L'Italian Horizon Scanning Project

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HTA e HS come strumenti decisionali per l'appropriatezza d'impiego dei farmaci

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Health Technology Assessment

As HTA as an activity became more common practice around the world, it was increasingly recognized that **timeliness** of the assessment was **key** in the support of healthcare decision makers.

Mowatt G et al. Implementing early warning messages on emerging health technologies. Int J Technol Assess Health Care. 1998;14:663-70

What is horizon scanning?

Horizon Scanning is defined by the Office of Science and Technology (OST) as:

'The systematic examination of potential threats, opportunities and likely future developments, including (but not restricted to) those at the margins of current thinking and planning.'

Why horizon scan for medicines?

- ✓ Manage budgets
- ✓ Plan services - new and redesign
- ✓ Anticipate pressures (financial and service delivery)
- ✓ Identify areas for disinvestment
- ✓ Manage entry into hospital/formulary/practice, etc
- ✓ Be prepared! It's better than fire fighting!

Early Warning System

Banta and Gelijns were the first to conclude that it is not satisfactory to react to technological developments only when confronted with their consequences. Their study for the Dutch government in the 1980s called for a systematic approach to identification and early assessment of new health technologies to provide early notice to decision makers in health care.

An Early Warning System was subsequently established at the Dutch Health Council

Banta HD, Gelijns AC. An early system for the identification and assessment of future health care technology: The Dutch STG project: Int J Technol Assess Health Care. 1998;4:607-12

Comparative and **timeliness** evaluation of new treatments is **the most important information** to provide policy makers with


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Host organization: Azienda ULSS 20 in Verona
AIFA
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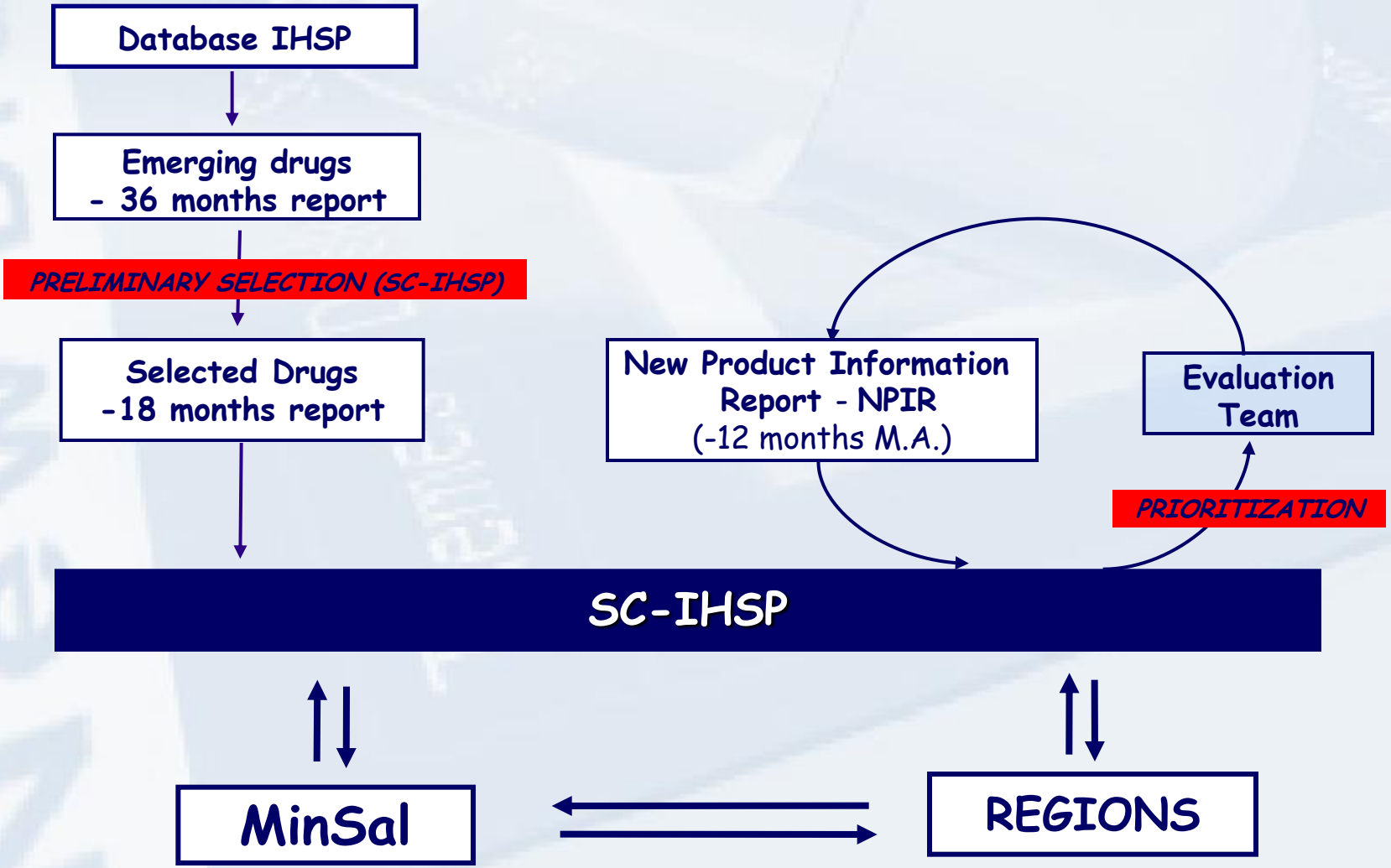
Aims

