Prescribing quality indicators
– challenges and opportunities in Europe

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Conflict of interest

Conflict of interest

- Employed by the regional health board of Stockholm, Sweden as head of the analysis unit at the Dept. of healthcare development
- Chairman of European Drug Utilization Research group
- Member of producer-independent international, national and regional groups involved in the decision making of drugs
- Associate professor at the Centre for Pharmacoepidemiology, Karolinska Institutet which is involved in independent and contract studies with specific companies. No personal funding.
- No other conflict of interest

Outline

An overview of prescribing quality indicators

- Definitions
- Types of indicators
- Datasources and their possibilities
- Opportunities and challenges

Why focus on drugs?

- Most common therapeutic intervention
- Rapid development and innovation
- Room for quality improvement
- Patient safety problems
- Environmental concern
- Rising expenditure,
  difficult to control

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Prescribing Quality Indicators

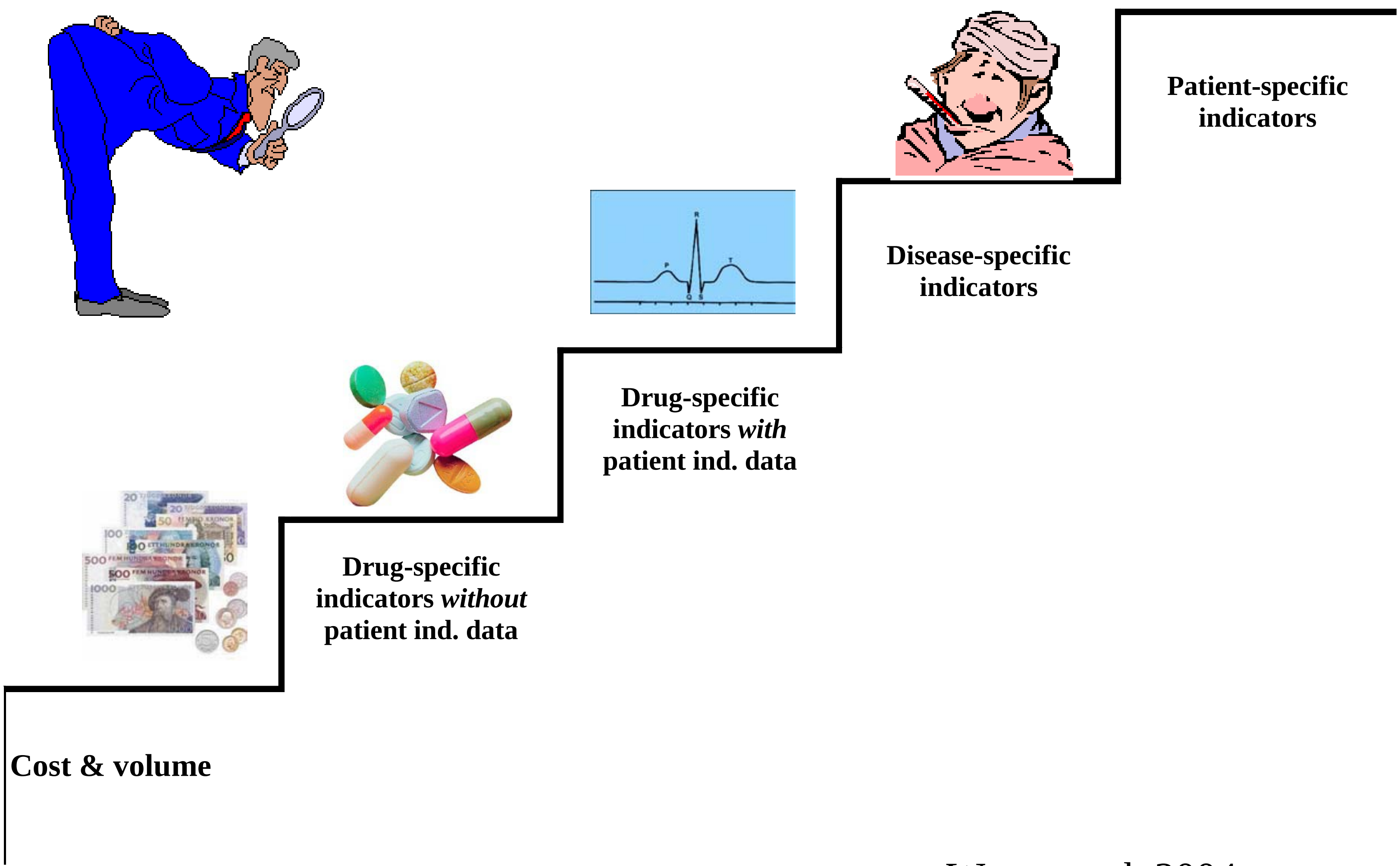
- **Definition:** “A measurable element of *prescribing* performance for which there is evidence or consensus that it can be used to assess quality, and hence in changing the quality of care provided”
- QI is part of a set of quality improvement tools

WHO DURQUIM 2004

Dimensions in PQI

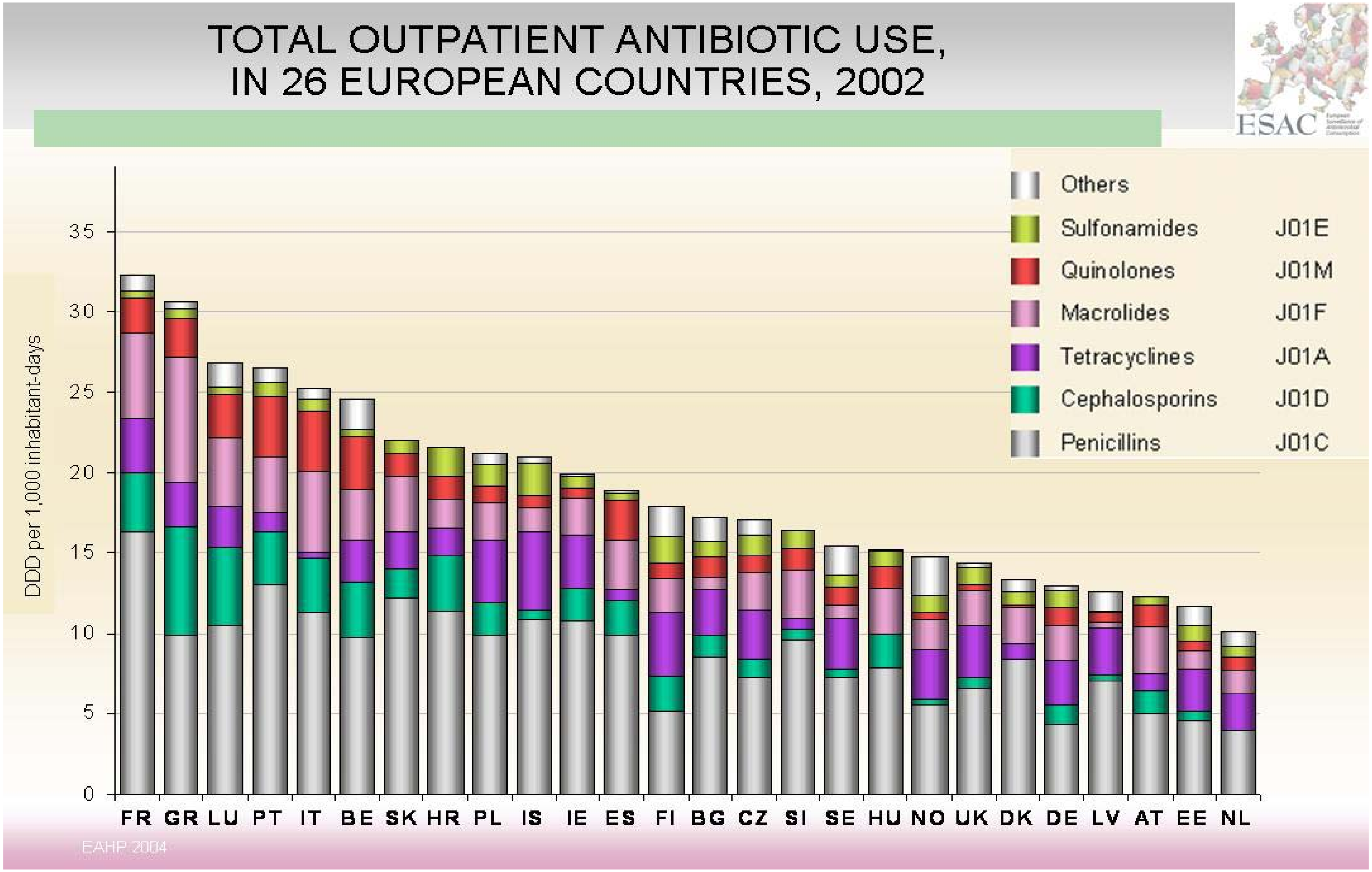
- Perspective – patient, prescriber, budget…
- Structure - process - outcome
- Drug, disease or patient-oriented

