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European Diagnostic Manufacturers Association

Please note our new address from 1 January 2006
Place des Maieurs 2 - 1150 Brussel, Belgium

2001
2002
2003

EUROPEAN IVD market estimates 2004

EDMA represents the In Vitro Diagnostic (IVD) Industry in Europe.

EDMA is pleased to publish consolidated Market Statistics at European level for 2004. EDMA Consolidated Market Statistics are one of the best tools available to understand the trends in our industry. It is an asset that the IVD industry has, and EDMA thanks the companies and countries participating in the European Diagnostic Market Statistics (EDMS) program. The accuracy of data is high and major countries have more than 85% of the market covered by companies reporting invoiced sales to an independent auditor.

IVDs provide critical health information allowing the potential for global health care savings

Increased testing can contribute significantly to the quality of health care:
- Allowing earlier and more appropriate treatment
- Helping to rule out expensive treatments
- Reducing costs of treatment of complications
- Reducing the spread of infectious diseases in the community

Increased testing can shorten length of hospital stay
- Making therapy more effective
- Ensuring subsequent treatment is relevant and cost-effective

These benefits will only be achieved if there is a change in the way that resources are allocated in order to take advantage of these opportunities.

It is important to note that the amount spent on IVD out of the total healthcare expenditures is minimal. **The sales of the IVD industry in Europe represent generally less than 2% of the total health care expenditure in Europe (i.e. less than 20 Euro per capita and per annum)**. The average growth for 2004 is estimated to be 4.4% but growth rates vary with country and category of reagents, some countries and some segments showing even negative growth rates.

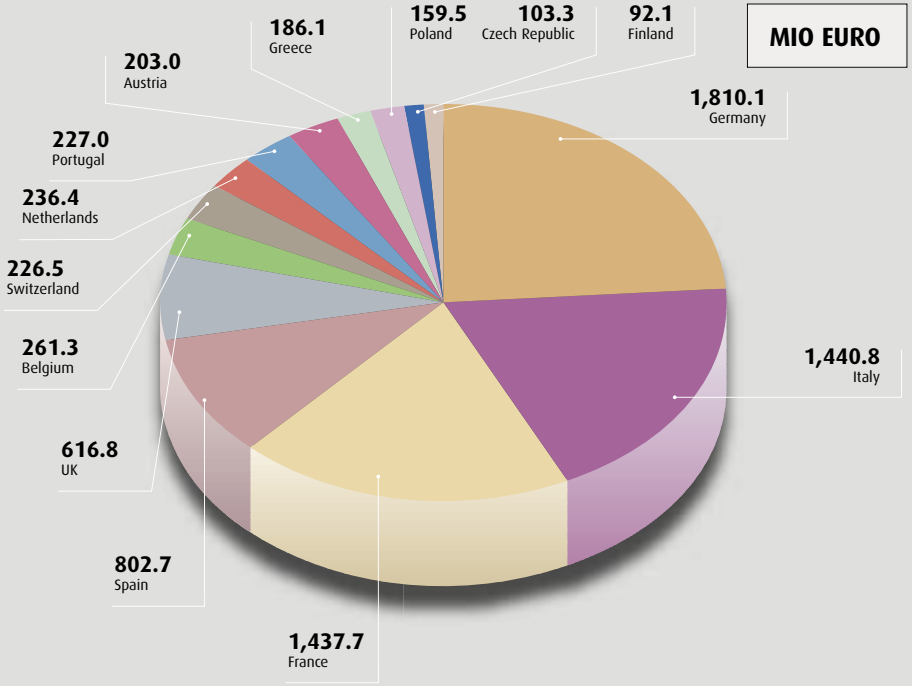
In vitro diagnostics are highly automated and provide valuable data at low cost. Increased testing will not significantly increase the costs of health care. Appropriate spending on IVD would have a positive impact on health care.