TO ORGANIZE and EVALUATE available information on emerging drugs BEFORE SUBMISSION of a MAA to Regulatory Agency and before any decision on COSTS and POSSIBLE CLASS OF REIMBURSEMENT

Specific aims:

- ✓ to produce **periodical lists** of emerging drugs for which a MA will be expected within **12-36 months**
- ✓ to evaluate **potential clinical impact and cost effectiveness** in terms of healthcare and cost for National Health Service
- ✓ to give **well-timed information** to improve regulatory decisions about emerging drugs
- ✓ to identify **further research fields** needed to be investigated

IHSP Workflow



Methods and tools of the IHSP

Organization Structure

- Scientific Committee (SC)
- Database Team (DT)
- Evaluation Team (ET)

Data Management

- Information sources
- Evidence considered
- Data presentation
- Trial Quality Assessment

IHSP Database

- Data Collection
- Check
- Archive
- Discussion Forum

IHSP Reports

- Priority-setting criteria
- Output

Scientific Committee

- To prioritise drugs
- To sign up experts to be involved in the assessment of prioritised drugs
- To review and approve New Product Information Reports

Database Team

- To maintain and update the database
- To guarantee the confidentiality of the stored data
- To collect information
- To produce the different reports of emerging medicines

Evaluation Team

- To produce the New Product Information Report

Information Sources

- Regulatory Agencies
- Medical-scientific literature
- Scientific databases
- Medical websites/Press-releases
- Pharmaceutical Bulletins

Evidence considered

Clinical Trial (Phase I-III):