(Quality) indicators for prescribing



Wettermark 2004

Aggregate volumes (DDD/TID)



Drug-oriented indicators (ratios)

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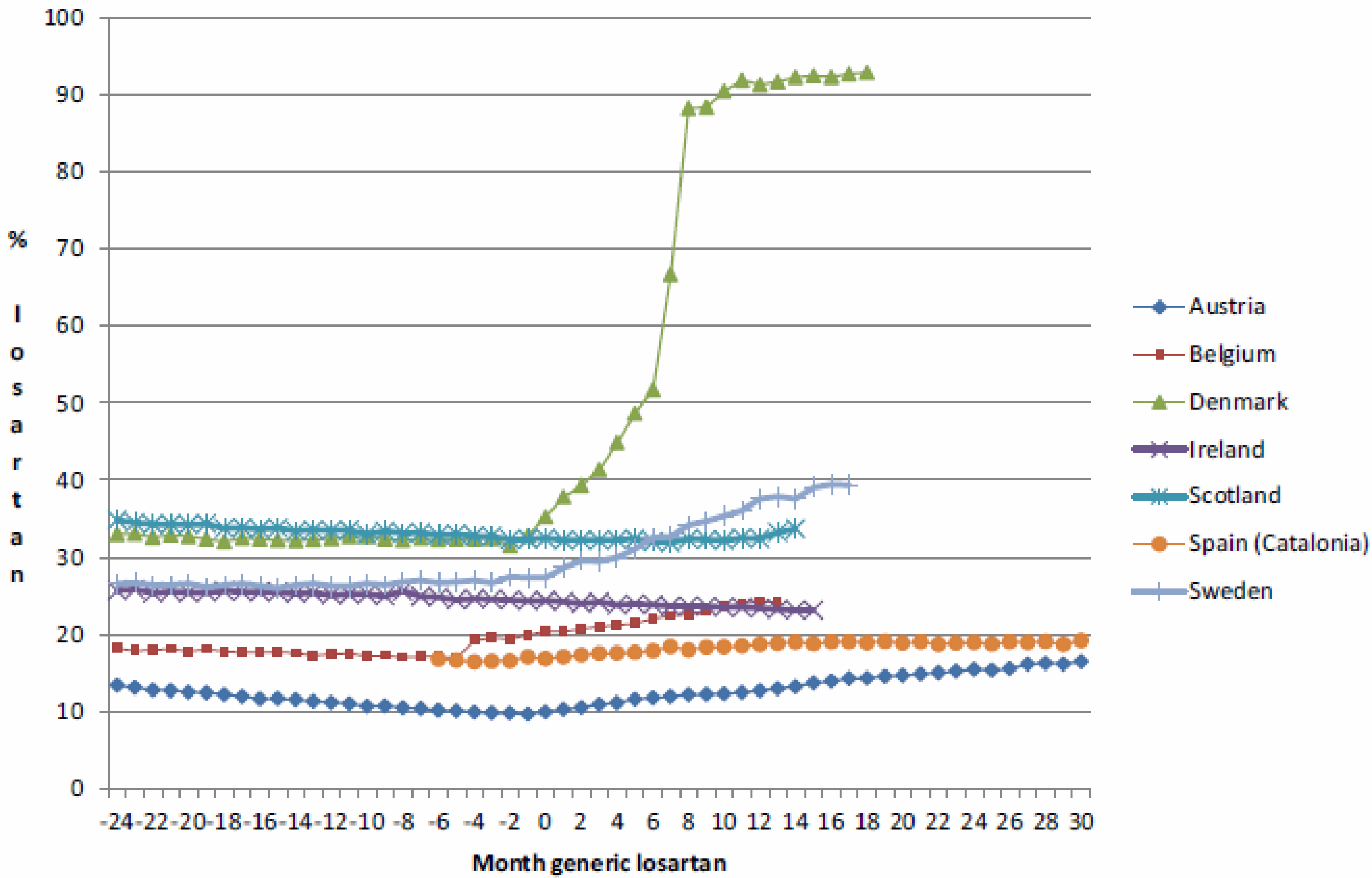

FIGURE 1 | Percentage utilization of losartan vs. all single ARBs (DDD basis) before and after the availability of generic losartan (Time 0) on a monthly basis.

Moon, Godman et al 2014

Drug-oriented indicators (DU90%)

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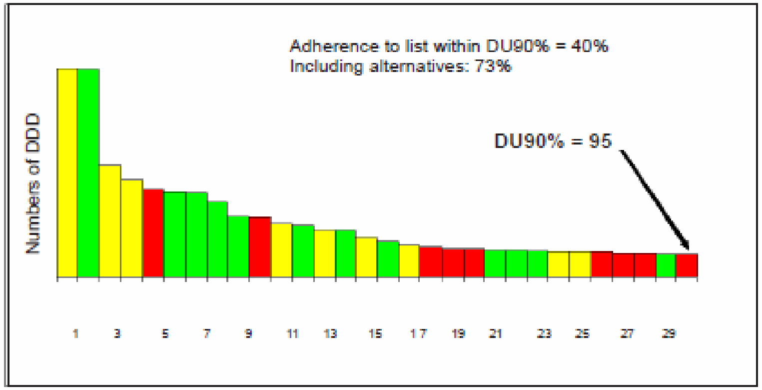
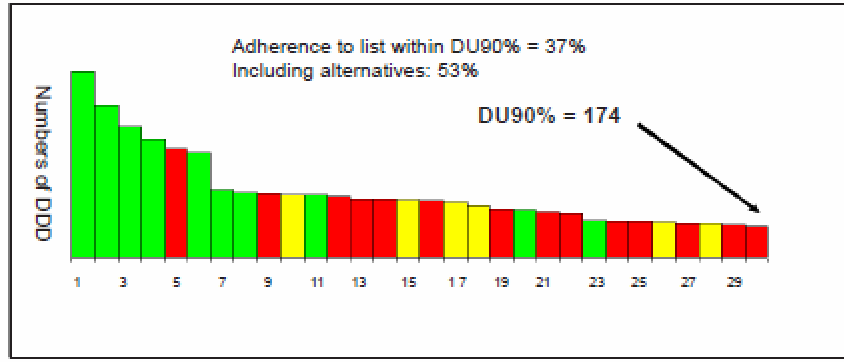


Green = medicines included in the core EML. Yellow = alternatives to medicines, i.e. those marked with a box symbol in the EML. Red = medicines not on the EML.

