

European **IVD** **Market** Statistics

Report 2013





OVERVIEW



The European Diagnostic Manufacturers Association, EDMA, is pleased to publish the market estimates of the In Vitro Diagnostic (IVD) industry in Europe, for the year 2013. The EDMA figures include macroeconomic and healthcare data for all 27 member states, as well as the European Free Trade Association (EFTA) members. For the first time, the report also includes figures from Turkey.

In vitro diagnostics (IVDs) are an essential part of today's healthcare. IVDs are used to diagnose, monitor screen and assess predispositions to diseases, thereby contributing to much of the available medical information regarding a patient. By allowing earlier and more targeted treatments. IVDs help to reduce hospitals stays and convalescences, resulting in a healthier population and economic growth in the long run.

The overall European IVD market followed the 2012 trend, decreasing for another consecutive year. However, the investment in IVDs was not as low as forecasted by EDMA last year. According the 2012 EDMA IVD Market Statistics report, the 2013 market was expected to continue a downward trend of -2.1% when actually was -0.6%. By the end of 2013, the IVD market revenue was €10.5 billion, accounting for 0.8% of the Total Healthcare Expenditure (THE) in Europe.

The IVD market showed signs of recovering from past years particularly in segments related to chronic diseases and genetics. The implementation of new IT procedures and the understanding of the role of IVDs in healthcare associated infections has also helped the market to grow.

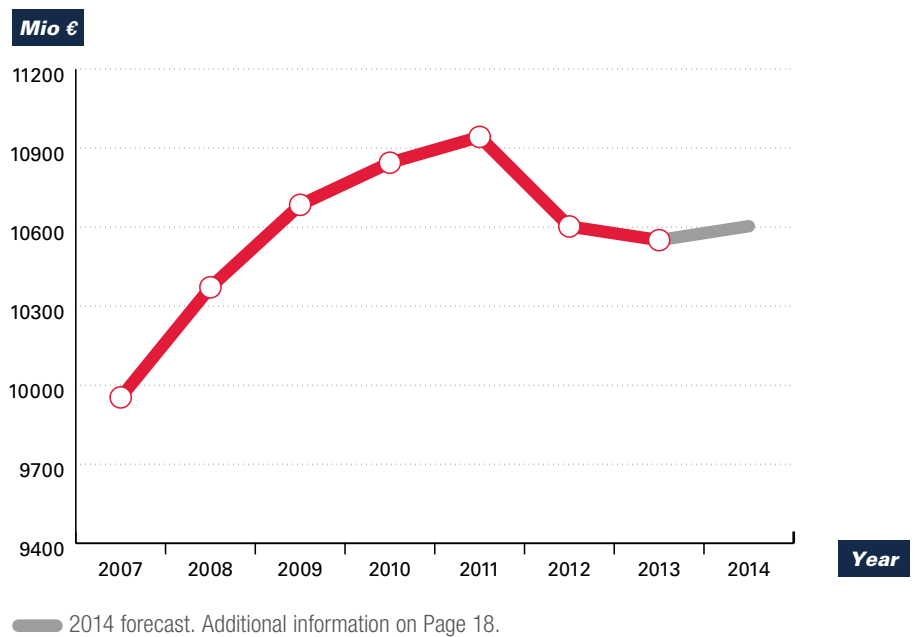
In 2013, the IVD market declined mainly due to governmental budgetary constrictions. This was particularly notable in countries such as Portugal, Greece, Italy and Spain, where the markets are also facing late payments issues. Furthermore, regulation restrictions on prescriptions of type II diabetes' strips, consolidation of laboratories and centralisation of tenders contributed to the reduced investment in IVDs.

OVERVIEW



In Germany, Belgium and Czech Republic, the IVD market was stagnant in 2013 as compared to previous years. On the other hand, in Poland, Switzerland and Turkey, IVD markets experienced growth rates in the range of 5% to 6%.

European IVD Market Revenues (million €)



The economic crisis continued to affect the general European IVD market in 2013. In Spain, Portugal, Italy, Greece, Sweden and Ireland it registered a 2.9% decline, causing a total of €102 million drop. Conversely, the IVD market had a positive growth in the new member states, which improved the situation of the market at the European level.

Combinations of governmental measures aimed at reducing expenses were implemented in most European countries during 2013. Despite the overwhelming benefits of IVDs in the context of cost-effective healthcare, strong price pressure by centralized tenders and exclusion of type II diabetes testing on public healthcare expenditure had a negative impact on the IVD market.