- ✓ Completed and published
- ✓ Completed not published
- ✓ Ongoing

Data presentation

- Narrative
- Tables of all Phase II-III studies

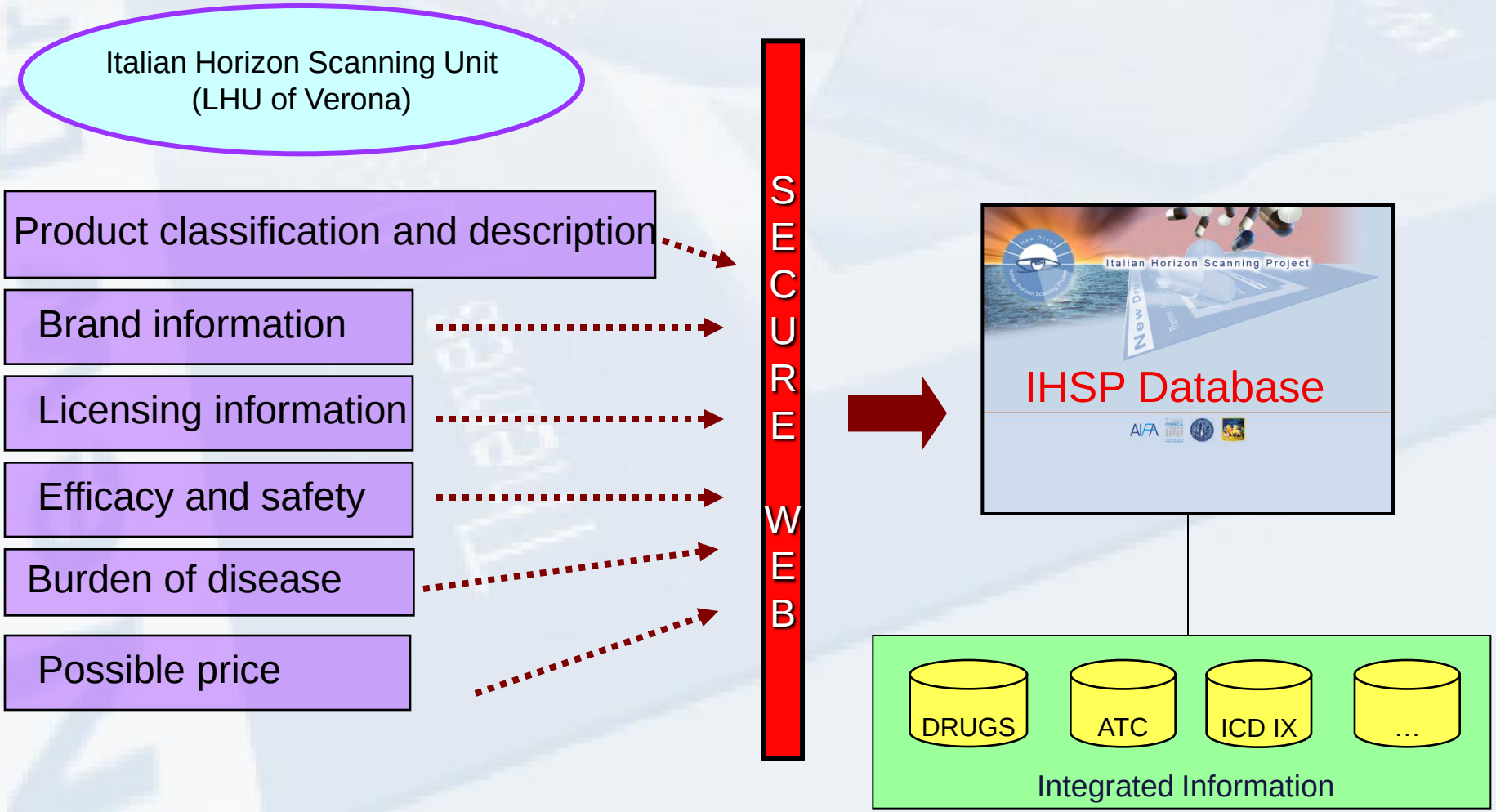
Trial Quality assessment

Item evaluated (Jadad modified + 3-level Likert scale):

- ✓ Design
- ✓ Allocation
- ✓ Blinding
- ✓ Lost to follow-up
- ✓ Protocol violation(s)
- ✓ Sample size
- ✓ Pre-specified secondary/sub-group analysis

The IHSP Database

Information Input



IHSP database - Drugs grouped by ATC

ATC code (I level)	ATC decsription	US+EU n	EU n	EU phase I n (%)	EU phase II n (%)	EU phase III n (%)	EU phase I/II+II/III n (%)
L	Antineoplastic and immunomodulating agents	851	406	30 (7.4)	153 (37.7)	197 (48.5)	26 (6.4)
N	Nervous system	229	100	16 (16.0)	32 (32.0)	49 (49.0)	3 (3.0)
A	Alimentary tract and metabolism	149	84	11 (13.1)	25 (29.8)	45 (53.6)	3 (3.6)
J	Antiinfectives for systemic use	123	64	8 (12.5)	18 (28.1)	36 (56.3)	2 (3.1)
C	Cardiovascular system	96	58	0 (0.0)	16 (27.6)	41 (70.7)	1 (1.7)
B	Blood and blood forming organs	79	52	3 (5.8)	17 (32.7)	32 (61.5)	0 (0.0)
M	Musculo-skeletal system	71	27	4 (14.8)	7 (25.9)	12 (44.4)	4 (14.8)
R	Sistema respiratorio	53	29	6 (20.7)	9 (31.0)	14 (48.3)	0 (0.0)
G	Genito-urinary system and sex hormones	35	16	2 (12.5)	5 (31.3)	9 (56.3)	0 (0.0)
D	Dermatologicals	25	13	1 (7.7)	5 (38.5)	7 (53.8)	0 (0.0)
S	Sensory organs	27	12	0 (0.0)	4 (33.3)	7 (58.3)	1 (8,3)
V	Various	21	5	0 (0.0)	0 (0.0)	5 (100.0)	0 (0.0)
H	Systemic hormonal preparations, excl sex hormones and insulins	13	7	0 (0.0)	2 (28,6)	4 (57.1)	1 (14.3)
P	Antiparasitic products, inseticides and repellents	2	1	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Total drugs in development	**1774**	**874**				
	Registered/launched drugs	322	175				
	Discontinued/Suspended drugs	236	121				
	Total number of items registered in the database	**2332**	**1170**				