European IVD Market Estimates 2004

> IVD Market estimates by country

The results presented in the tables enclosed are based on individual estimates made in **14 European countries: Austria, Belgium, Finland, France, Germany, Greece, Italy, Poland, Portugal, Spain, Switzerland, the Netherlands, UK, and for the first time this year Czech Republic.**

- Germany
- Netherlands
- Italy
- Portugal
- France
- Austria
- Spain
- Greece
- UK
- Poland
- Belgium
- Czech Republic
- Switzerland
- Finland

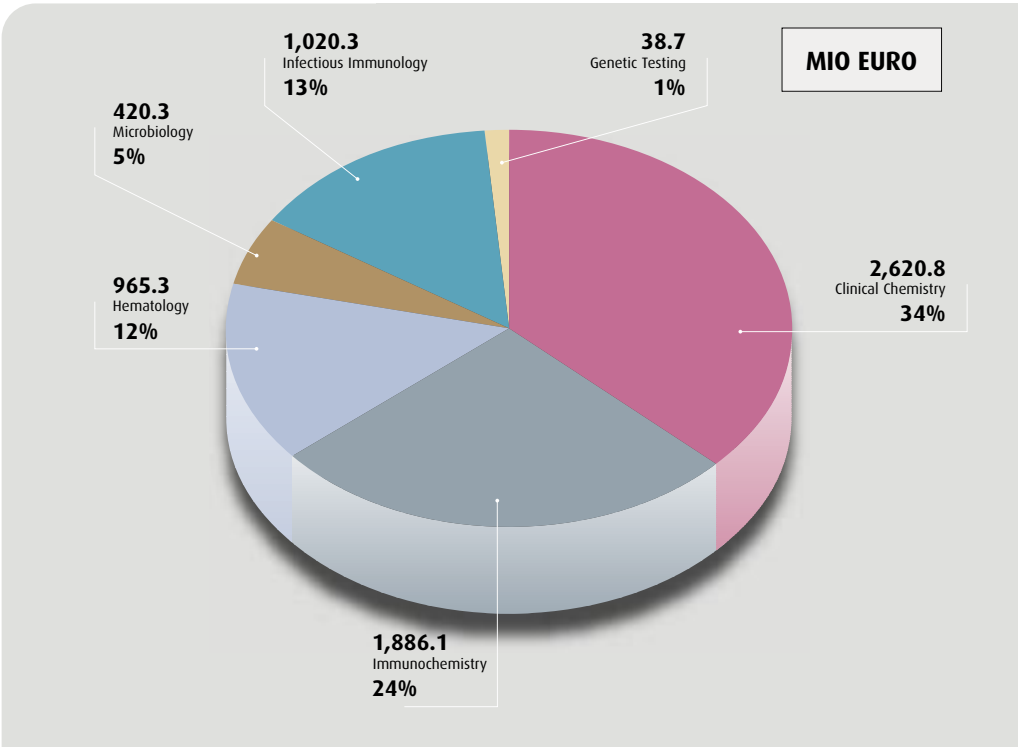


***Total IVD Market** (14 European countries) 7,803.2 MIO EURO - 2004 (EDMA source)*

European IVD Market Estimates 2004

> IVD Market estimates by category of reagents

- Clinical Chemistry
- Immunochemistry
- Hematology
- Microbiology
- Infectious Immunology
- Genetic Testing



Total Reagent Market (14 European countries) 6,951.1 MIO EURO - 2004 (EDMA source)

