



European Diagnostic Manufacturers Association

PRESS RELEASE

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IVDs in Europe

EDMA presents the 2008 Market Estimates

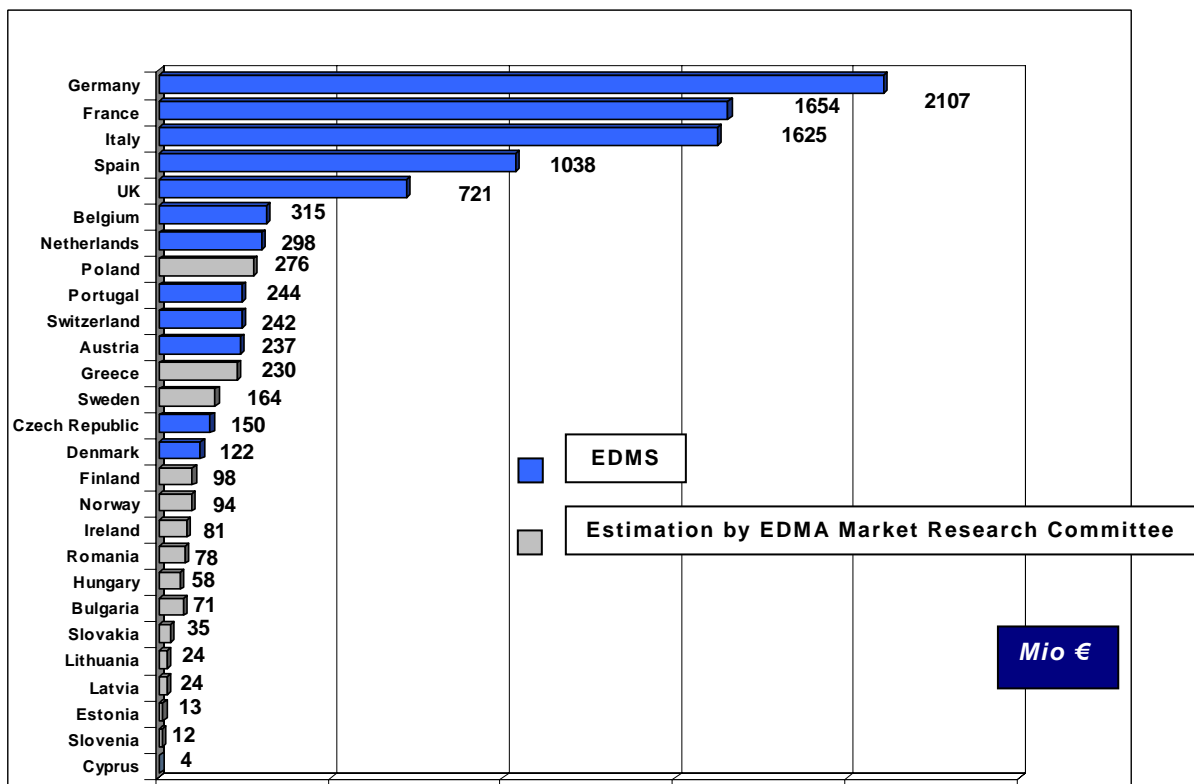
EDMA, the European Diagnostic Manufacturers Association, is pleased to publish market estimates of the *In Vitro* Diagnostic industry in Europe for the year 2008. European sales reached **€10,016** million and the IVD market growth was in the range of **4.2% versus 2007**. The report combines data from EU countries as well as the European Free Trade Association (EFTA).

In 2008, the average IVD sales in most European countries represented less than 1% of the Total Healthcare Expenditure (THE).

EDMA data includes macroeconomic and healthcare expenditure figures for the 27 EU Member States and EFTA.

The original EU15 countries spent 0.8% of THE on IVDs (i.e. €22.9 per capita), while the later joining Member States dedicated an average of 1.3% of THE to IVDs (i.e. €7.3 per capita).

Ageing population in need of routine testing, especially for metabolic and cardiovascular diseases as well as hospital acquired infections, can be accounted for most IVD sales in Europe.



TOTAL IVD Market 2008 (EDMA source):

* EU-27 (except Luxembourg & Malta): 9,680 Mio €

* EU-27 (except Luxembourg & Malta) + EFTA (except Iceland & Liechtenstein): 10,016 Mio €

Healthcare budget deficits in the majority of European markets continue leading to closure of small hospitals and laboratories, rationalisation of testing, and also delaying the introduction or reimbursement of new IVD tests. Laboratory consolidation leads to an increasing need of pre- and post-analytical systems and IT solutions, which are very important elements in selecting IVD suppliers. There is growing demand for biomarkers due to the interest in “companion diagnostics”, which aim at demonstrating the effectiveness of drugs in individual patients.