Updated in June 2011

Priority-setting criteria used by SC-IHSP

AREA to INVESTIGATE	PARAMETERS	EVALUATION	
Burden of disease			
	Epidemiology	Rare	Not rare
	Severity	Severe	Not severe
	Duration	Acute	Chronic
	Treatment	Available	Absent
Patient impact			
	Efficacy vs. current treatments *(mortality, morbidity, quality of life, etc.)*	Higher	Equal or Lower
	Safety vs. current treatments	Higher	Equal or Lower
	Compliance vs. current treatments	Higher	Equal or Lower
NHS Pressures			
	Social impact (Media, patients associations, lobbies ...)	YES	NO
	Service reorganization and/or staff training required	YES	NO
	Economic impact on the NHS	High	Low
Others			
	Possible launch date	≤ 18 months	> 18 months
	Drug in development for other indications of interest	YES	NO
	Other drugs in development for the same indication	YES	NO

Outputs

-36 MONTHS REPORT

Produced annually

- general information
  - *Drug/brand name/ active substance*
  - *Company*
  - *ATC Group*
- licensee
- stage of development
- possible submission date of the MAA
- main proposed indication(s)
- ongoing studies

-18 MONTHS REPORT

Produced every 6 months

- general information
  - *Drug/brand name /active substance*
  - *Company*
  - *ATC Group*
  - *Route of administration*
- possible submission date of the MAA
- proposed indication(s)
- summary of the available data on clinical efficacy and safety
- overview of all ongoing trials and completed studies not published
- possible price and economic impact (if available)
- alternative(s) already on the market
- possible competitors in development

NPIR

(-12 months to M.A.)

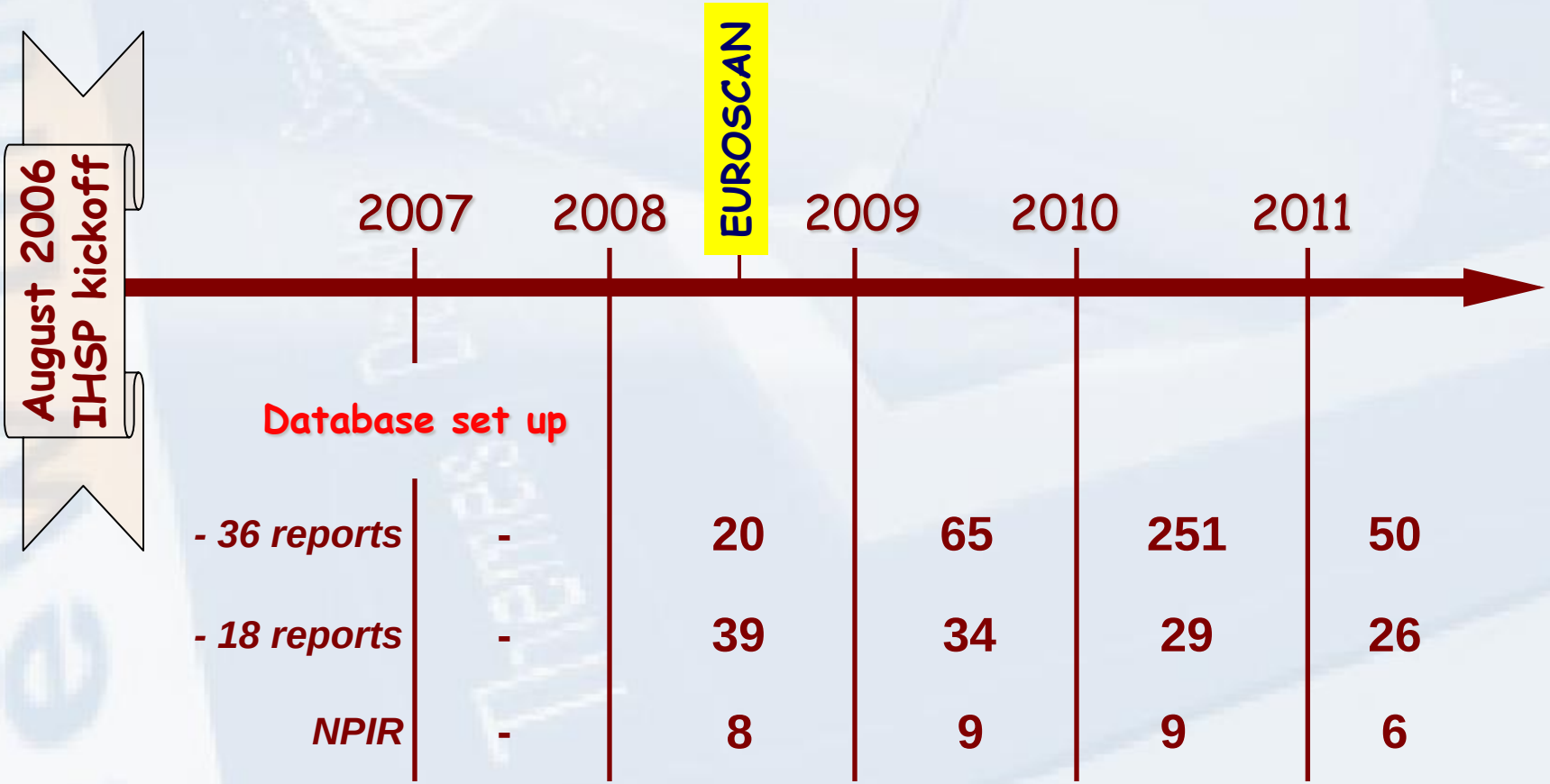
"Drug Name"
"Drug Indication"