European IVD Market Estimates 2004

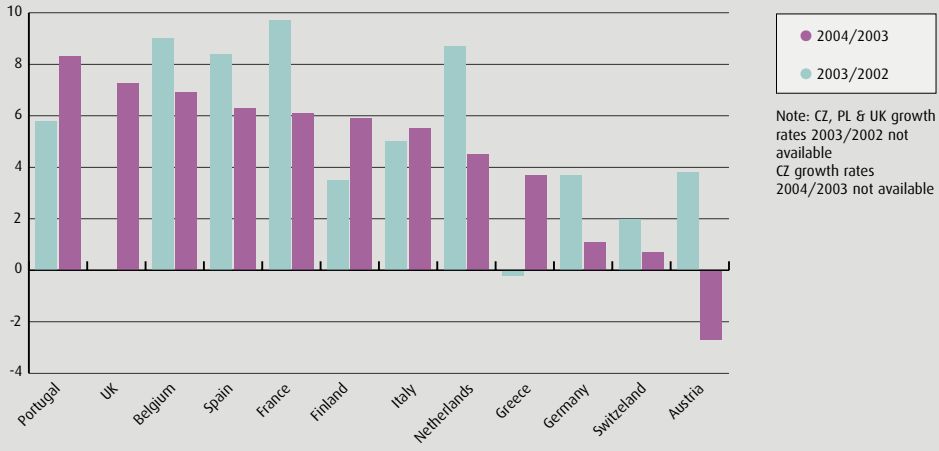
> IVD Market estimates by country and by category

EDMA source		MIO EURO	TOTAL		Reagents						Reagents		Patient Self Testing
Country		TOTAL	Instru-ments	Reagents	Clinical Chem.	Immuno Chem.	Haema-tology	Micro-Culture	Infect. Immuno	Genetic Testing	Laboratory Reagents Total	Rapid Tests Total	=Rapid Tests Tot (-) Lab Rap Tests
Germany	Euro	**1,810.1**	201.0	1,609.1	746.2	389.0	216.1	87.2	163.5	7.1	951.9	657.2	614.0
24%	%	**100%**	11%	89%	41%	21%	12%	5%	9%	<1%	53%	36%	34%
Italy	Euro	**1,440.8**	95.0	1,345.8	466.9	398.9	188.1	59.0	222.9	10.0	1,063.5	282.2	235.7
19%	%	**100%**	7%	93%	32%	28%	13%	4%	15%	1%	74%	20%	16%
France	Euro	**1,437.7**	232.3	1,205.4	362.5	349.7	180.7	97.0	208.9	6.7	937.0	268.4	248.5
19%	%	**100%**	16%	84%	25%	24%	13%	7%	15%	<1%	65%	19%	17%
Spain	Euro	**802.7**	53.7	749.0	265.6	201.6	123.5	52.1	102.5	3.8	578.9	170.1	149.9
10%	%	**100%**	7%	93%	33%	25%	15%	6%	13%	<1%	72%	21%	19%
UK	Euro	**616.8**	42.7	574.1	250.5	142.2	59.4	36.0	82.4	3.7	390.6	183.5	174.1
7%	%	**100%**	7%	93%	41%	25%	11%	6%	15%	1%	63%	30%	28%
Belgium	Euro	**261.3**	42.9	218.4	70.0	68.9	26.6	16.0	35.3	1.7	174.6	43.8	40.3
3%	%	**100%**	16%	84%	27%	26%	10%	6%	13%	1%	67%	17%	15%
Netherlands	Euro	**236.4**	33.4	203.0	79.0	46.0	25.0	16.5	34.5	2.0	139.7	63.4	55.2
3%	%	**100%**	14%	86%	33%	19%	11%	7%	15%	1%	59%	27%	23%
Portugal	Euro	**227.0**	17.5	209.6	59.8	58.8	30.1	10.5	50.1	0.3	170.0	39.5	31.0
3%	%	**100%**	8%	92%	26%	26%	13%	5%	22%	<1%	75%	17%	14%
Switzerland	Euro	**226.5**	37.8	188.7	69.0	47.9	30.8	12.2	27.9	0.8	138.6	50.1	28.9
3%	%	**100%**	17%	83%	30%	21%	14%	5%	12%	<1%	61%	22%	13%
Austria	Euro	**203.0**	27.5	175.5	61.3	50.1	25.8	8.7	28.8	0.8	131.5	44.0	38.7
3%	%	**100%**	14%	86%	30%	25%	13%	4%	14%	<1%	65%	22%	19%
Greece	Euro	**186.1**	16.7	169.4	58.4	43.3	33.9	7.5	25.2	1.0	142.4	27.0	23.0
2%	%	**100%**	9%	91%	31%	23%	18%	4%	14%	<1%	77%	14%	12%
Poland**	Euro	**159.5**	29.7	129.9	70.2	26.9	11.3	6.3	14.8	0.8	NR	NR	NR
2%	%	**100%**	19%	81%	44%	17%	7%	4%	9%	<1%			
Czech Republic	Euro	**103.3**	13.3	90.0	24.2	41.6	4.0	5.8	14.5	NR	76.2	13.9	3.4
1%	%	**100%**	13%	87%	23%	40%	4%	6%	14%		74%	13%	3%
Finland	Euro	**92.1**	8.7	83.4	37.2	21.3	10.2	5.6	9.1	NR	44.7	38.7	29.5
1%	%	**100%**	9%	91%	40%	23%	11%	6%	10%		49%	42%	32%
Europe 04	Euro	**7,803.2**	**852.1**	**6,951.1**	**2,620.8**	**1,886.1**	**965.3**	**420.3**	**1,020.2**	**38.7**	**4,939.6**	**1,881.7**	**1,672.2**
	%	**100%**	**11%**	**89%**	**34%**	**24%**	**12%**	**5%**	**13%**	**<1%**	**63%**	**24%**	**21%**