	SUBSTANCE	(DDD)	Mill. DDD	% TOT	Mill Euro	Euro/DDD
1	Estradiol	2 mg	85	7.7%	1.1	0.01
2	Acetylsalicylic acid	1 tabl	84	7.7%	2.3	0.03
3	Lisinopril	10 mg	45	4.1%	12.3	0.27
4	Amlodipine	5 mg	39	3.6%	10.0	0.25
5	Diclofenac	0.1 g	36	3.3%	6.6	0.19
6	Ascorbic acid (vit C)	0.2 g	35	3.2%	1.1	0.03
7	Furosemide	40 mg	34	3.1%	1.6	0.05
8	Diazepam	10 mg	31	2.8%	3.0	0.10
9	Atenolol	75 mg	25	2.3%	3.5	0.14
10	Simvastatin	15 mg	24	2.2%	16.2	0.67
11	Isosorbide mononitrate	40 mg	22	2.0%	4.0	0.19
12	Levothyroxine	0.15 mg	21	1.9%	0.4	0.02
13	Oxazepam	50 mg	19	1.7%	4.4	0.23
14	Glibenclamide	7 mg	19	1.7%	1.8	0.09
15	Alprazolam	1 mg	16	1.5%	2.5	0.16
16	Verapamil	0.24 g	15	1.3%	2.5	0.17
17	Cilazapril	2.5 mg	13	1.2%	4.3	0.34
18	Loratadine	10 mg	12	1.1%	3.3	0.27
19	Metildigoxin	0.2 mg	11	1.0%	0.9	0.08
20	Chlortalidone	25 mg	11	1.0%	0.8	0.07
...						
95						
DU90%	1-95		987	90.1%	241	0.24
	96-388		109	9.9%	93	0.85
TOTAL	1-388		1096	100.0%	334	0.30

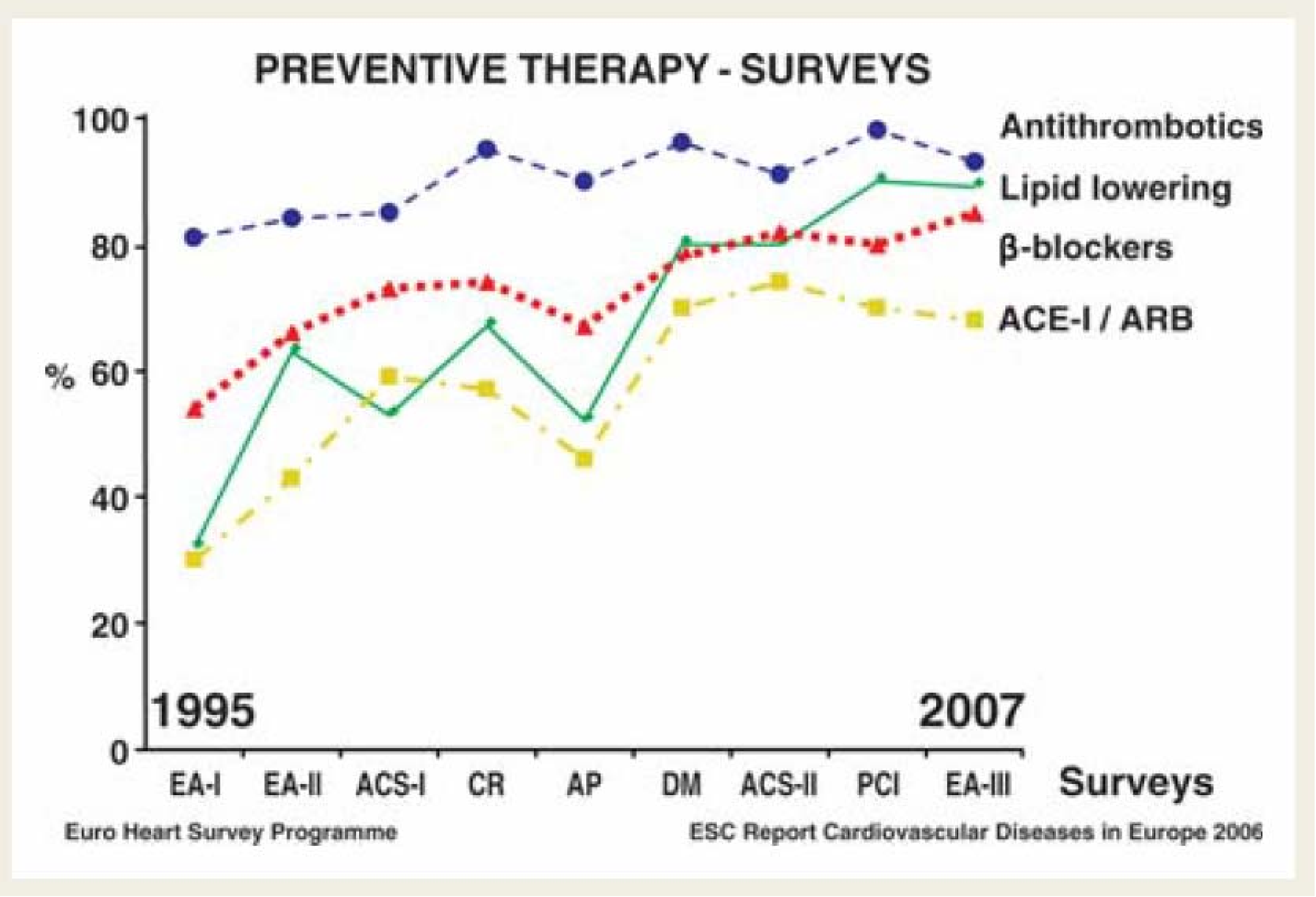


Green = medicines included in the core EML. Yellow = alternatives to medicines, i.e. those marked with a box symbol in the EML. Red = medicines not on the EML.

	SUBSTANCE	(DDD)	Mill. DDD	% TOT	Mill Euro	Euro/DDD
1	Acetylsalicylic acid	1 tablet	201	4.6%	10	0.05
2	Furosemide	40 mg	164	3.7%	14	0.08
3	Sodium fluoride	1.1 mg	142	3.2%	11	0.07
4	Ascorbic acid (vit C)	0.2 g	128	2.9%	3	0.02
5	Simvastatin	15 mg	118	2.7%	52	0.44
6	Paracetamol	3 g	113	2.6%	49	0.43
7	Enalapril	10 mg	73	1.7%	10	0.13
8	Levothyroxine	0.15 mg	71	1.6%	9	0.12
9	Lactulose	6.7 g	70	1.6%	8	0.11
10	Ramipril	2.5 mg	68	1.5%	22	0.32
11	Atenolol	75 mg	68	1.5%	9	0.13
12	Citalopram	20 mg	67	1.5%	27	0.41
13	Atorvastatin	10 mg	64	1.4%	45	0.71
14	Cyanocobalamin	1 mg	63	1.4%	8	2.00
15	Metoprolol	0.15 g	63	1.4%	39	0.63
16	Multivitamins and iron	1 tablet	62	1.4%	4	0.06
17	Felodipine	5 mg	60	1.4%	23	0.37
18	Isosorbide mononitrate	40 mg	57	1.3%	9	0.15
19	vitamin b-mixed	1 tablet	53	1.2%	9	0.16
20	Ibuprofen	1.2 g	51	1.2%	21	0.42
...						
174						
DU90%	1-174		3,970	90.1%	1,535	0.39
	175-828		438	9.9%	961	2.19
TOTAL	1-828		4,408	100.0%	2,496	0.57

Wettermark et al 2014

Disease-oriented PQI



Simoons. Eur Heart J 2011

Patient level drug dispensing data

Opens up a new dimension of possibilities to monitor quality of drug prescribing

May be used to derive indicators focusing on

- Prevalence/incidence
- Drug-drug combinations
  (e.g. drug-drug interactions, polypharmacy)
- Drug as a marker of disease/risk
- First/second line drugs
- Refill adherence/persistance

Data sources

Prescriber

Pharmacy

Patient

Medical records

+ Contain clinical data, age & sex, patient id…
+ Reflects prescriber behaviour

- Not always a complete picture of a patients’ treatment
- Validity of diagnoses uncertain
- May be difficult to compare data from different settings
- Mainly small samples possible (but new technique and coding systems may facilitate)
- No information of the drug actually has been taken (exception hospital records)

Pharmacy dispensing data

- + May contain age & sex, patient and prescriber id
- + May include OTC and herbal products
- + Easily available and comparable in many countries if based on a common methodology, e.g. ATC/DDD

- \- Limited amount of clinical data
- \- May lack drugs dispensed without reimbursement
- \- Validity of data may vary
- \- Although closer to patients' actual use, we still don´t know how the patients take their medicines

