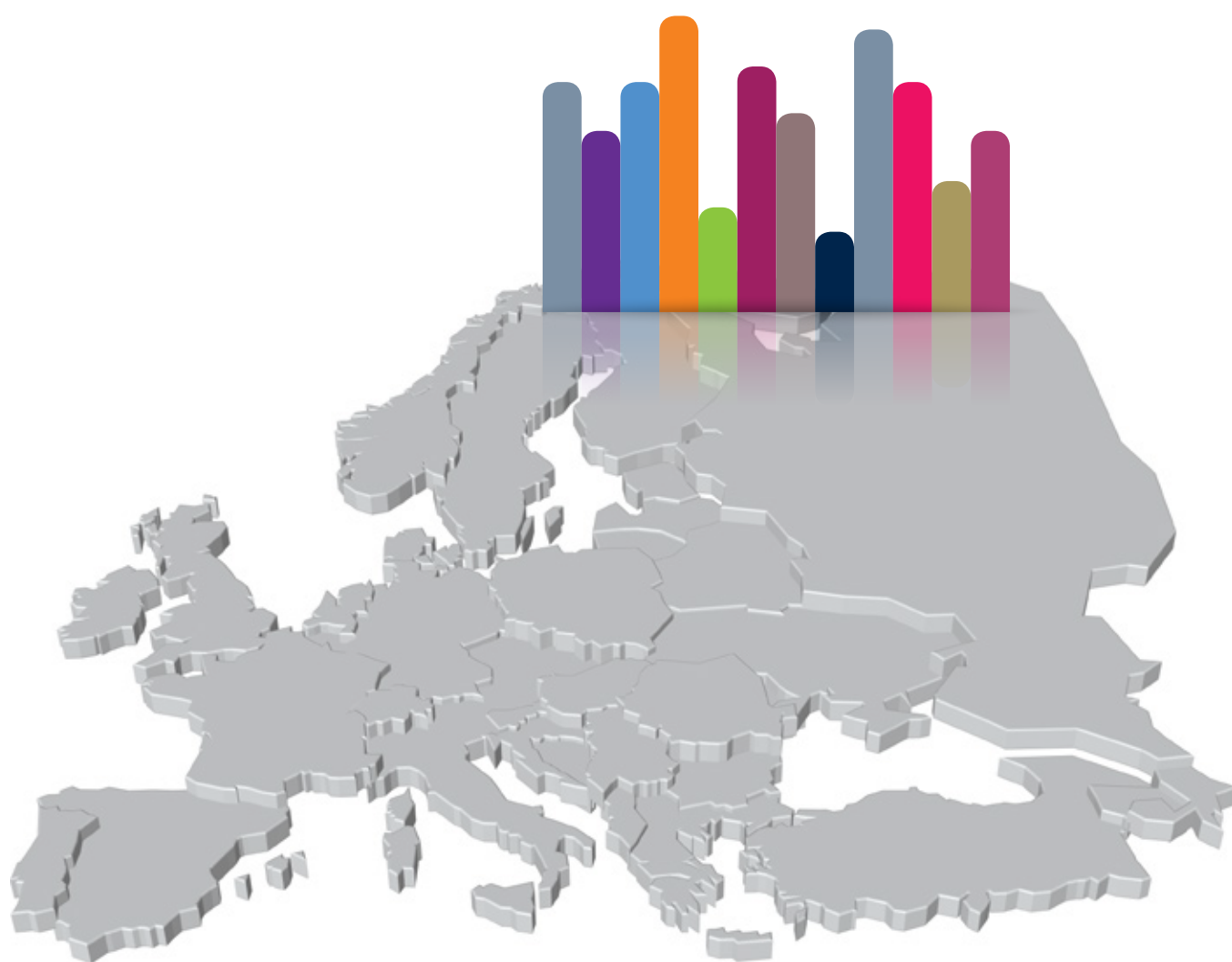


European IVD Market Statistics

Report 2012





OVERVIEW

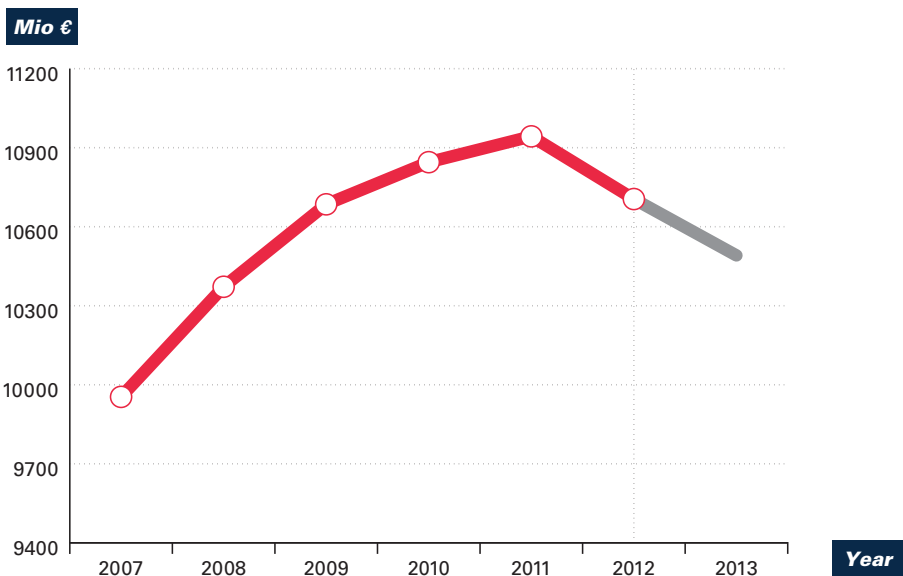


In vitro diagnostics (IVDs) are an essential part of today's healthcare. IVDs are used to diagnose, monitor, screen and assess predispositions to diseases, thereby contributing to much of the available medical information regarding a patient. By allowing earlier and more targeted treatments, IVDs help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

Despite the tremendous benefits that IVDs hold, in the wake of the economic downturn, the investment in IVDs has decreased. In 2012, the European IVD market decreased by 2.2%. The IVD market revenues of €10.7 billion only account for 0.8% of the total healthcare expenditure (THE) in Europe.

In this summary, the European Diagnostic Manufacturers Association (EDMA) presents market estimates of the In Vitro Diagnostic market in Europe for the year of 2012 as well as an outlook for 2013. The figures include macroeconomic and healthcare expenditure data of the 27 EU Member States of 2012, as well as of the European Free Trade Association (EFTA) members.

European IVD Market Revenues (million €)



The repercussions of the economic crisis affected the European IVD market, in particular Greece, Poland and Portugal, where double-digit declines were seen. Furthermore, the large IVD markets in Germany, France, Italy, and Spain showed negative growth. As these four countries comprise more than 60% of the European market, their decrease had a major impact on the overall decline of 2.2%. Already in 2011, the market had started to slow down and the revenue growth was only 0.9%. The previous 5 years saw growth of around 2-4% annually. Negative trends are likely to continue and for 2013 the European IVD market is expected to decrease around 2%.