NR: Not Reported for this specific grouping
Note: the totals are taking into account decimal values

European IVD Market Estimates 2004

> Average growth by country



IVD growth rates (%) by country (EDMA source)

Country	Europe	Germany	Italy	France	Spain	UK	Switzerland	Belgium	Netherlands	Austria	Portugal	Poland	Greece	Finland
Variance 04/03 %	**4.4**	1.1	5.5	6.1	6.3	7.3	0.7	6.9	4.5	-2.7	8.4	2.4	3.7	5.9

In 2002, the IVD market increased significantly in many European countries and **the average growth rate (2002/2001) was estimated to be around 6%.**

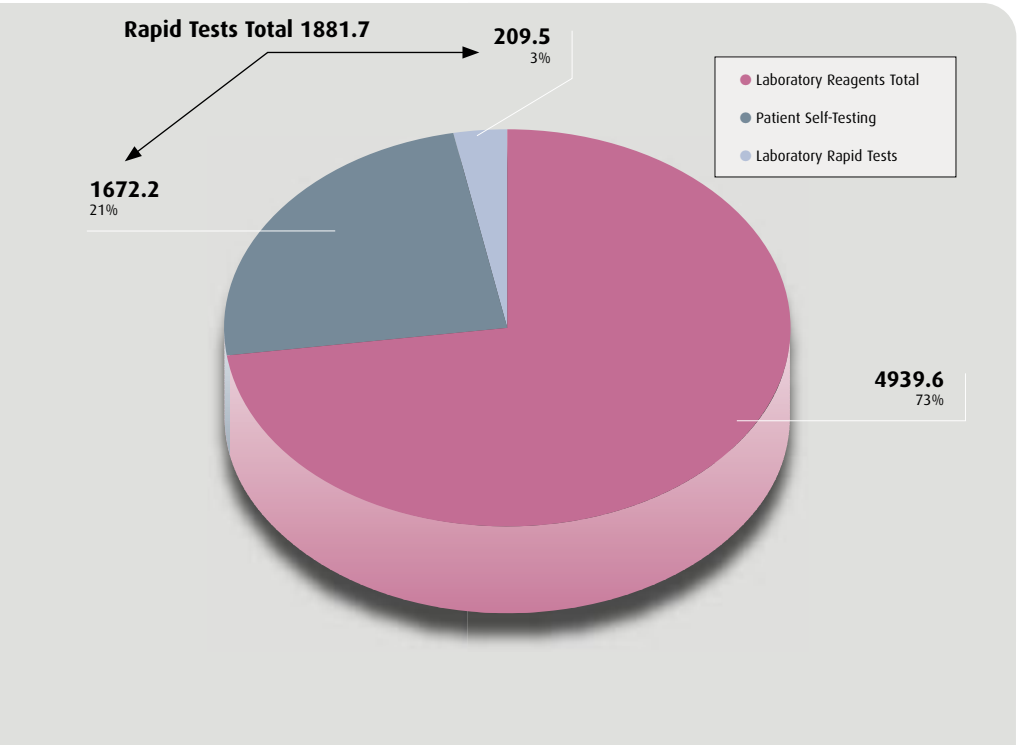
In 2003, the average growth rate (2003/2002) decreased and was estimated to be around 5.6%.