Data captured from patients

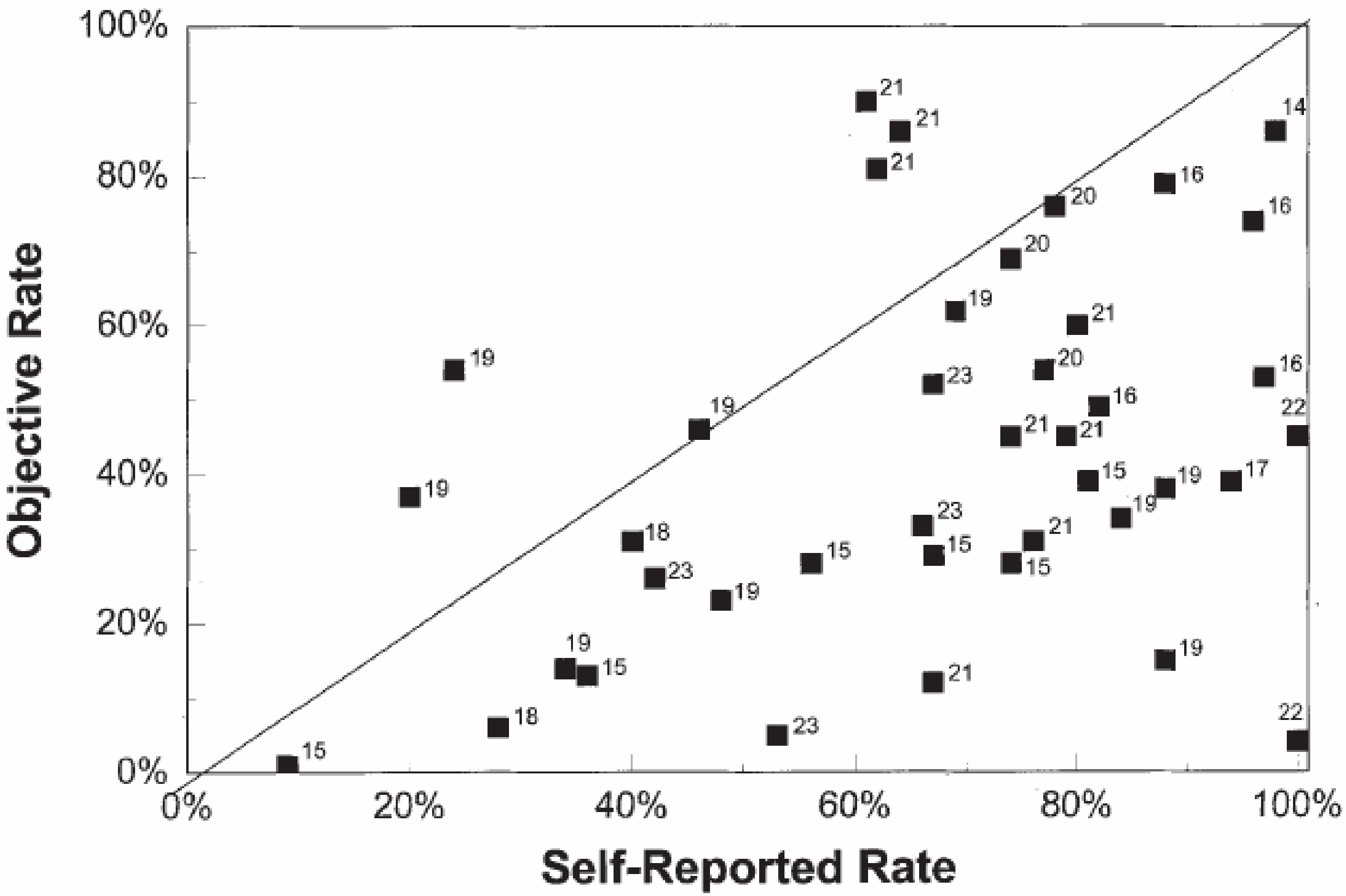
+ The only ”true” source, i.e. collecting data relevant from a patient perspective
+ Reflects patient behaviour (or what they claim to do!)

- Problems of recall bias
- Problems of overestimation of compliance
- Difficult to obtain clinically relevant data
- May be difficult to compare data from different settings
- Time consuming to collect. Only small samples possible
- Lost competition with the privat mobile/internet-market?

Why using registries for quality assessment

- The registries already exist (reduced time and cost)
- Large sample size (high statistical precision)
- Long-term and complete follow-up
- Much information has high validity
- Data collected routinely for other purposes than to monitor quality