OVERVIEW

2013 Market Statistics

Countries	Population Thousands	GDP Mio €	GDP / capita €	THE Mio €	THE / capita €	THE as % GDP %	IVD mkt.2013 Mio €	IVD mkt.2012* Mio €	IVD mkt. growth rate 12-13 %	IVD mkt. / THE %	IVD mkt. / capita €
Source Eurostat 2012		Source WHO 2012					Source EDMA				
Germany	80,524	2,737,600	33,997	298,311	3,705	10.9%	2,159	2,159	0.0%	0.7%	26.8
France	65,579	2,059,852	31,410	238,459	3,636	11.6%	1,786	1,764	1.0%	0.7%	27.2
UK ¹	63,905	1,899,098	29,718	171,362	2,682	9.0%	784	790	-0.8%	0.5%	12.3
Italy	59,685	1,560,024	26,138	143,547	2,405	9.2%	1,660	1,694	-2.0%	1.2%	27.8
Spain	46,728	1,022,988	21,892	100,947	2,160	9.9%	971	1,017	-4.5%	1.0%	20.8
Netherlands	16,780	602,658	35,915	74,702	4,452	12.4%	309	309	0.0%	0.4%	18.4
Greece	11,063	182,054	16,456	17,963	1,624	9.9%	220	225	-2.2%	1.2%	19.9
Portugal	10,487	165,690	15,800	15,628	1,490	9.4%	216	226	-4.7%	1.4%	20.6
Belgium	11,162	382,692	34,285	40,677	3,644	10.6%	353	352	0.6%	0.9%	31.6
Sweden	9,556	420,849	44,040	39,527	4,136	9.4%	185	188	-1.4%	0.5%	19.3
Austria	8,452	313,067	37,041	35,533	4,204	11.3%	249	247	1.0%	0.7%	29.5
Denmark	5,603	248,974	44,436	27,325	4,877	11.0%	144	138	4.4%	0.5%	25.7
Finland	5,427	193,443	35,645	17,790	3,278	9.2%	105	103	1.9%	0.6%	19.3
Ireland	4,591	164,050	35,733	13,227	2,881	8.1%	131	135	-2.9%	1.0%	28.6
Luxembourg	537	45,478	81,749	3,044	5,669	6.7%	-	-	-	-	-
EU-15	400,079	11,998,517	29,990	1,238,042	3,094	10.3%	9,272	9,347	-0.9%	0.7%	23.1
Poland	38,533	389,695	10,113	25,578	664	6.6%	281	262	7.3%	1.1%	7.3
Romania	20,020	142,245	7,105	7,027	351	4.9%	93	86	8.0%	1.3%	4.6
Czech Rep	10,516	149,491	14,216	11,361	1,080	7.6%	143	143	0.0%	1.3%	13.6
Hungary	9,909	97,948	9,885	7,454	752	7.6%	61	59	3.4%	0.8%	6.1
Bulgaria ²	7,285	39,940	5,482	2,967	407	7.4%	32	30	6.7%	1.1%	4.4
Slovakia	5,411	72,134	13,331	5,577	1,031	7.7%	44	41	6.5%	0.8%	8.1
Lithuania	2,972	34,631	11,652	2,144	721	6.2%	27	25	8.0%	1.3%	9.1
Latvia	2,024	23,372	11,547	885	437	3.4%	23	25	-8.0%	2.6%	11.4
Slovenia	2,059	35,275	17,132	3,107	1,509	8.8%	33	35	-5.7%	1.1%	16
Estonia	1,320	18,435	13,966	1,010	765	5.5%	14	13	7.7%	1.4%	10.6
Cyprus	865	16,504	19,080	1,318	1,524	8.0%	2	3	-5.0%	0.2%	2.3
Malta	421	7,221	17,152	601	1,428	8.3%	2	2	0.0%	0.3%	4.8
New MS	101,335	1,026,891	10,134	69,029	681	6.7%	755	724	4.0%	1.1%	7.5
EU-27 (EU-15 + new MS)	501,414	13,025,408	25,977	1,307,071	2,607	10.3%	10,027	10,071	0.5%	0.8%	20
Switzerland ³	8,039	490,027	60,956	2,131	265	0.4%	345	356	2.9%	16.2%	42.9
Norway	5,051	385,747	76,370	33,708	6,674	8.7%	168	165	1.7%	0.5%	33.2
Iceland	322	11,000	34,161	958	2,975	8.7%	11	11	0.0%	1.1%	34.2
EFTA	13,412	886,774	66,118	36,797	2,744	4.2%	524	532	1.5%	1.4%	39.1
TOTAL (EU-27 + EFTA)	514,826	13,912,182	27,023	1,343,868	2,610	9.7%	10,551	10,603	-0.6%	0.8%	20.5
Turkey	75,627	616,345	8,150	35,419	468	5.7%	367	355	3.4%	1.0%	4.6
TOTAL (EU-27 + EFTA + Turkey)	590,453	14,528,527	24,606	1,379,287	2335.98	9.5%	10,918	10,958	-0.4%	0.8%	18.5

- The applied exchange rates are the 2013 annual average exchange rates published by Oanda (www.oanda.com). Applying a single exchange rate to both 2012 and 2013 sales data eliminates possible fluctuations of market size and market growth due to exchange variations.
- During the data collection of 2013 year's figures the 2012 market size was re-estimated at the same time. That, together with the use of a single exchange rate, explains why some countries show different revenues compared to the figures presented in last year's report for 2012. The growth rate between 2012 and 2013 has been calculated using the re-estimated figures.
- The data regarding population, GDP and healthcare expenditure are from the World Health Organisation (WHO).