In **France**, the grouping into “plateaux techniques” of thousands of laboratories continues. Esoteric or specialised tests are referred to dedicated specialised labs. The laboratory market has become a target for takeovers by global operating laboratories, but French labs are also pursuing to merge or invest in international laboratory chains.

In **Italy**, the number of beds and hospitals is decreasing as well as the number of hospital days. Especially the consolidation within the private laboratory segment continues, as they are either purchased by larger labs or integrated into networks. Labs were instructed to consolidate and to maximise their efficiency within the laboratory networks, resulting in larger tenders and increasing length of contracts, with a lower budget level as well as an increase of late payments.

Germany, as one of the major European markets, has experienced market erosion over the past years. It has become one of the slowest growing markets despite of having the largest, and significantly ageing, population in Europe. It is very difficult to receive reimbursement for new markers, and patients are increasingly paying for diagnostic tests without seeking reimbursement. The laboratory market continues to consolidate with private laboratories penetrating the hospital market by purchasing labs or operating them on behalf of the hospital administration. These trends have also led to the creation of purchasing groups impacting the value market growth. In **Austria**, a strong shift towards lab centralisation and formation of buyer networks is recognised. In combination with budget constraints this will have a major impact on the future market growth.

The IVD market in **Spain** experienced positive growth in recent years and came closer to the overall provision of healthcare of other Western European states. Lab centralisation continues, as well as the emergence of specialist satellite labs. Core hospital labs are experiencing test volume increases due to the integration of out-patient testing.

In the **UK**, current and future pressure on funding for the National Healthcare System (NHS) means that previous levels of investment have been significantly reduced, and that cost-savings programmes (efficiency savings) will be implemented in many areas. For pathology this will increase pressure to consolidate and combine pathology services. The Department of Health is interested in innovative solutions, to reduce costs in all areas, and perhaps this will provide some opportunities for IVDs. Although still very small, there is increasing activity from private and hybrid sector pathology service providers. There is still no reimbursement system for IVDs in England.

In the **Netherlands**, due to changes in the system of hospital financing, there is a tendency towards collaboration, centralisation and outsourcing. Labs are seeking for ways to provide better patient management and to strengthen their position within the hospital organisation and versus the healthcare insurance providers. As well as in **Belgium**, creation of hospital networks and consolidation of labs increased centralised purchasing power. In **Sweden**, labs have consolidated during the last 20 years, but the market continues to be highly regulated with very complex tenders.

NOTE:

The results presented by EDMA are based on *individual estimates made in 27 European countries:*



- 12 countries participating in the European Diagnostic Market Statistics (EDMS) programme: *Austria, Belgium, Czech Republic, Denmark, France, Germany, Italy, Portugal, Spain, Switzerland, the Netherlands and the UK.*
- The National Associations members of EDMA and the EDMA Market Research Committee have estimated the IVD market in 15 other countries not participating in the EDMS programme: *Bulgaria, Cyprus, Estonia, Finland, Greece, Hungary, Ireland, Latvia, Lithuania, Norway, Poland, Romania, Slovakia, Slovenia, and Sweden.*

The EDMA figures per country are compiled from the “*European Diagnostic Market Statistics*” (EDMS) programme (where companies report invoiced sales of reagents, instruments and consumables to an independent auditor, CIP, based on the EDMA Classification), in association with the EDMA Market Research Committee and the National Associations members of EDMA.

More than 85% of the market is covered by EDMS, ensuring the reliability and objectiveness of the information provided by EDMA and its members. EDMA encourages all companies and countries to participate to the EDMS programme, which is the largest *In Vitro* Diagnostic audit in Europe and the most accurate source of information to understand and foresee the market trends.

