a network of institutions responsible for price and reimbursement in each EU countries. The principal purpose of MEDEV is to share timely information on drug policy initiatives (in development or already in place), performing cost/benefit analysis and price comparisons of same pharmaceuticals on different EU markets. MEDEV has decided to set up an European observatory to collect and share this kind of information. IHSP could provide MEDEV with some relevant information and the technological infrastructure to achieve this purpose.

10. Relationship with pharmaceutical industry

IHSP should in all respects remain entirely independent from industry, should act impartially and should not be influenced by social or business relations.

Relationship between IHSP and pharmaceutical companies aims to collect information to be used in producing specific reports on emerging medicines (see paragraphs 6.1, 6.2, 6.4).

Any contact with industry whether written or verbal must be transparent, documented and retrievable¹⁸.

11. Conflict of interests

Each IHSP collaborator has to declare any partnership with pharmaceutical or other health products companies within the last two years.

Some interests conflicting with the IHSP aims can exclude or restrict the cooperation with IHSP

All the conflict of interests declarations should be recorded and kept up to date.

12. Confidentiality

The information utilized by IHSP in its assessments should be regarded as confidential. Each IHSP collaborator should commit her- himself to confidentiality and to use the confidential information for IHSP purposes only.

13. Future activities

13.1 IHSP will collaborate with the International Society of Drug Bulletins (ISDB) and in general with Italian independent drug bulletins.

13.2 Pharmacoeconomic modelling/evaluations will be developed to quantify appropriate and sustainable costs for emerging pharmaceuticals. This kind of assessment could be useful to the Italian Price and Reimbursement Committee (Italian Medicines Agency).

14. Institutions partner in the IHSP

The Italian Medicines Agency, the Veneto Region and the Verona's Local Health Unit have initiated the Italian Horizon Scanning Project. Future collaboration with other local, regional and national institutions is open.

15. Funds

IHSP is publicly funded. Private sponsors are accepted only if they have no conflict of interest with IHSP activities.

IHSP can be supported with regional Pharmacovigilance funds.

Glossary

Health Technology Assessment (HTA): is a form of policy research that studies the short- and long-term consequences of the introduction of health technologies in a healthcare system, in terms of safety, clinical benefit, costs, effects on organization of health services, and legal, social, and ethical consequences

Early warning system/Horizon scanning system: is a stable no-profit organisation which aims to:

1. to identify emerging health technologies,
2. to filter and prioritise those technologies most likely to have a significant future impact
3. to make an assessment of either potential clinical impact and cost effectiveness of the emerging technologies.

Prioritization: is a process which aims to rank the emerging pharmaceuticals according to explicit priority-setting criteria defined by the Scientific Committee of the Italian Horizon Scanning Project. The prioritized medicines are to be assessed with respect of their potential clinical impact and their cost effectiveness

Emerging technology: a technology that is in early or late development

New technology: a technology that will generally be in the launch or early post-marketing stages.

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