1 UK data does not reflect the market share of companies which do not participate in GDMS but this is estimated to be no more than 5% of the total market.
 2 The Bulgarian IVD market was recalculated after having access to a more consistent data. This market was overestimation in previous year.
 3 Swiss data include Lichtenstein.

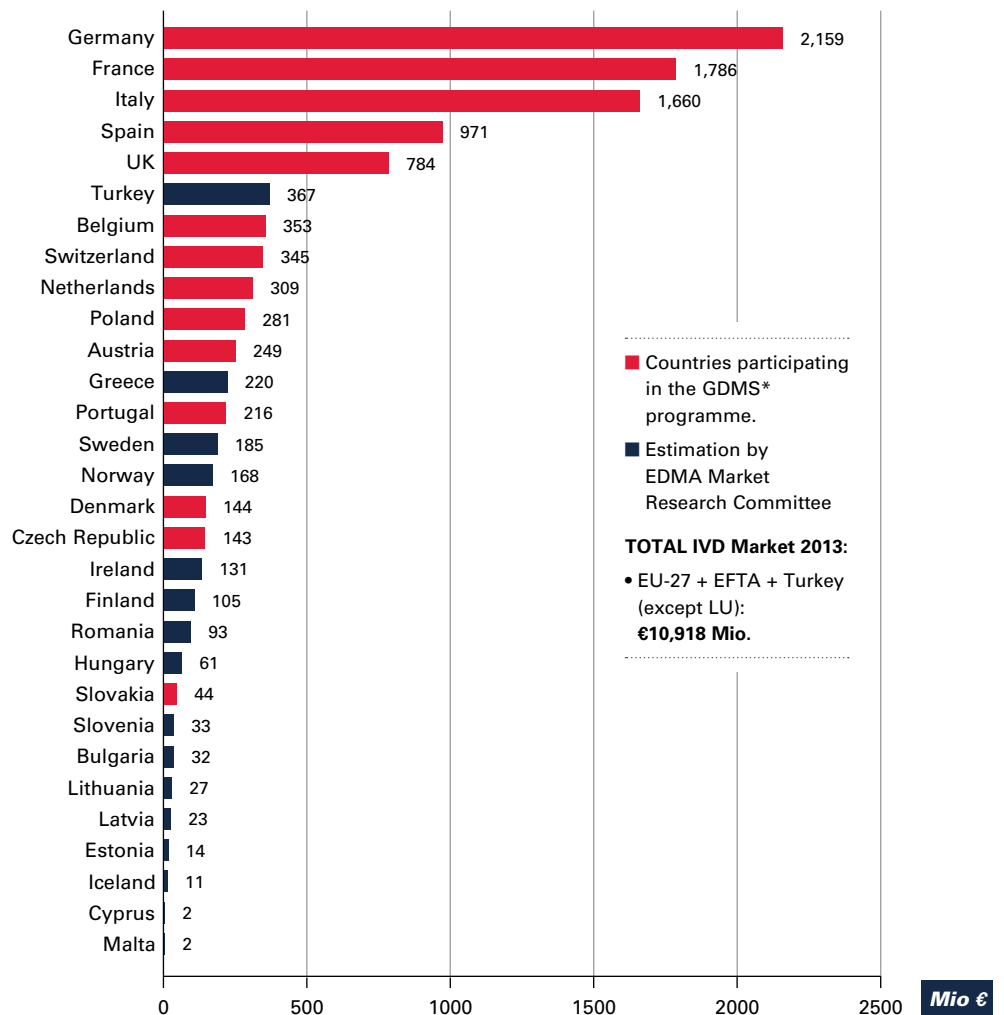
2013 EUROPEAN IVD MARKET



In 2013, IVDs experienced a decline (-0.5% compared to 2012) caused by the actions of healthcare cost containment. Spending review, the consolidation of procurement in central unified purchase with the effects of price cuts on new tenders and renewals, control over the testing volumes through the application of appropriateness criteria on clinical analysis, as well as a lower purchasing power of citizens limited the opportunities for development of the sector. In addition, the automation of the analytical process, specifically due to continued consolidation of laboratories, was concentrated in fewer sites. On the other hand, the payment of public facilities registered an improvement in the average Days Sales Outstanding (DSO).

The decline in prices can be seen specifically in areas such as haematology and blood count, infectious diseases (Hepatitis / HIV) and some immunochemical tests (thyroid etc.). The only test segment that experienced a slight increase in 2013 was microbiology.

