European Diagnostic Manufacturers Association

PRESS RELEASE
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THE EUROPEAN *IN VITRO* DIAGNOSTIC (IVD) MARKET IN 2009

The European Diagnostic Manufacturers Association (EDMA) today released its estimates for the 2009 revenues generated by the IVD industry in Europe. The IVD market revenues of €10.2 billion are just 0.8% of the Total Healthcare Expenditure (€1,228 billion).

Brussels, 01 December 2010 – The EDMA data includes macroeconomic and healthcare expenditure figures for the EU 27 Members, as well as data for the European Free Trade Association (EFTA).

Revenue growth in 2009 versus 2008 was 3.0%, which was below that recorded in the previous year (4.2%). The overall European average IVD sales amount to 0.8% of Total Healthcare Expenditure (THE).

The demand for IVD testing is increasing because there is a growing awareness that it is a cost-efficient way of providing the information required for earlier diagnosis and treatment of many disease states. It is estimated that over 60% of the information on patients' files are based on the results of IVD tests. Other factors driving the increasing demand for IVD testing are the ageing population, better informed patients and the availability of improved technologies. There is an increasing interest in "theranostics" or "personalised medicine". This is where the use of biomarkers helps in predicting the outcome of a particular therapy for an individual patient, so that effective treatment regimens can be selected early, saving time and money, and helping ensure a better outcome for the patient.

Despite evidence showing that IVD testing can lead to cost savings in the treatment of patients, limitations have been imposed on testing volumes and reimbursements, as governments try to balance budgets. Government cutbacks resulted in a significant decrease in sales of IVD products in Norway, Hungary, Greece and Romania.

At present, most IVD testing is performed in public hospitals but the role of private laboratories is increasing as hospitals outsource their routine pathology services to take advantage of the efficiencies of scale and transparency of costs offered by large private laboratories. The degree of outsourcing varies widely from country to country with Germany being the leading proponent.

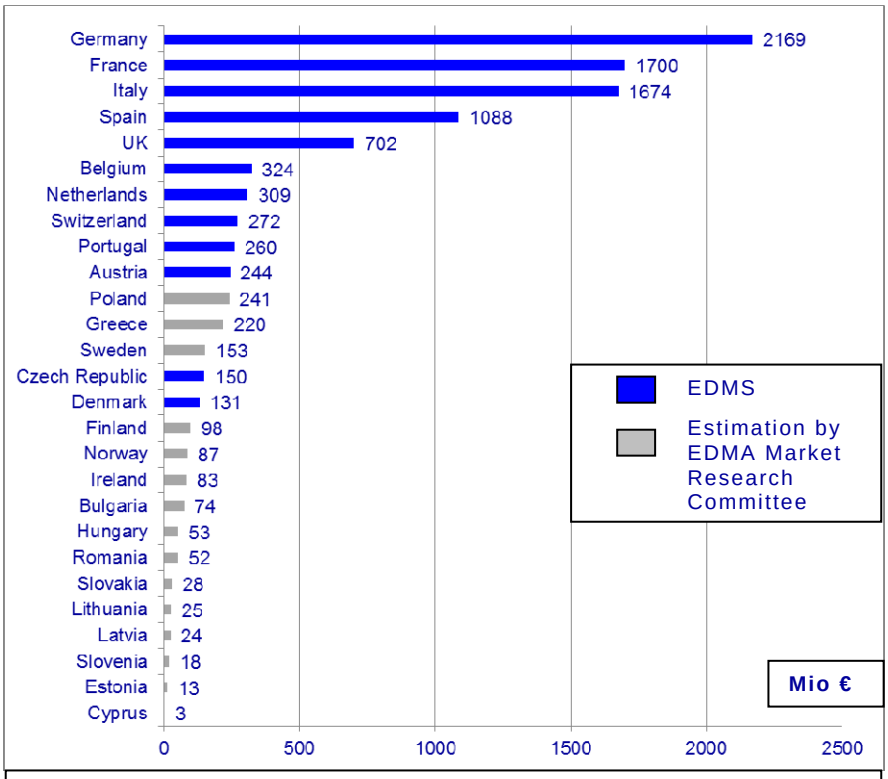
In many countries, there is a move for smaller laboratories to consolidate in order to be able to provide wider ranges of tests. Efficient logistics for the transport of samples and secure data networks allow treating physicians' access to patient results as quickly as (and in many cases, faster than) was the case before consolidation.

Germany: Despite an ageing population, growth in IVD sales in Germany has been low due to restrictions placed on the reimbursement of blood test strips and new tests and the increasing consolidation of the market. Outsourcing by hospitals of their laboratory services is well established in Germany and the trend is set for it to increase. The larger laboratory chains are incorporating smaller laboratories and at the same time operating more laboratories on behalf of the hospital administrations.