In 2004, the average growth rate (2004/2003) has decreased again and is now estimated to be around 4.4%.
The IVD market continues to increase in most of the European countries, except Austria (-2.7%). However, the average growth rates (2003/2002) are again very low in Switzerland (0.7%) and Germany (1.1%).
One explanation for these low growth rates could be that these countries already have a high level of health care.
In comparison to other countries, the estimated growth rates are relatively high in Portugal (8.4%) and in the UK (7.3%). Portugal seems to come back from recession, and there has been some investment by the UK government to modernize the pathology service.

European IVD Market Estimates 2004

> IVD Market estimates by category of reagents

for Laboratory reagents and Patients Self-testing reagents



Total Reagents (13 European countries – without Poland) 6821.2 MIO EURO - 2004
(EDMA source)

European IVD Market Estimates 2004

> Average growth 2004/2003 by country

for Laboratory reagents and Patients Self-testing reagents

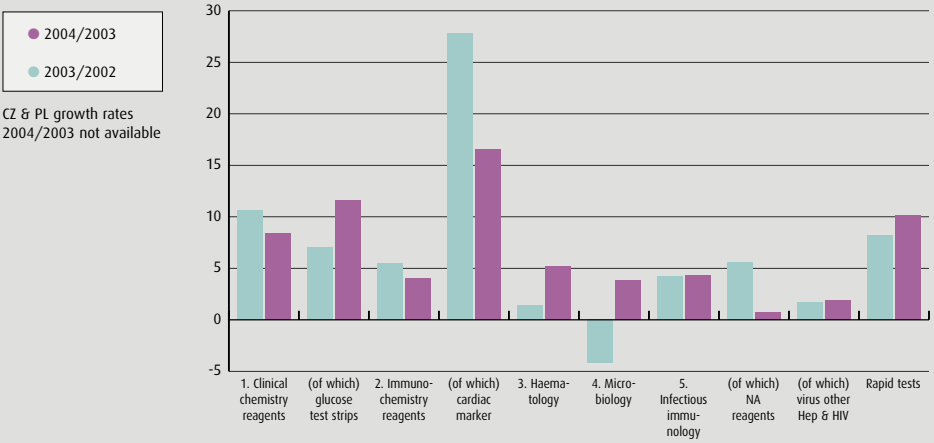
IVD growth rates (%) by country for Laboratory reagents and Self-tests
(EDMA source)

Country	Europe	Spain	Belgium	UK	Portugal	Italy	France	Netherlands	Greece	Finland	Germany	Switzerland	Austria
Lab Reagents	**3.7**	6.9	6.7	6.6	5.6	5.4	3.8	3.8	2.8	1.5	-0.5	-0.6	-2.8
Self-Tests	**10.5**	8.5	10.1	14.2	24.5	10.8	25.2	0.4	8.6	14.3	6.0	5.2	0.2

In fact, the average growth rate for patient self-testing reagents is still high in most of the countries (but it represents only 21% of the total market for IVD reagents), and the average growth rate of laboratory reagents market (representing 73% of the total market for IVD reagents) is very low, and even decreasing in Austria (-2.8%), Germany (-0.5%) and Switzerland (-0.6%).

European IVD Market Estimates 2004

> Average growth by category of reagent



***IVD growth rates (%) by category of reagent** (EDMA source)*

In 2004, there is strong growth in the majority of the countries for:

- Glucose Testing (11%)
- Cardiac Markers (16.6%). This is mainly due to the increased testing of BNP, pro-BNP and Troponin.

Despite the fact that EU governments attempt to cut health care expenditure, the continuing growth observed in recent years for the two of the market segments self monitoring of blood glucose and cardiac markers could be explained by the fact that health authorities are becoming increasingly aware of the economic and clinical benefits of IVD testing in these areas.