European IVD Market 2013 (million €)



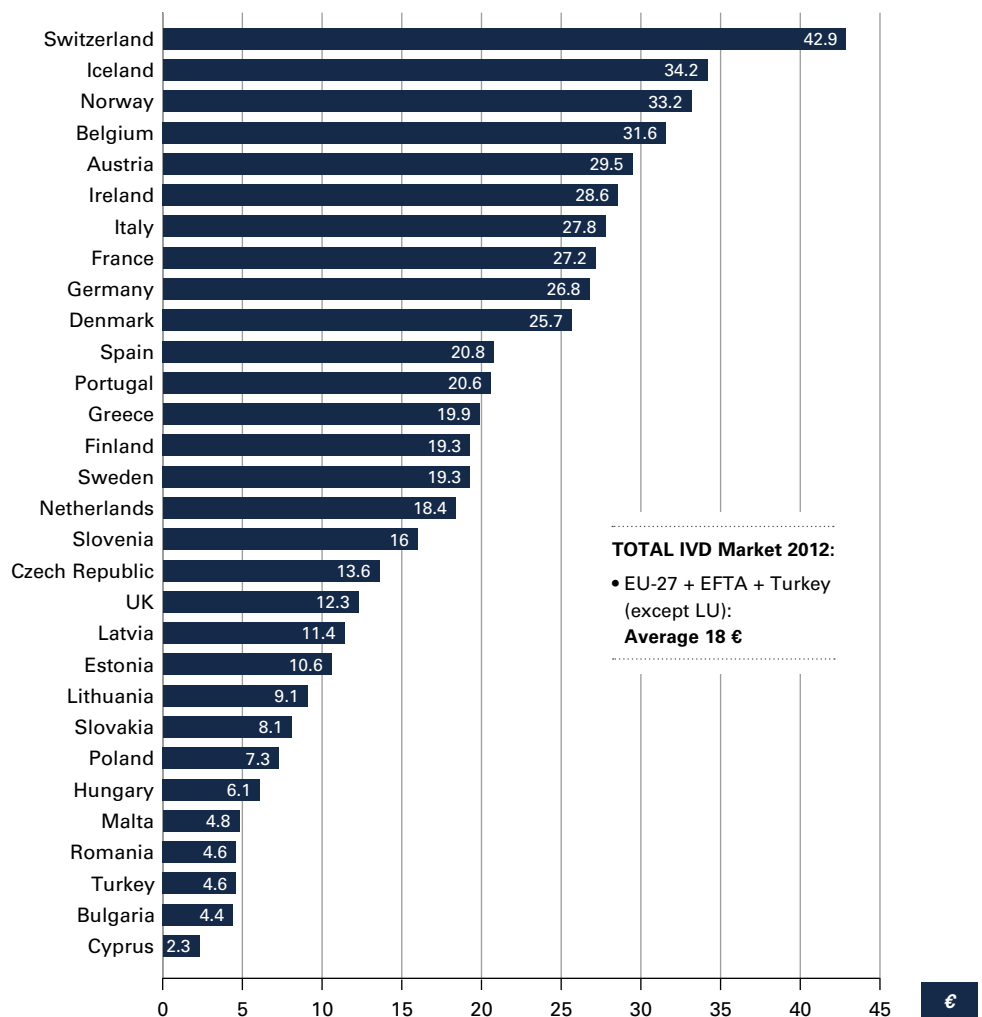
*GDMS = Global Diagnostic Market Statistics (formerly EDMS)

COUNTRY-SPECIFIC DATA

Variances in the IVD market are visible on a country-by-country basis. This is a reflection of not only the different levels of emphasis in individual public health programmes, but also of a lack of uniform reimbursement procedures. Patients from different European countries have unequal access to IVDs as the resources spent on IVDs differ significantly between different member states.

The economic crisis in Europe had an impact on the total healthcare expenditures and in turn on the access to IVDs. Most of the countries reduced the healthcare expenditure's budget particularly related to the type II diabetes testing segment. Discrepancies existent in Europe were maintained, from €2.3 to €42.9 per capita expenditure on IVD per annum [2013]. In Europe, an average of €18 is spent on IVDs per person, and this number includes Turkey. IVD market growths were observed in Romania and Lithuania (8%) followed by Estonia (7.7%) and Poland (7.3%).

IVD Per Capita (€)



GERMANY - FRANCE DATA

Germany

"After a small decrease in 2012, the IVD market was stagnant at €2 billion in 2013. The market slightly moved in a positive direction during the last quarter of 2013.

Positive results are also visible in other areas. The market for microbiology reagents reached respectable growth in 2013. An increase of 7.9% in 2013 was seen, due to the amendment of the German law for prevention of healthcare-associated infections, in conjunction with better reimbursement conditions for outpatient physicians.

Nevertheless, similar to previous years, growth trends differ within individual market segments. Laboratory diagnostics grew 1.8%, whereas the rapid test market decreased by 2.8%, specifically, glucose self-testing, which dominates the group, dropped 3% in 2013. Such decline was below average for generic providers.