France: after many years of debate, the government has introduced new rules regarding private laboratories. While one major consequence of these regulations will be to dramatically reduce the number of private labs (~4200 today) to between 800 and 1500 in 2016, they are intended to insure quality and to reinforce the message that "Labs are vital". Two of principal rules in the new decree are:

- The role and responsibilities of the laboratory biologist are strengthened.
- All laboratories must be accredited before November 1st, 2016 for the pre-analytical, analytical and post-analytical phases. Any laboratory wishing to practice must demonstrate that it has started the accreditation process before November 2013.

Italy: The situation of private laboratories varies considerably from region to region. While Northern Italy has few but large laboratories, Southern Italy has many very small laboratories. Public hospitals and laboratories have been subject to restrictions on testing volumes and budgets. A major problem for IVD suppliers in Italy has been the issue of late payments. The national average is close to 300 days' sales outstanding (DSO) – five times greater than the EU maximum recommendation of 60 days.



TOTAL IVD Market 2009:
EU-27 (except LU&MT): €9,836 Mio.
EU-27 (except LU&MT) + EFTA (except ICE&LIE): €10,195 Mio.

Spain: The Spanish IVD market has grown strongly in recent years. Several international laboratory chains have extended their networks into the Spanish market. Most testing takes place in hospitals but private laboratory chains are trying to win this business. At the same time, the governments of some of the Autonomous Communities are looking at outsourcing the hospital testing. In the Madrid Community, a novel approach has been adopted in which all new hospitals will be built and managed by a UTE ("Unión Temporal de Empresas" - temporary union of companies). Included in this UTE is a laboratory chain that will provide clinical analyses at a fixed price per patient, irrespective of the tests requested.

UK: Almost all laboratory based IVD testing in the UK takes place in NHS laboratories which are part of NHS hospitals. There are no plans at present for a 'reimbursement' type system for IVDs in England. From April 2011, there is no expectation of any increases in NHS funding, and economies are underway this year to help address future possible

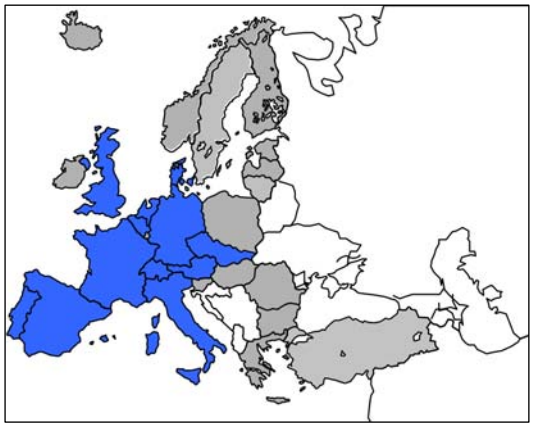
deficits. Health authorities have been instructed to make plans to realise savings from pathology service budgets that have been projected in recent reviews (Lord Carter's reviews). There are expectations that the number of laboratories may be considerably reduced, and that there will be greater involvement from private and semi-private sector providers of pathology services.

Switzerland: Among European countries, Switzerland is unique in the level of IVD testing that is carried out in doctors' offices. In an effort to reduce deficits and slow down the growth in insurance premiums, health insurance companies have reduced reimbursement for IVD tests. From 2012, a DRG (Diagnostic Related Groups) system will be introduced into Swiss hospitals. Under this scheme, hospitals will be reimbursed according to the patient's medical condition and not for the individual procedures, including testing.

Portugal: The IVD market in Portugal slightly increased in 2009 (+2.85%), due to the positive evolution in rapid tests. Nevertheless, the laboratory market was negatively impacted by government budget restrictions. The Stability and Growth Programme contained a number of measures which had an effect on the IVD industry, e.g. the revision of the list of reimbursed tests and a reduction of reimbursement levels as well as the introduction of mandatory electronic prescriptions which lead to a decrease of prescribed tests. Furthermore, the concentration of public hospitals and the arrival of international laboratory chains to the Portuguese market created new rules on negotiations for both public tenders and the private sector. Finally, late payments to suppliers by the public sector – over one year delay – are the major issue for IVD companies. APIFARMA is trying to minimise this problem by proposing a system of charging interests for payment delays.

Turkey[1]: For a few years, reimbursement of IVD products in Turkey has decreased, thus selling prices of reagents have also decreased significantly. However, the volume of testing has increased which is reflected in an overall stagnating market value.

The results presented below are based on individual estimates made in 27 European countries, EFTA and Turkey:



- 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 Association Members of EDMA and the EDMA Market Research Committee have estimated the IVD market in 16 other countries not participating in the EDMS programme: *Bulgaria, Cyprus, Estonia, Finland, Greece, Hungary, Ireland, Latvia, Lithuania, Norway, Poland, Romania, Slovakia, Slovenia, Sweden and Turkey*.

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.

[1] For the first time, the Turkish Association Member of EDMA, TIVD, has provided an estimate of their market which is around 250 million euros.