- general information
  - *Active substance*
  - *Brand name*
  - *Company*
  - *ATC Group*
  - *Dosage*
  - *Route of administration*
  - *Development state*
  - *.....*
- clinical need and burden of disease
- summary of efficacy/safety data from available clinical trials
- clinical critical assessment
- social / economic impact
- ongoing trial(s) for the same or other indication(s)

Molecules for which an M.A. in EU is expected within 18 months (with prioritisation results of November 2011)

ATC	Molecule	Indication	Classification	Orphan status	Prioritisation results
L01	**AFLIBERCEPT**	Metastatic colorectal cancer, second-line	NCE	–	**P**
L01	**ALPHARADIN (radium-223)**	Bone metastasis in patients with hormone-refractory prostate cancer	NCE	–	**KW**
L01	**CABOZANTINIB**	Unresectable, locally advanced or metastatic medullary thyroid cancer	NCE	US	**KW**
L01	**CARFILZOMIB**	Relapsed-refractory multiple myeloma (monotherapy)	NCE	EU/US	**KW**
L01	**CRIZOTINIB**	Previously-treated, advanced ALK-positive non-small cell lung cancer	NCE	US	**P**
L01	**EVEROLIMUS**	Postmenopausal ER+ HER2- metastatic breast cancer progressing after endocrine therapy	NI	–	**P**
L01X	**PERTUZUMAB**	HER2-positive, metastatic breast cancer, first-line plus trastuzumab and docetaxel	NCE	–	**P**
L01	**VEMURAFENIB**	BRAF V600E mutation-positive metastatic melanoma	NCE	–	**P**
L01	**VISMODEGIB**	Locally advanced or metastatic basal cell carcinoma	NCE	–	**KW**
C10	**MIPOMERSEN**	Homozygous and severe heterozygous familial hypercholesterolemia	NCE	–	**P**
L04A	**ALEMTUZUMAB**	Relapsing-remitting multiple sclerosis (treatment-naive patients)	NI	–	**KW**
L04A	**ALEMTUZUMAB**	Relapsing-remitting multiple sclerosis (treatment-refractory patients)	NI	–	**KW**
N07	**LAQUINIMOD**	Relapsing-remitting multiple sclerosis	NCE	–	**KW**
N07	**TERIFLUNOMIDE**	Relapsing multiple sclerosis with or without progression (add-on)	NCE	–	**KW**
N07	**TERIFLUNOMIDE**	Relapsing multiple sclerosis with or without progression (monotherapy)	NCE	–	**KW**

IHSP chronology



Total IHSP documents (n): 546

Update November 2011

EuroScan

In 1999 several Horizon Scanning Systems (HSS) established EuroScan, an information network on new and changing health technologies.

The network currently consists of 21 representatives (Canada, Denmark, Norway, Sweden, Australia, New Zealand, The Netherlands, The United Kingdom, Israel, Spain, France, Switzerland, Germany, Ireland, Austria, Italy, Finland).

Any HSS is a non-profit organization with at least 50% funding from public sources

Douw K, Vondeling H. Selection of new health technologies for assessment aimed at informing decision making: A survey among horizon scanning systems. Int J Technol Assess Health Care. 2006;22 (2):177-83

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The International Information Network on New and Emerging Health Technologies (EuroScan) is a collaborative network of member agencies for the exchange of information on important emerging new drugs, devices, procedures, programmes, and settings in health care.

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