The legal framework for IVDs continued to be restrictive in 2013. Patients with type-II-diabetes using oral anti-diabetic drugs were excluded from reimbursement by the statutory health insurance. In addition, physicians were forced to prescribe low-price test strips for insulin-dependent patients. Last but not least, a floating quota arrangement of laboratory service fees caused price-pressure effects on the market."

- VDGH, German IVD industry association



France

"For the second consecutive year, the turnover of the laboratory market, which was estimated at €1436 million in 2013, which represents 80% of total IVD market, declined 0.3% in comparison to 2012.

After a significant decline in market value in 2011 and 2012, related to the implementation of the regulation limiting the reimbursement of strips for type II diabetes in February 2011, the Diabetes Management Rapid Testing Market returned to growth.

These two tendencies resulted in the IVD market to remain more or less stagnant, with a market value estimated at €1786 million, with a slight increase of 1.2% compared to 2012 but still 0.1% under its 2011 level."

- SIDIV, French IVD industry association



THE: Total Healthcare Expenditure
GDP: Gross Domestic Product

UNITED KINGDOM DATA

United Kingdom

"2013 was the first year the overall reported market size decreased in the United Kingdom. The reduction in reagent revenues in absolute terms was very small except for clinical chemistry, rating -£18 million (-€21.2 million). Of this decrease, all except from £1m refers to rapid test and POC testing, predominantly blood glucose testing. This may reflect true market conditions, as attempts were made to control expenditure by restriction of testing for people, particularly those with type II diabetes. However, it may also reveal an increase in share of the market by non-participant companies, which is not estimated here.

In other market sectors, a much smaller percentage decrease occurred, apart from the cases of haematology (which, once again, grew a significant 8.5%), genetic testing (reporting a 21.95% growth) and infectious immunology (where revenue growth was roughly in line with inflation).

The UK government strongly supports the uptake of innovation within the National Healthcare Service, particularly where it can provide more cost-effective solutions, and other initiatives promoting early detection of disease and prevention of ill health. Likewise, a major element in the fight against the increasing antibiotic resistance is the control of antibiotic prescription. Yet, unfortunately, other arms of government continue to focus on the reduction of non-pay expenditure through indirect price control at the expense of some of these innovative solutions."

- BIVDA, British IVD industry association



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ITALY DATA

Italy

"Like in 2012, 2013 was negatively influenced by public provisions' yearly reduction on National Health Services expenditure: -4.4% less in 2013 than in 2012. In order to understand this trend, two main factors need to be considered.

First, the serious economic crisis affecting Italy and other industrialised western countries. Secondly, the latent problems that Italy has failed to address for decades, with the introduction of various measures between July 2011 and the present time as a response to the situation in the National Health Service (NHS).

There was a 5% reduction in the spending on outstanding contracts for goods and services in 2012, as well as a 10% spending cut in services and on medical devices based on the national funding of the NHS in 2013. Another measure aimed to incur savings was the determination of reference prices for some categories of medical devices, not covering IVDs. While the first two measures encompass all goods and services, placing an annual ceiling on such expenditures related specifically to all medical devices, making the various regions responsible. This influenced the acquisition of IVDs.

Furthermore the national medical formulary, describing ELA (Essential Level of Assistance), enforced a cut in the IVD prices of 35% causing a severe impact in the private segment within the NHS rule, with many small laboratories defaulting, and accelerating a further consolidation. The IVD market still addresses, mainly, public hospitals and laboratories, which represent 72.1% of the market. The implementation of co-payment on laboratory diagnosis for patients for a specified time, the so-called "ticket", is likely to have a negative impact on the number of IVDs tests. In the meantime, the reorganisation of laboratory networks hubs in the territory ('Lab Hubs'), and centralised bids reduced the number of laboratories also impacted the price dynamic.

Last but not least, fewer funds were allocated in 2013 as a consequence of late payments (over six months delay, on national average). The Italian public administration has now, however, recognised the serious situation faced by its creditors."

- Assobiomedica, Italian IVD industry association



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SPAIN - THE NETHERLANDS DATA

Spain

"During 2013, the Spanish IVD market was confronted with lack of both, capital investment and investment options in the areas of technical service sales, high DSO (Iberia 185 days average), testing protocol aimed to optimize demand control and market mix (70% public and 30% private). A remarkable market growth was registered in all testing associated with chronic diseases. Other growing markets were diabetes and metabolic disorders, and infectious immunology.

In other areas, the IVD market declined in 2013 over a flat test number evolution and suffered from very strong price pressure, related mainly to budget restrictions and aggregated purchasing. Between 2012 and 2015, the Spanish laboratory market aims to centralize. Up until now, tenders are being implemented in regions and apply for a period of eight years (maximum), which causes the mentioned high price pressure. Yet, such practice also represents cost reductions due to the length of tenders. This market environment is driven by price criterion.