Several sectors are under pressure, in particular the Instrumentation, showing a negative "growth" (- 2.9%). There is a clear tendency to provide instrumentation on a rental basis, or to transfer its cost by incorporation into the price of the consumable component of the testing system. The lack of growth can also be explained by the reduction of numbers of laboratories in several EU countries.

Note:
The market audit is supported by the **EDMA nomenclature system**, a detailed classification of all IVD products. Some of these products are grouped in the following table (for more details, see the EDMA website www.edma-ivd.be / products classification).

EDMA source	Europe 2004 Mio EURO	European Estimated Variance 04/03 (%)*
TOTAL DIAGNOSTICS(1)	**7,803.2**	**4.4**
Instruments	**852.1**	**-2.9**
Reagents	**6,951.1**	**5.4**
Clinical Chemistry Reagents(1)	2,620.8	6.4
Clin Chem Laboratory Reagents	755.3	1.5
Clin Chem Calibrators & Controls	66.2	-2.2
Clin Chem Rapid tests	1,729.2	9.7
Immunochemistry Reagents(1)	1,886.1	4.0
Specific proteins	135.4	5.2
Allergy	128.4	2.3
Tumour markers	246.7	2.0
Thyroid function	235.7	2.1
Fertility/Pregnancy	130.0	-1.1
Individual/Specified hormones	98.8	3.7
Anaemia /Vitamins	113.9	6.5
Therapeutic drugs	96.9	-1.9
Drug of abuse & Toxicology	68.9	-0.8
Auto-Immune diseases	98.1	9.9
Rheumatoid diseases	104.2	-2.6
Specific organ function	1.9	172.9
Cardiac markers	145.8	16.6
Calibrators & Controls	80.6	7.3
Rapid tests: Immunochemistry	116.4	5.0
Other Immunochemistry	57.5	8.5
Haematology/Histology/ Cytology Reagents(1)	965.3	5.2
Haematology	276.2	6.2
Haematology: Calibrators & controls	20.7	9.8
Haemostasis	305.6	5.1
Haemostasis: Calibrators & Controls	20.9	8.7
Rapid tests: Haemostasis	18.7	68.0
Immunohaematology	183.2	1.8
Immunohaematology: Controls	2.8	36.8
Tissue Typing Reagents	21.7	10.8
Monoclonal Abs for Cell Surface Ag	54.7	0.7
Cytokines / Immunmodulators	10.9	-5.1
Histology / Cytology Reagents	35.3	4.3
Other Haematology	2.3	-55.8

* Variance 03/04 calculated without Czech Republic (data not available for 2003)

(1) The estimates for the 4 categories of reagents (Clinical Chemistry, Immunochemistry, Haematology, Infectious Immunology) include data from Poland. These totals do not reflect the sum of the subcategories as the detailed levels were not provided by this country.

EDMA source	Europe 2004 Mio EURO	European Estimated Variance 04/03 (%)*
Microbiology (Culture) Reagents(2)	420.3	3.8
Bacteriology Culture excl. Blood Culture	181.7	2.1
Blood Culture	50.4	3.6
Bacteriology Identification & Susceptibility	145.8	5.7
Other Culture Tests	21.1	0.1
Microbiology: Calibrators & Controls	2.0	2.4
Rapid tests: microbiology	2.5	-13.4
Infectious Immunology Reagents(1)	1,020.2	4.3
(of which) NA Reagents	238.1	0.7
Bacteriology	112.9	6.8
Hepatitis Viruses	476.5	2.7
Retroviruses	201.7	7.4
Other Viruses	118.2	1.9
Parasitology	52.4	1.9
Other Infectious Immunology	19.8	27.3
Calibrators & Controls	10.1	0.8
Rapid Tests: Infectious Immunology	13.9	3.8
Genetic Testing(3)	38.7	15.5
Inborn Gene or Chromosome Alterations	25.4	21.8
Acquired Gene or Chromosome Alterations	4.9	8.8
Other Genetic Testing	3.9	19.7