Most physicians (and others) overestimate their adherence to guidelines



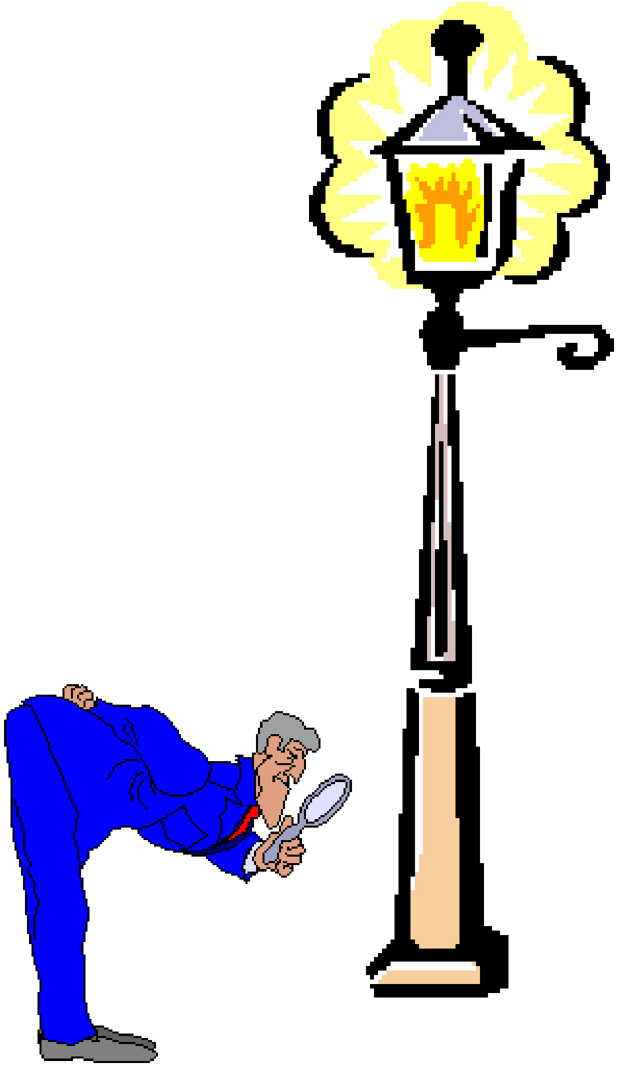
Adams et al 1999

Successful PQI initiatives in Europe

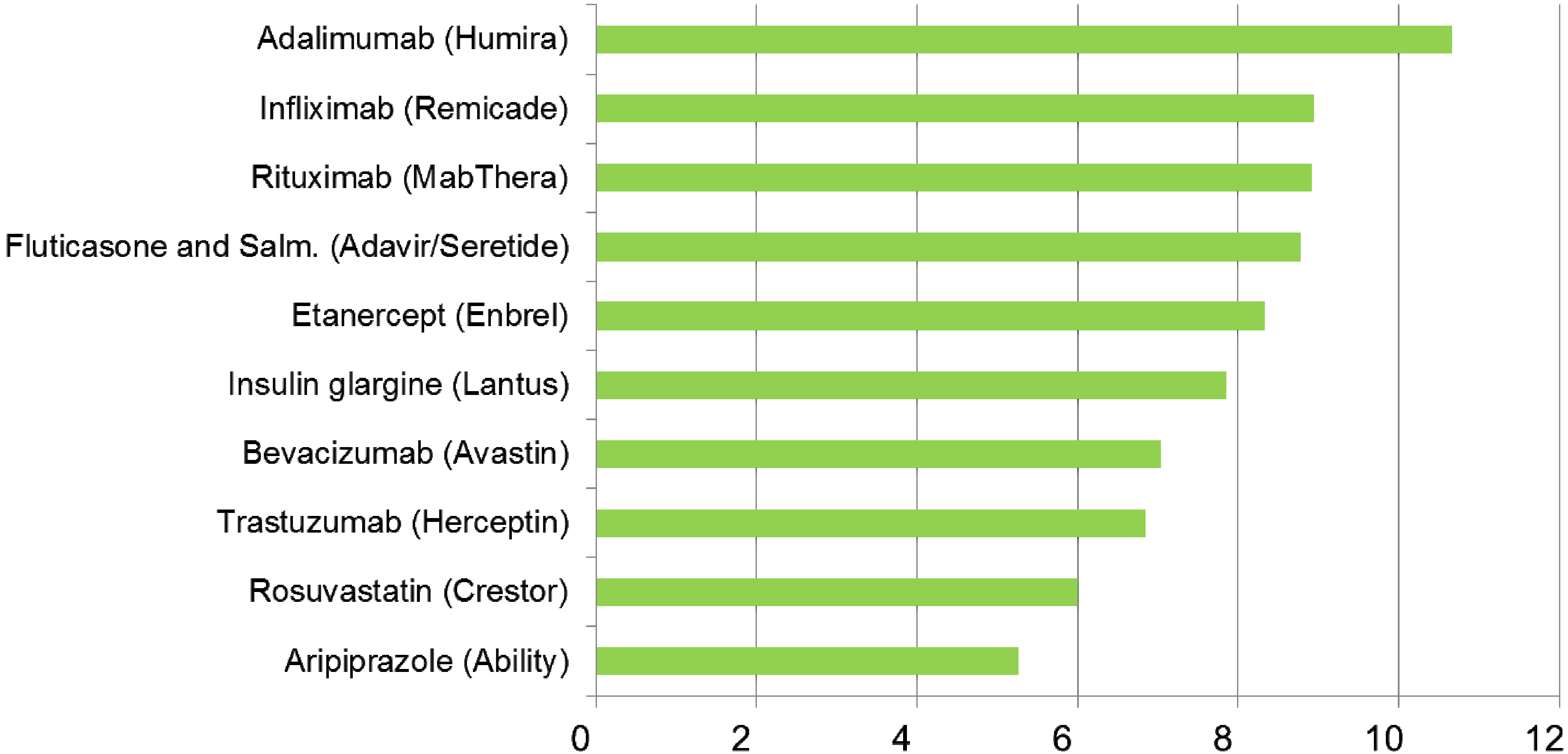
- Disease based indicators & development of registries
- Guidelines & HTA integrated with indicators
- Indicator sets for rational drug treatment of elderly
- European collaboration, e.g. ESAC - antibiotic surveillance, OECD-indicators & EuroAspire
- Good & bad experiences of
  - quality improvement driven by professional bodies
  - indicators linked to payment (P4P, P4R)
  - indicators made publicly available for patients and the general population

Some challenges

- The balance between conflicting interests
  - professional ownership
  - public involvement
  - payer demands
- Validity & data availability
- Limited experience of PQI for new medicines



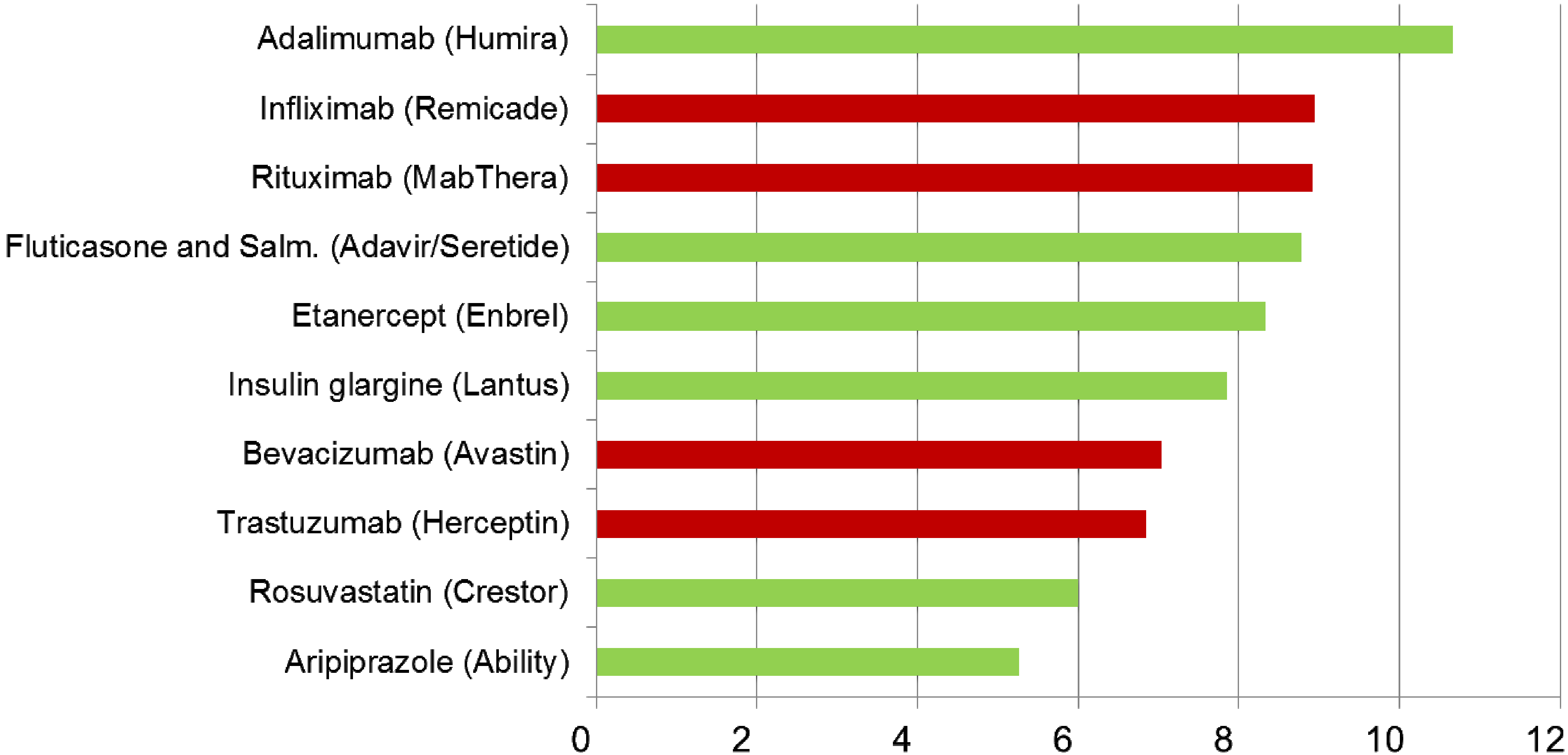
Top 10 Selling Drugs of 2013 in the World ($ billion)



Source:Genetic Engineering & Biotechnology News, Mar 3, 2014

Top 10 Selling Drugs of 2013 in the World ($ billion)