In Spain, laboratory centralization is being executed at two levels. On the one hand, all healthcare institutions are working with core laboratories, integrating traditional IA/CC testing, microbiology laboratories and haematology laboratories. On the other hand, public healthcare has been operating via regional reference laboratories. As small-sized hospitals only have emergency laboratories, routine are being sent to core ones. This policy is intended to advance in 2013."

- FENIN, Spanish IVD industry association



The Netherlands

"Overall, the IVD market was stagnant in 2013. As a consequence of the ever-increasing financial pressure, there is an on-going consolidation of clinical centres in The Netherlands. This also makes the number of decision centres lower than ever before, with only 90 of them left. With the Value-Based Procurement scheme, there is a new trend within public tendering, where hospitals are not looking for a solution, but for a partner to achieve their goals instead."

- EDMA Market Research Committee



GREECE DATA

Greece

"In 2013, the Greek economy remained in recession for the sixth consecutive year, experiencing a 3.7% decrease that sums up to a cumulative depression reaching -22.5%. The Greek IVD market declined by 2.2% in 2013, and now stands at €220 million.

The private sector, accounting for, approximately, 30% of the national healthcare expenses, was also under a lot of pressure in 2013. Private healthcare providers experienced substantial losses in the form of claw backs and rebates towards Greece's state-owned health insurer, EOPYY. They are now attempting to pass these losses over to their suppliers.

On the other hand, DSO improved significantly in 2013, with 450 days at the end of the year versus 595 days in 2012. Still, these figures are very high in comparison to the rest of the European Union. The relevant legal framework has already been established, and both centralised and electronic procurement are expected to become of greater importance in the future.

In the public sector, which accounts for approximately 70% of the total IVD market, hospital operating expenses have been reduced by 42% during the last four years. The relevant closed budget for 2014 is 14% lower than 2013's expenses. At the same time, the healthcare budget of the state for 2014 is 18.9% lower than it was for 2013. Public procurement is dictated by the Observatory of Prices of the Medical Officer for Health (MOH), which keeps on pushing prices down regardless of technical specifications, volumes or methods."

- SEIV, Greek IVD industry association



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PORTUGAL DATA



Portugal

“During 2013, the IVD market continued to decline, -4.7% in comparison to -10.3% in 2012. This drop was mainly due to a widespread combination of prescription control and price erosion in all medical sectors. In addition, the government reduced the reimbursement of tests, which had a negative impact on reimbursement policies.

One of the most important and critical point continues to be late payments. Conversely, Portugal experienced an increase in payment terms last year. At the end of 2012, payments were delayed for 499 days, while 571 DSO were reported in 2013.

In the private sector, a strong consolation trend of laboratory centres was observed. Because several private laboratories closed in 2013, analyses were developed in fewer sites, as 25 laboratories had to cover the total number of tests for all patients.”

- APIFARMA, Portuguese IVD industry association



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BELGIUM DATA

Belgium

"In 2013, the IVD market grew by 0.6%. Reagents' growth was 1% whereas instruments or consumable sales were negative, in the range of 9% as compared to 2012. Like in other countries, microbiology sales growth was above 5% in Belgium.

Within the total national healthcare budget for 2013, IVD expenditures increased 0.50% more than in 2012; yet reimbursement dossiers are still on hold. Although there was no budget for innovation in 2013, it managed to stand still thanks to the postponement of the revision of the current nomenclature and silo budgeting, which shows a lack of transversal view on healthcare.

On the other hand, there was a noticeable increase in the power of purchasing departments in 2013, as well as in the degree of purchasing centralisation. Despite of the increase in expenditure, both centralisation and tenders were associated with decreasing price levels. As a consequence, this pressure led to transfer of responsibility from hospitals to companies in 2013.

In addition, reimbursement in the tickets for outpatient services was cut by 7.7%, which added a total saving of €32.6 million in 2013. Private laboratories were affected the most, and hospitals to a lesser extent.

In December 2013, the results of the market orientation regarding the Belgian reimbursement system were published. Diagnoses Related Group (DRG) systems of neighbouring countries were also reviewed, which created the basis for the next discussion round with all concerned parties. In 2014, the first proposals will be formulated in order to start trials in 2015. Additionally, since July 2013, the institutions were obliged to go for EU tendering if less than 50% of there is based on public funding. This included nearly all core laboratories' renewal projects.

It is, therefore, coherent to expect further consolidation. Likewise, there is an on-going rationalisation of resources in both the private and public Belgian sector."

- UNAMEC, Belgian IVD industry association



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DENMARK - FINLAND DATA

Denmark

"The Danish IVD marked increase of 4.4% in 2013, mainly influenced by the number of tests sold during the year."

In Denmark, there is a focus on consolidation, as several hospitals and regions are now merged together into bigger hospitals and core units. Nevertheless, the Danish market had an increased amount of large tenders even in a regional basis during 2013, which had negative consequences on pricing pressure. As a result, instruments were mostly sold as capital sales, and reagent purchase based on price-per-patient became more common than it used to be in previous years."