	Population	GDP	GDP per capita	THE	THE/capita	THE as % GDP	IVD mkt est. 08	Growth rate 08	IVD mkt. est. 08 / THE 07	IVD mkt est. 08 per capita
Countries	Thousands	Mio €	€	Mio €	€	%	Mio €	%	%	€
	OECD 2007 source						EDMA source ¹			
EU-15										
Germany	82,257	2,422,900	29,455	252,751	3,073	10.4	2,107	3.0	0.8	25.6
France	61,707	1,892,132	30,663	208,441	3,378	11.0	1,654	4.0	0.8	26.8
UK	60,975	1,764,865	28,944	148,526	2,436	8.4	721	11.2 ²	0.5	11.8
Italy	58,880	1,544,915	26,238	134,777	2,289	8.7	1,625	2.7	1.2	27.6
Spain	44,873	1,050,595	23,413	88,828	1,980	8.5	1,038	7.0	1.2	23.1
Netherlands	16,382	567,066	34,615	55,484	3,387	9.8	298	3.8	0.5	18.2
Greece	11,193	228,180	20,386	21,893	1,956	9.6	230	0.0	1.1	20.5
Portugal	10,604	163,119	15,383	15,786	1,489	9.7	244	-1.2	1.5	23.0
Belgium	10,623	334,917	31,528	34,031	3,204	10.2	315	5.7	0.9	29.6
Sweden	9,148	319,194	34,892	28,957	3,165	9.1	164	1.6	0.6	17.9
Austria	8,315	270,837	32,572	27,453	3,302	10.1	237	4.3	0.9	28.5
Denmark	5,457	226,397	41,487	22,102	4,050	9.8	122	5.2	0.6	22.4
Finland	5,289	179,659	33,968	14,706	2,780	8.2	98	-1.0	0.7	18.5
Ireland	4,339	190,603	43,928	14,432	3,326	7.6	81	3.8	0.6	18.7
Luxembourg	476	36,278	76,214	2,461 ³	2,844 ⁴	6.8 ⁵				
EU-27										
Poland	38,121	336,608	8,830	21,655	568	6.4	276	11.4 ⁶	1.3	7.2
Romania	21,565	110,514	5,125	5,364	249	4.9	78	2.6	1.5	3.6
Czech Rep	10,323	141,739	13,730	9,591	929	6.8	150	3.8	1.6	14.5
Hungary	10,056	101,677	10,111	7,526	748	7.4	61	5.5	0.8	6.1
Bulgaria	7,679	28,940	3,769	1,877	244	6.5	71	4.5	3.8	9.2
Slovakia	5,398	59,493	11,021	4,610	854	7.7	35	3.7	0.8	6.5
Lithuania	3,385	28,633	8,459	1,490	440	5.2	24	4.3	1.6	7.1
Latvia	2,281	20,074	8,800	977	428	4.9	24	4.3	2.5	10.5
Slovenia ⁷	2,001	32,774	16,379	2,823	1,411	8.4	12	0.0	0.4	6.0
Estonia	1,342	15,270	11,379	663	494	4.3	13	8.3	2.0	9.7
Cyprus	789	26,647	33,762	899	1,139	3.4	4	0.0	0.4	4.0
Malta	408	12,614	30,916	419	1,028	3.3				
EFTA										
Switzerland	7,550	322,977	42,778	34,897	4,622	10.8	242	4.1	0.7	32.1
Norway	4,709	277,671	58,966	24,745	5,255	8.9	94	-2.1	0.4	20.0
Iceland	311	10,465	33,651	973	3,129	9.3				
Liechtenstein										

¹ The applied exchange rates are the 2008 annual average exchange rates published by Oanda (www.oanda.com). Applying a single exchange rate to both 2007 and 2008 sales data eliminates possible fluctuations of market size and market growth due to exchange variations.

² Removing anomalies in the market due to blood glucose strips and point of care tests suggests the growth in the pathology market was around 7%.

³ 2006 data taken from the OECD Health Data 2009 (www.oecd.org/publishing).

⁴ 2006 data taken from www.oecd.org/dataoecd/45/43/38980822.pdf.

⁵ 2006 data taken from www.oecd.org/dataoecd/45/43/38980822.pdf.

⁶ Removing the growth related to blood glucose strips and point of care tests suggests that the growth in the pathology market was around 9.1%.

⁷ 2006 data taken from the WHO World Health Statistics (www.who.int/countries/svn/en/).

About EDMA:

EDMA, the European Diagnostic Manufacturers Association represents National Associations and major companies engaged in the research, development, manufacture or distribution of *In Vitro* Diagnostic (IVD) medical devices in Europe. Through its affiliated National Associations, EDMA represents in total more than 500 companies (over 700 legal entities) across Europe. The mission of EDMA is to raise awareness of the importance, usefulness and added-value that diagnostic information can provide to healthcare. For this purpose, EDMA cooperates with European institutions, patients groups, trade associations, health professionals and academia to support an appropriate regulatory system, to work towards a realistic economic environment for healthcare in Europe and to be an effective voice in globalisation.

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