4 /10 are usually administered in hospitals / hospital settings

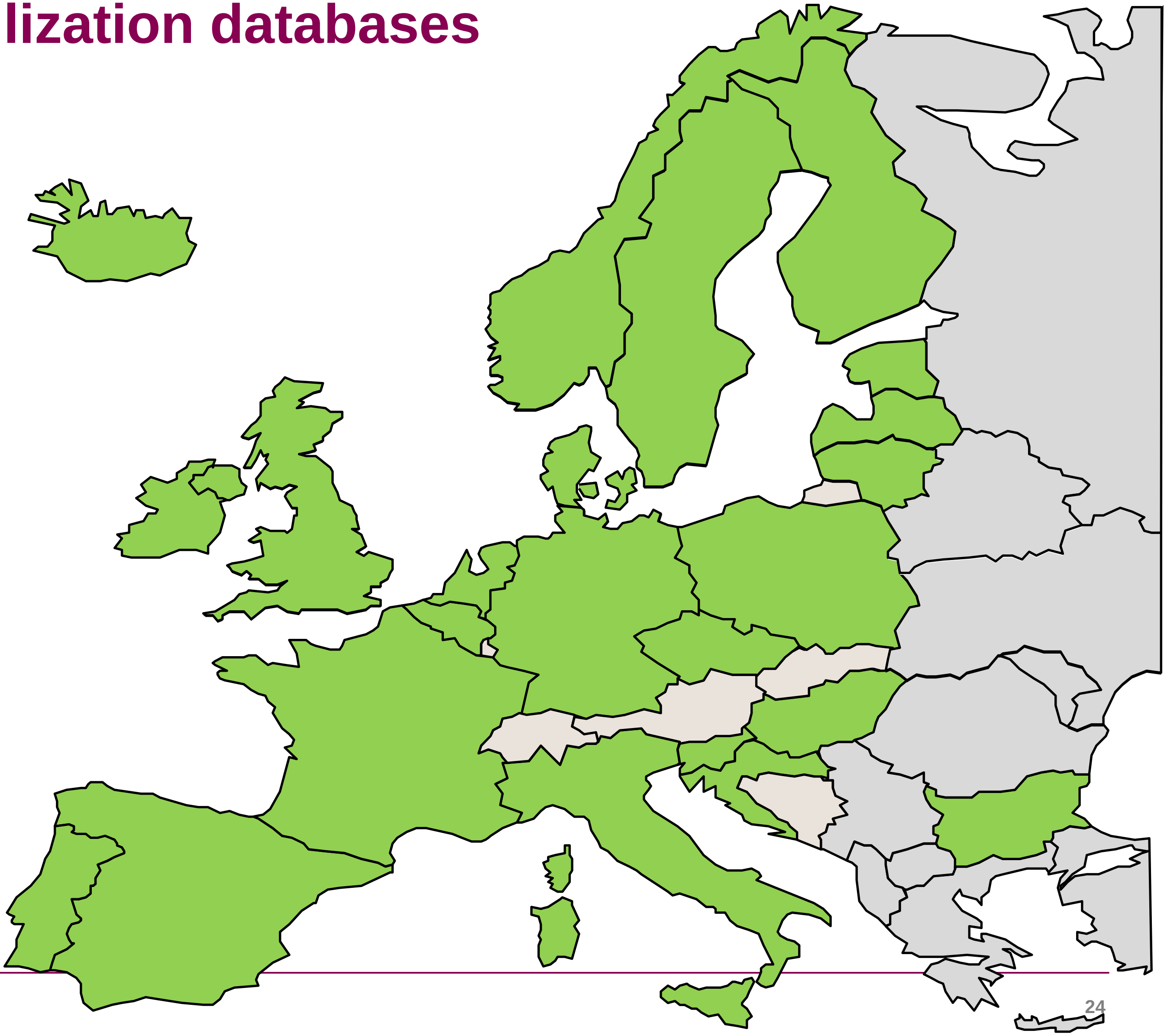


Source:Genetic Engineering & Biotechnology News, Mar 3, 2014

European drug utilization databases

Ambulatory care

- 23 countries



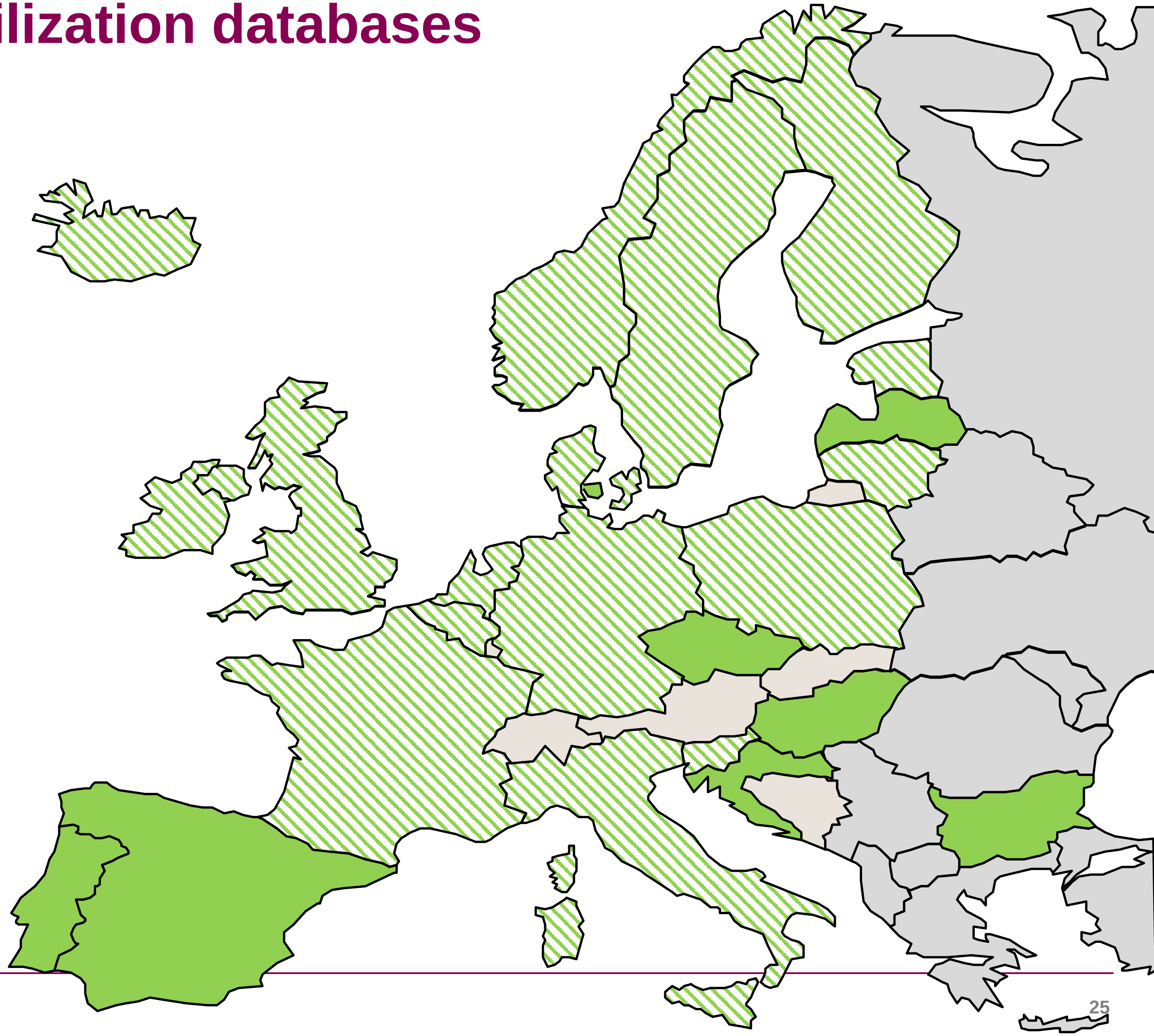
Source: PROTECT and Ferrer et al 2014

European drug utilization databases

Ambulatory care

- 23 countries

- **17** countries have databases including patient identifier

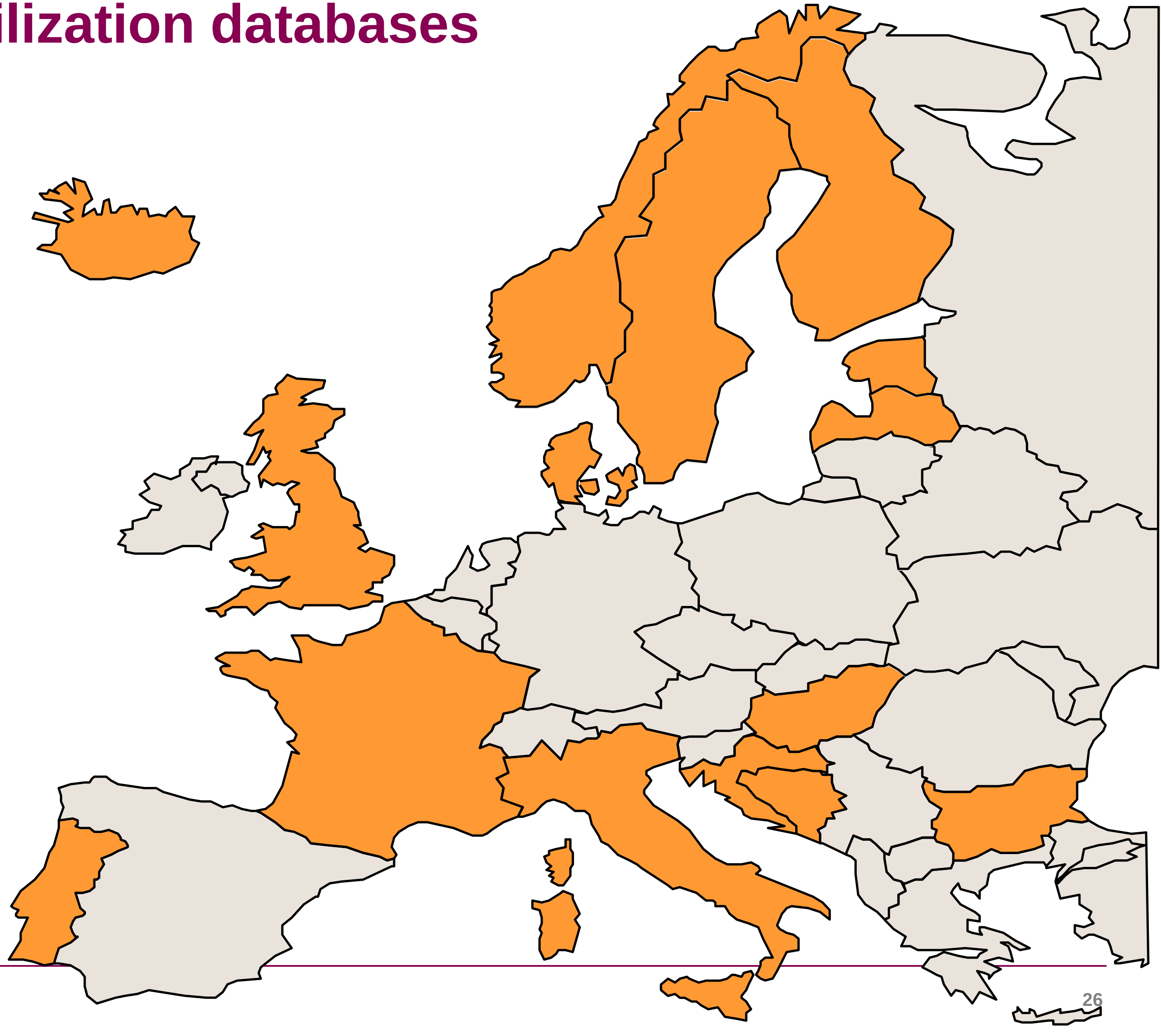