**- DiaLab, Danish IVD industry association,
including input from EDMA Market Research Committee**



Finland

"Private laboratory sector in Finland is quite small in comparison to other Nordic European countries, as services to clinicians are mainly produced by central laboratory networks that are owned by hospital districts. On-going healthcare structure reorganization will enlarge existing hospital districts in the future."

In 2013, the small Finish private sector faced competition from foreign companies providing laboratory services in Estonia. As a consequence, reactions and actions to competition changed, and Finland's interest on the eyes of global service providers might grow, depending on publicly owned laboratory networks."

For Finland, major laboratory networks plan tenders for the next two to three years. This will drive more centralised volumes, as well as price pressure associated with large, long-term contracts and higher levels of automation, including IT systems enabling regional usage of available resources in the laboratories. On a longer term, specifically three to five years, consolidation of laboratory networks will shut down smaller units of the networks, and volumes on core laboratories will grow significantly. This will allow both vendors and customers to operate more efficiently."

- EDMA Market Research Committee



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POLAND - ROMANIA - CZECH REPUBLIC DATA

Poland

"In 2013, the IVD market increased by 7%, which amounted to €281 million, mainly due to the high growth experienced by the blood glucose tests market. The market saw a 22% increase in 2013. This marked the recovery of the market after its huge drop in 2012 and had a very positive impact on both the total market figures and growth factor."

Nonetheless, the IVD market growth rate without glucose test was only 1.7% in 2013."

- IPDDL, Polish IVD industry association



Romania

"The national economic growth led to an increase in the Romanian IVD market, achieving 8% in 2013 versus 2012. The exchange rate remained stable during 2013."

- AFPM, Romanian IVD industry association



Czech Republic

"The Czech market remained flat in 2013 due to decline in the laboratories market of approximately 2%. Meanwhile, the blood glucose monitoring market experienced double digit growth."

- CZEDMA, Czech Republic IVD industry association



HUNGARY - SLOVAKIA - SLOVENIA DATA

Hungary

"The total IVD market grew by 3.4% in 2013. The most dynamic segments in Hungary included self-testing, especially glucose tests strips and instruments, with a 38% share of the total IVD market in 2013. It increased 23% in local currency, for which no limit has been yet applied for reimbursement.

However, the budget for the reimbursement of laboratory services has been frozen since 2002. The laboratory reagents and instruments' shares of the total IVD market declined in 2013. Additionally, laboratory tests required in treatment protocols were not performed due to the lack of funding. In other words, the permanent restriction generated unfulfilled demands.

Last but not least, the private laboratory service market with out-of-pocket payment with a 3% share in 2013 represented over 50% increase of the total market."

- HIVDA, Hungarian IVD industry association



Slovakia

"The Slovakian IVD market experienced an overall increase of over 6% in 2013, and it is expected to be on the same level in 2014. Nonetheless, an implementation of diagnosis-related group (DRG) systems is only expected by 2015."

- SEDMA, Slovakian IVD industry association



Slovenia

"Due to the economic situation, Slovenian IVD companies experienced big price pressures in 2013. On the other hand, public healthcare institutions either streamlined or decreased orders, in that order. Additionally, the diabetes market was even more affected due to a reduction in reimbursement by health insurance providers. These three trends explain the decrease experienced in the IVD market during 2013."

- SIEDMA, Slovenian IVD industry association



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SWITZERLAND - NORWAY DATA

Switzerland

"The total Swiss IVD market grew by 3.0% in 2013. This progress was especially remarkable in the fields of immunochemistry, microbiology and infectious immunology; allergology, proteins, endocrinology and autoimmune diseases.

Due to the existence of a large number of Physician Office Laboratories (POL) in Switzerland, the rapid test market represented around 30% of the total market."

- SVDI, Swiss IVD industry association



Norway

"Norwegian governmental hospitals were confronted with strong competition from private laboratories for IVD services in 2013, and seemed to lose customers resulting in test volume reductions. This trend is expected to continue if no action is taken from regional healthcare bodies. In the bigger health regions, the focus was on IT and how to optimise communication between the different regional bodies and their general practitioners. This was partly a consequence of the competition from Fürst Laboratory, providing high quality IT solutions. Effective and flexible middleware solutions will therefore be important for the future IVD market in Norway.

Although it did not reach Danish laboratories' consolidation levels, there was focus on consolidation in 2013 in Norway too. Having more focus on automation, even the smallest laboratories looked into laboratory automation and most of the medium-large tenders launched included automation.

On the other hand, high price pressure is impacting new tenders and dramatic drop of the IVD market value will probably be seen in the coming years. Otherwise, all university hospitals will maintain their own tenders in the future. Some smaller hospitals will be closed down or reduced and one-to-three new hospitals will be constructed during the next 10 years. Despite all the change in dynamics, the Norwegian IVD market is expected to grow 2% to 3%."