Laboratory Market(4)	5,762.0	2.8
Instruments Total(5)	852.1	-2.0
Instruments Instruments	295.1	-3.4
After Sales	166.7	-1.0
Consumables	158.2	-1.8
Laboratory Reagents Total(4)	4,939.6	3.7
(of which) Calibrators & Controls	203.3	4.4
(of which) NA based Reagents	276.0	2.8
Rapid Tests(4)	1,881.7	9.7
(of which) Self-Testing	1,672.2	10.5

(2) The estimates for Microbiology include data from Poland and Portugal. These totals do not reflect the sum of the subcategories as the detailed levels were not provided by these countries.

(3) The estimates for Genetic Testing include data from Poland and UK. These totals do not reflect the sum of the subcategories as the detailed levels were not provided by these countries.

(4) The estimates for Laboratory Market (Instruments and reagents) and Rapid Tests do not include data from Poland.

(5) The estimates for Instruments Total include data from Germany. These totals do not reflect the sum of the subcategories as the detailed levels were not provided by this country.

European IVD Market Estimates 2004

> Health expenditures

Countries	Population	GDP	GDP per capita	THE	THE / capita	THE as % GDP	IVD mkt est. 2004	% IVD 04 / THE 02	IVD 04 / capita
	Thousands	Mio EURO	EUR	Mio EURO	EUR	%	Mio EURO		EUR
EU	OECD source 2002						EDMA source		
Germany	82,489	2,110,400	25,584	230,066	2,789	10.9	1,810.1	0.8	21.9
France	59,486	1,520,804	25,566	148,082	2,489	9.7	1,437.7	1.0	24.2
UK	59,232	1,538,636	25,977	118,896	2,007	7.7	616.8	0.5	10.4
Italy	57,994	1,260,428	21,734	106,784	1,841	8.5	1,440.8	1.3	24.8
Spain	41,874	696,208	16,626	53,080	1,268	7.6	802.7	1.5	19.2
Poland	38,425	172,846	4,498	10,462	272	6.1	159.5	1.5	4.2
Netherlands	16,149	444,649	27,534	40,554	2,511	9.1	236.4	0.6	14.6
Greece	10,604	141,334	13,328	13,462	1,270	9.5	186.1	1.4	17.5
Portugal	10,368	129,557	12,495	12,001	1,158	9.3	227.0	1.9	21.9
Belgium	10,333	260,011	25,164	23,646	2,288	9.1	261.3	1.1	25.3
Czech Republic	10,205	71,477	7,004	5,293	519	7.4	103,3	2.0	10.1
Sweden	8,925	257,345	28,834	23,765	2,663	9.2			
Austria	8,053	218,333	27,112	16,806	2,087	7.7	203.0	1.2	25.2
Switzerland	7,290	277,210	38,028	31,078	4,263	11.2	226.5	0.7	31.1
Denmark	5,376	182,947	34,031	16,147	3,004	8.8			
Finland	5,201	139,803	26,882	10,208	1,963	7.3	92.1	0.9	17.7
Norway	4,538	181,961	40,095	15,787	3,479	8.7			
Ireland	3,932	164,228	41,769	11,934	3,035	7.3			
Luxembourg	446	22,395	50,192	1,395	3,128	6.2			
Iceland	288	8,950	31,131	885	3,071	9.9			
US	288,369	8,359,434	28,988	1,222,707	4,240	14.6			
Japan	127,400	3,705,879	29,089						

GDP = Gross Domestic Product - THE = Total Health Care Expenditure

In 2002, Health Care cost an EU citizen only 272 EURO in Poland or 1158 EURO in Portugal (lowest levels) rising to 3479 EURO in Norway or 4263 EURO in Switzerland (highest levels), where as a US citizen spent 4240 EURO.

In Europe, less than 10% of GDP is spent on Health Care in most countries (more than 14% for USA). The US policy is to limit these expenditures.

However, this is not an appropriate approach in Europe where we are still a long way from reaching the level of Health Care expenditure they have in the US.

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