Source: PROTECT and Ferrer et al 2014

European drug utilization databases

Inpatient care

- 15 countries

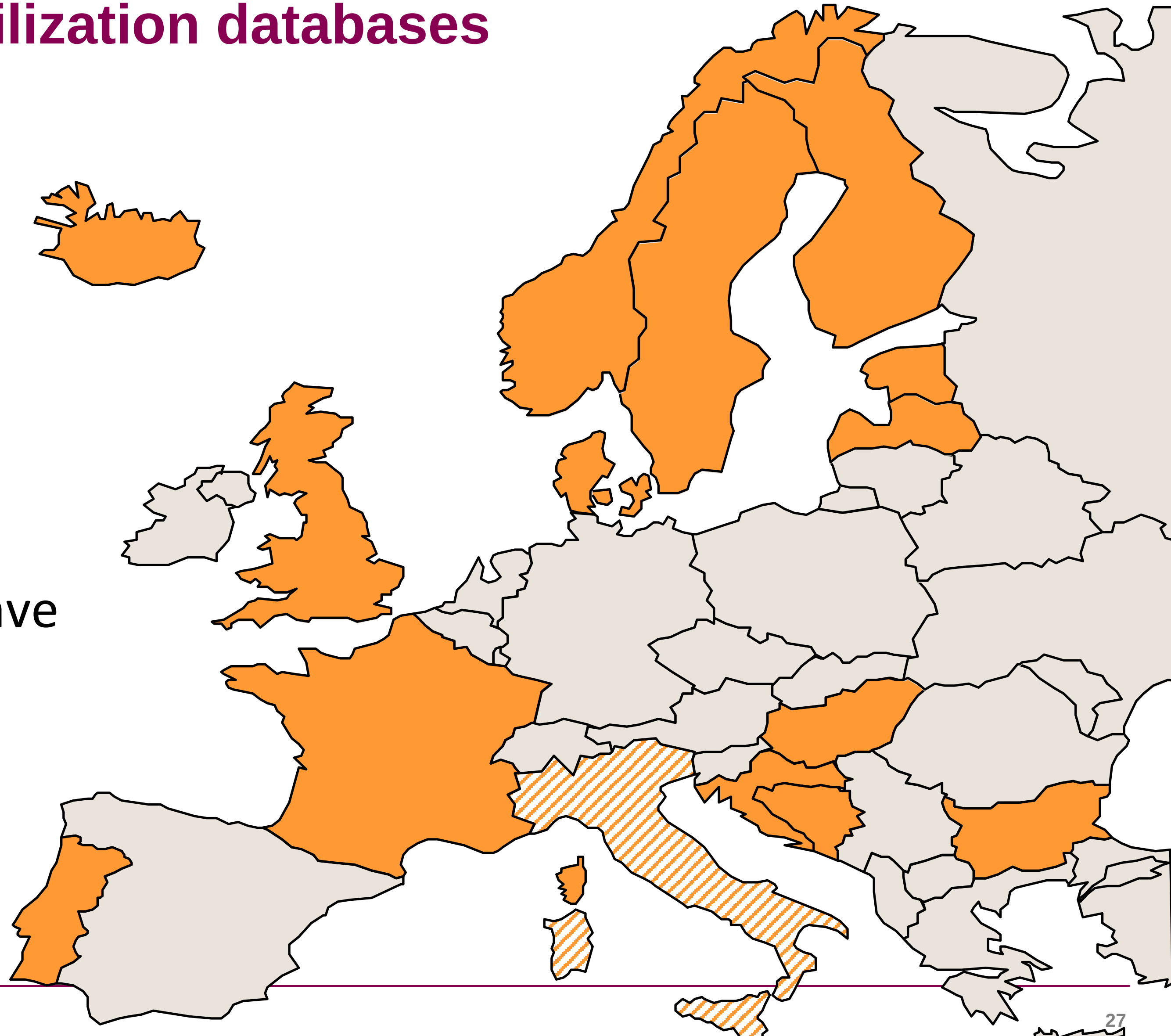


Source: PROTECT and Ferrer et al 2014

European drug utilization databases

Inpatient care

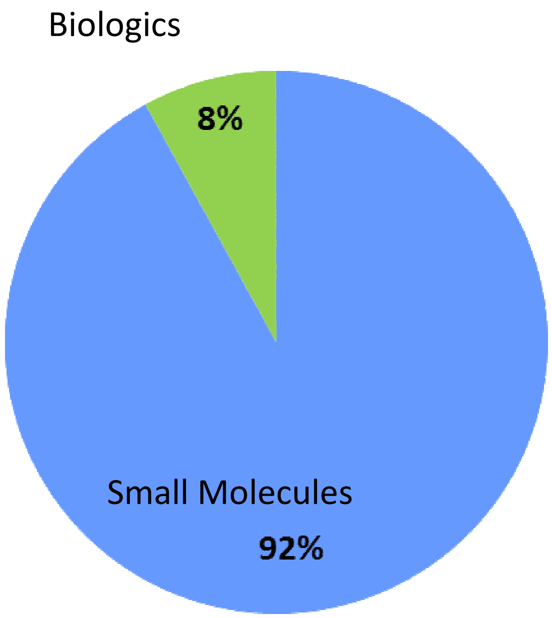
- 15 countries
- **1** country (*Italy*) have inpatient drug data including patient id (*regional level*)



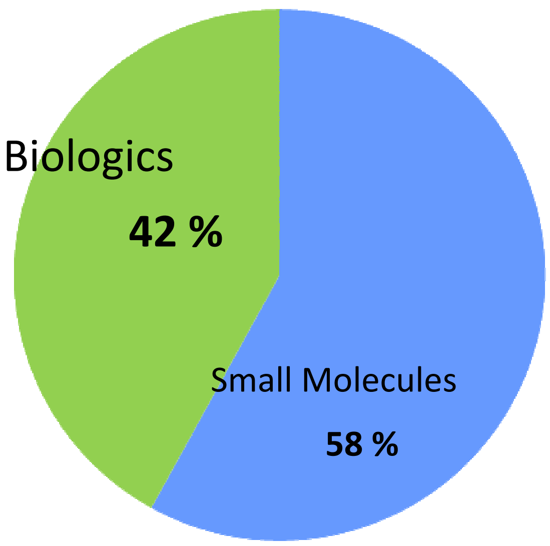
Source: PROTECT and Ferrer et al 2014

What will the future bring?