Countries	Population	GDP	GDP / capita	THE	THE / capita	THE as % GDP	IVD mkt. 09	IVD mkt. growth rate 08-09	IVD mkt. / THE	IVD mkt. / capita
	'000	Mio €	€	Mio €	€	%	Mio €	%	%	€
	Source: OECD 2008						Source: EDMA			
Germany	82,807	2,495,800	30,396	263,216	3,206	10.5%	2,169	2.09%	0.8%	26.2
France	62,149	1,948,511	31,509	217,352	3,515	11.2%	1,700	1.79%	0.8%	27.3
UK	60,930	1,627,106	26,885	140,869	2,328	8.7%	702	9.05%	0.5%	11.5
Italy	58,947	1,567,851	26,636	141,900	2,411	9.1%	1,674	3.02%	1.2%	28.4
Spain	44,511	1,088,502	24,565	97,614	2,203	9.0%	1,088	6.79%	1.1%	24.4
Netherlands	16,418	595,883	36,356	58,775	3,586	9.9%	309	3.69%	0.5%	18.8
Greece	11,252	239,141	21,318	21,893	1,952	9.2%	220	-4.35%	1.0%	19.6
Portugal	10,646	166,435	15,672	15,786	1,486	9.5%	260	2.85%	1.6%	24.4
Belgium	10,542	344,676	32,773	35,272	3,354	10.2%	324	2.86%	0.9%	30.7
Sweden	9,301	297,513	32,279	27,946	3,032	9.4%	153	3.24%	0.5%	16.5
Austria	8,366	281,867	33,825	29,549	3,546	10.5%	244	2.95%	0.8%	29.2
Denmark	5,519	233,357	42,514	22,102	4,027	9.5%	131	7.14%	0.6%	23.7
Finland	5,327	184,179	34,705	15,453	2,912	8.4%	98	0.00%	0.6%	18.4
Ireland	4,298	181,816	42,780	15,895	3,740	8.7%	83	2.47%	0.5%	19.3
Luxemb.	475	39,348	83,541	2,461	5,225	6.3%				
EU-15	**391,488**	**11,291,985**		**1,106,083**	**2,840**	**9.80%**	**9,155**	**3.28%**	**0.8%**	**23.4**
Poland	38,153	295,566	7,754	20,729	544	7.0%	241	7.25%	1.2%	6.3
Romania	21,499	139,753	6,491	5,364	249	3.8%	52	-21.59%	1.0%	2.4
Czech Rep	10,271	139,887	13,632	9,951	970	7.1%	150	0.00%	1.5%	14.6
Hungary	10,021	95,290	9,496	6,936	691	7.3%	53	-2.62%	0.8%	5.3
Bulgaria	7,607	35,431	4,637	1,877	246	5.3%	74	4.23%	3.9%	9.7
Slovakia	5,397	67,221	12,464	5,263	976	7.8%	28	0.00%	0.5%	5.2
Lithuania	3,350	32,288	9,591	1,490	443	4.6%	25	4.17%	1.7%	7.5
Latvia	2,261	23,037	10,145	977	430	4.2%	24	0.00%	2.5%	10.6
Slovenia	2,020	37,135	18,429	3,093	1,535	8.3%	18	0.00%	0.6%	8.9
Estonia	1,340	16,073	11,986	983	733	6.1%	13	0.00%	1.3%	9.7
Cyprus	797	17,248	21,852	899	1,139	5.2%	3	0.00%	0.3%	3.8
Malta	414	5,744	13,998	419	1,021	7.3%				
EU-27 (EU-15 + new MS)	**494,617**	**12,196,656**		**1,164,065**	**2,363**	**9.5%**	**9,836**	**3.09%**	**0.8%**	**19.9**
Switzerland	7,742	358,933	46,932	38,504	5,034	10.7%	272	2.04%	0.7%	35.1
Norway	4,829	291,449	61,126	24,887	5,220	8.5%	87	-1.54%	0.3%	18.0
Iceland	319	8,674	27,191	788	2,469	9.1%				
Liechtenst.										
TOTAL (EU-27 + EFTA)	**507,507**	**12,855,712**		**1,228,243**	**2,430**	**9.6%**	**10,195**	**3.02%**	**0.8%**	**20.1**
Turkey	75,643	578,792	7,741	23,512	314	4.1%	250	0.40%	1.1%	3.3

Notes:

- The applied exchange rates are the 2009 annual average exchange rates published by Oanda (www.oanda.com). Applying a single exchange rate to both 2008 and 2009 sales data eliminates possible fluctuations of market size and market growth due to exchange variations.
- The data regarding population and healthcare expenditure come from the annual OECD report.
- UK data does not reflect the market share of companies that do not participate in EDMS.

About *In Vitro* Diagnostics:

In Vitro Diagnostics (IVDs) are non-invasive tests performed on biological samples to diagnose or exclude a disease. They are used for disease screening, monitoring therapy and to ensure the safety of the blood used in transfusions. IVDs have a broad scope ranging from sophisticated technologies performed in clinical laboratories to simple self-tests, such as for pregnancy.

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) tests in Europe. Through its membership, EDMA represents in total more than 500 companies (or 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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