- EDMA Market Research Committee



TURKEY DATA

Turkey

"In 2013, Turkey experienced price erosion due to an increasing bargaining power, stemming from the consolidation of public hospitals under public hospital consortiums. Then, limited single-digit growth followed as a consequence of cost-containment measures on the healthcare sector. This was also reflected in hospital budgets and reimbursement tariffs of the social security institution, the main payer for public hospitals."

- Arted, Turkish IVD industry association



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2014 IVD Market Outlook



According to the EDMA Management Information System (MIS) programme, the first few months of 2014 have shown a slight improvement of approximately 0.5%. Such growth presents a small recovery due to bone markers. The laboratory segment has registered more than a 0.6% increase in the first semester of 2014, while the diabetes segment has decreased by 0.6%.

However, in the second half of the year, various public administrations faced progressive loss of funds. Additionally, price dynamics in tenders should not lead to substantial changes to the market. A slight progress could define 2015 due to the growing demand for automation and technological innovation, inclusion of some tests in the new NHS, economic recovery and other factors.

To learn more about the MIS programme, visit

<http://www.edma-ivd.eu/index.php?page=Market-Intelligence-Programmes>



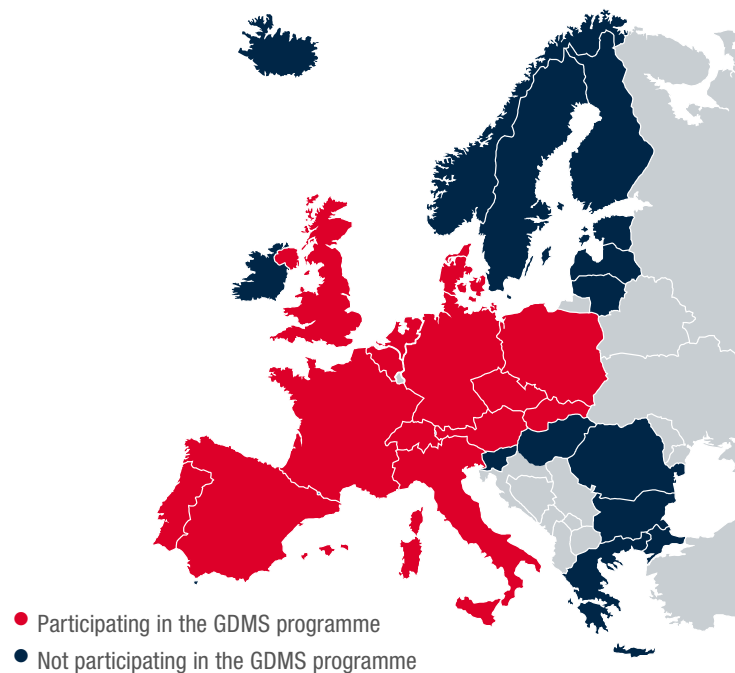
DATA GATHERING



The results presented above are based on individual estimates made for 26 EU countries and the EFTA countries:

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

14 countries participating in the Global Diagnostic Market Statistics (GDMS) programme



The EDMA figures per country are compiled from the Global Diagnostic Market Statistics (GDMS) programme, through which companies report invoiced sales of reagents, instruments and consumables to an independent auditor, CIP, as based on the Global IVD (former EDMA) Classification. This is done in association with the EDMA Market Research Committee and the National Association Members of EDMA.

More than 85% of the market is covered in major countries by GDMS, ensuring the reliability and objectiveness of the information provided by EDMA and its members. EDMA encourages all IVD suppliers and countries to participate in the GDMS programme, which is the largest in vitro diagnostic audit in Europe and the most accurate source of information for understanding and predicting market trends.



IN VITRO DIAGNOSTICS

About In Vitro Diagnostics

In vitro diagnostics (IVDs) are non-invasive tests performed on biological samples (for example blood, urine or tissues) to diagnose or exclude a disease. IVDs provide valuable information about how the body is functioning and the state of health. They are used for diagnosis, screening and therapeutic monitoring of diseases. IVDs have a broad scope ranging from sophisticated technologies performed in clinical laboratories to simple self-tests, such as those for pregnancy and glucose monitoring.

About EDMA

European Diagnostic Manufacturers Association (EDMA) is an international, non-profit organisation representing the interests of the medical in vitro diagnostics (IVD) industry in Europe. Its mission is to promote the value of IVDs in delivering sustainable and effective public health systems, and provide technical, regulatory and market research information to its members. The European IVD industry is a market worth around €11 billion. Driven by research and development, 95% of the industry is comprised of small and medium size enterprises and approximately 1 billion euros per year is reinvested in R&D. EDMA is a member of MedTech Europe, an alliance of European medical technology industry associations. For more information, visit www.edma-ivd.eu.

For more information

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