Marketed & Approved Products

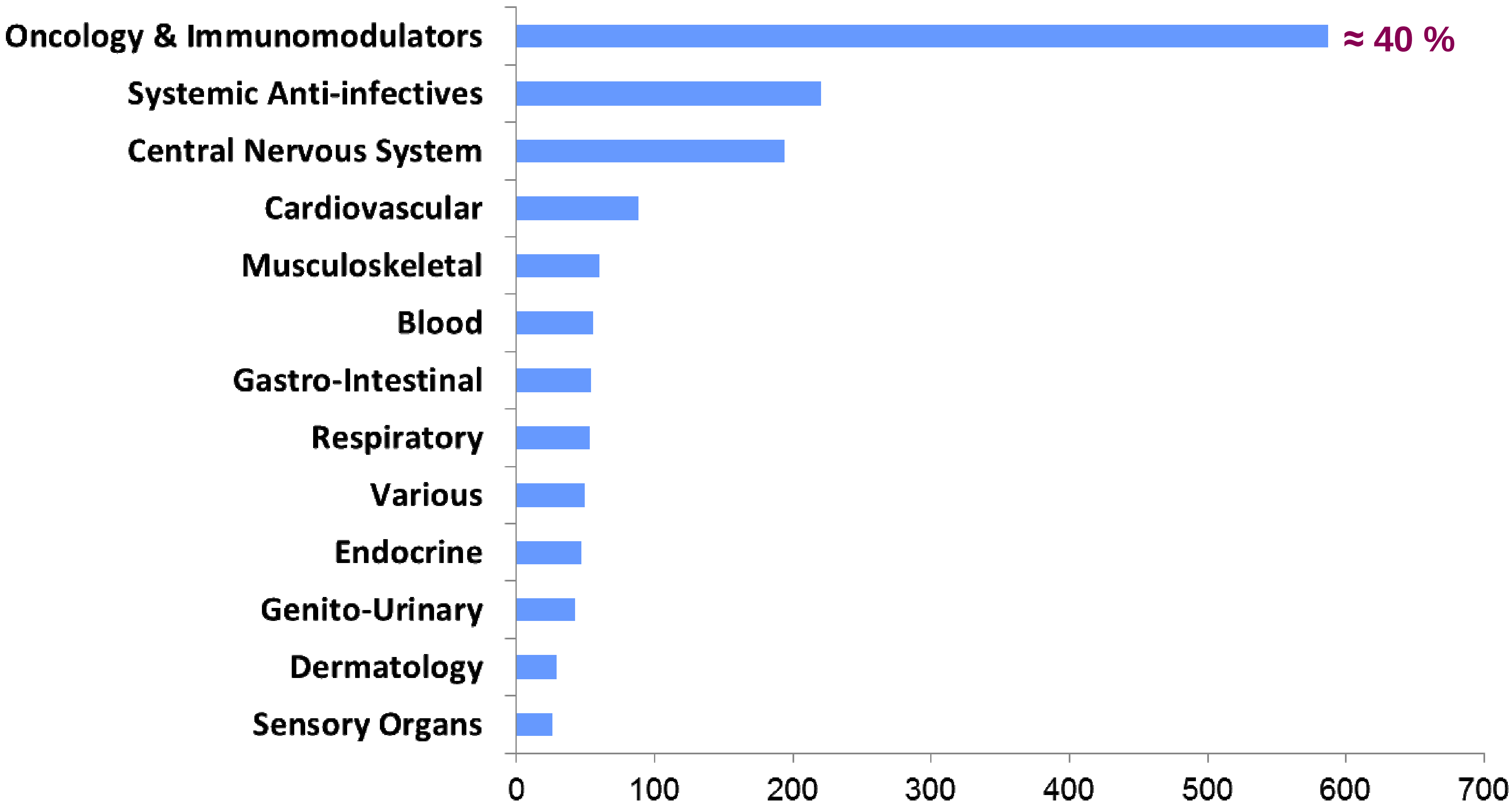


Pipeline Products



Source: EvaluatePharma, 2012 (Nasdaq Biotechnology Index pipeline)

Substances in ”pipeline” by therapeutic area



Source: EvaluatePharma, 2012 (Nasdaq Biotechnology Index pipeline)

Indicators to monitor new medicines

Structure

- Systems in place for rational introduction

Process

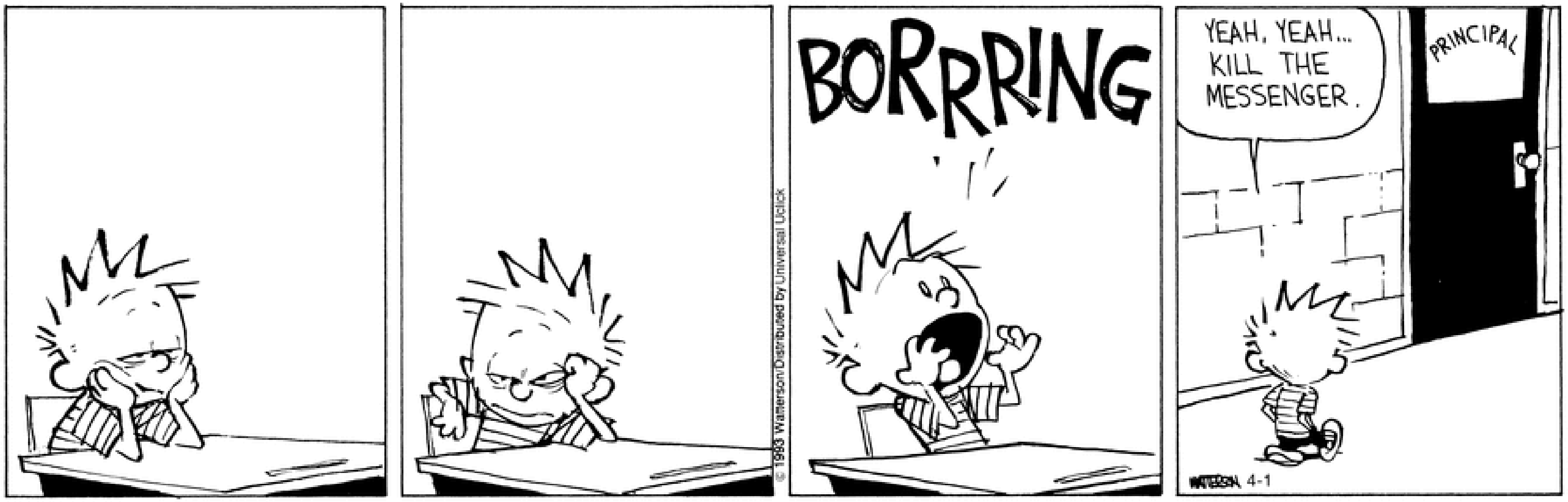
- Prevalence/incidence of use (in targeted populations)
- Ratios between different drugs
- Is the drug used as stated in the EMA approval and/or reimbursement decision
- Same patient groups as in the clinical trials?

Outcome

- Morbidity, mortality
- Quality of life

Campbell et al. Basic Clin Pharmacol Toxicol 2014

Thank you for your attention!



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