OVERVIEW

2012 Market Statistics

Countries	Population	GDP	GDP / capita	THE	THE / capita	THE as % GDP	IVD mkt. 2012	IVD mkt.2011*	IVD mkt. growth rate 11-12	IVD mkt. / THE	IVD mkt. / capita
	Thousands	Mio €	€	Mio €	€	%	Mio €	Mio €	%	%	€
Source WHO 2011							Source EDMA				
Germany	81,779	2,592,600	31,703	286,787	3,507	11.1%	2,135	2,169	-1.6%	0.7%	26.1
France	65,176	1,996,583	30,634	232,172	3,562	11.6%	1,764	1,788	-1.3%	0.8%	27.1
UK*	62,735	1,869,841	29,805	174,260	2,778	9.3%	885	860	3.0%	0.5%	14.1
Italy	60,749	1,580,220	26,012	150,138	2,471	9.5%	1,691	1,731	-2.3%	1.1%	27.8
Spain	46,125	1,063,355	23,054	100,426	2,177	9.4%	1,009	1,071	-5.8%	1.0%	21.9
Netherlands	16,691	601,973	36,066	71,984	4,313	12.0%	309	319	-3.2%	0.4%	18.5
Greece	11,310	208,530	18,438	18,841	1,666	9.0%	225	250	-10.0%	1.2%	19.9
Portugal	10,651	170,928	16,048	17,703	1,662	10.4%	217	242	-10.3%	1.2%	20.4
Belgium	10,978	369,836	33,689	39,189	3,570	10.6%	352	340	3.5%	0.9%	32.1
Sweden	9,442	401,494	42,522	37,574	3,979	9.4%	188	200	-5.7%	0.5%	19.9
Austria	8,421	300,712	35,710	31,987	3,798	10.6%	247	246	0.3%	0.8%	29.3
Denmark	5,569	238,857	42,890	26,633	4,782	11.2%	138	136	1.4%	0.5%	24.8
Finland	5,388	189,368	35,146	16,765	3,112	8.9%	103	105	-1.6%	0.6%	19.1
Ireland	4,491	156,438	34,834	14,673	3,267	9.4%	135	135	0.0%	0.9%	30.1
Luxembourg	518	42,625	82,288	3,279	6,330	7.7%	-	-	-	-	-
EU-15	400,023	11,783,361	29,457	1,222,411	3,056	10.4%	9,399	9,591	-2.0%	0.8%	23.5
Poland	38,526	364,863	9,471	24,579	638	6.7%	263	309	-15.0%	1.1%	6.8
Romania	21,346	131,572	6,164	7,686	360	5.8%	86	80	7.3%	1.1%	4
Czech Rep	10,543	151,725	14,391	11,198	1,062	7.4%	150	165	-8.9%	1.3%	14.2
Hungary	9,974	97,439	9,769	7,549	757	7.7%	59	58	1.4%	0.8%	5.9
Bulgaria	7,459	38,540	5,167	2,801	376	7.3%	82	79	3.5%	2.9%	11
Slovakia	5,441	69,058	12,692	6,003	1,103	8.7%	41	44	-6.8%	0.7%	7.5
Lithuania	3,222	30,791	9,557	2,032	631	6.6%	25	25	1.0%	1.2%	7.8
Latvia	2,239	20,402	9,112	1,258	562	6.2%	25	25	0.5%	2.0%	11.1
Slovenia	2,053	36,172	17,619	3,276	1,596	9.1%	31	33	-5.0%	0.9%	15.1
Estonia	1,340	15,973	11,920	951	710	6.0%	13	13	2.0%	1.4%	9.7
Cyprus	862	17,761	20,604	1,317	1,528	7.4%	3	3	-1.0%	0.2%	3.5
Malta	419	6,544	15,618	572	1,365	8.7%	2	2	-1.0%	0.3%	4.8
EU-27 (EU-15 + new MS)	503,447	12,764,201	25,354	1,291,633	2,566	10.1%	10,179	10,427	-2.4%	0.8%	20.2
Switzerland*	7,869	486,931	61,880	52,893	6,722	10.9%	350	348	0.7%	0.7%	44.5
Norway	4,953	367,918	74,282	33,378	6,739	9.1%	165	157	5.0%	0.5%	33.3
Iceland	319	10,100	31,661	915.57135	2,870	9.1%	11	11	-1.0%	1.2%	34.5
TOTAL (EU-27 + EFTA)	516,588	13,629,149	26,383	1,378,819	2,669	10.1%	10,705	10,943	-2.2%	0.8%	20.7

* The applied exchange rates are the 2012 annual average exchange rates published by Oanda (www.oanda.com). Applying a single exchange rate to both 2011 and 2012 sales data eliminates possible fluctuations of market size and market growth due to exchange variations.

* During the data collection of 2012 year's figures the 2011 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 2011. The growth rate between 2011 and 2012 has been calculated using the re-estimated figures.

* The data regarding population, GDP and healthcare expenditure are from the World Health Organisation (WHO).

* 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.

* Swiss data include Lichtenstein.

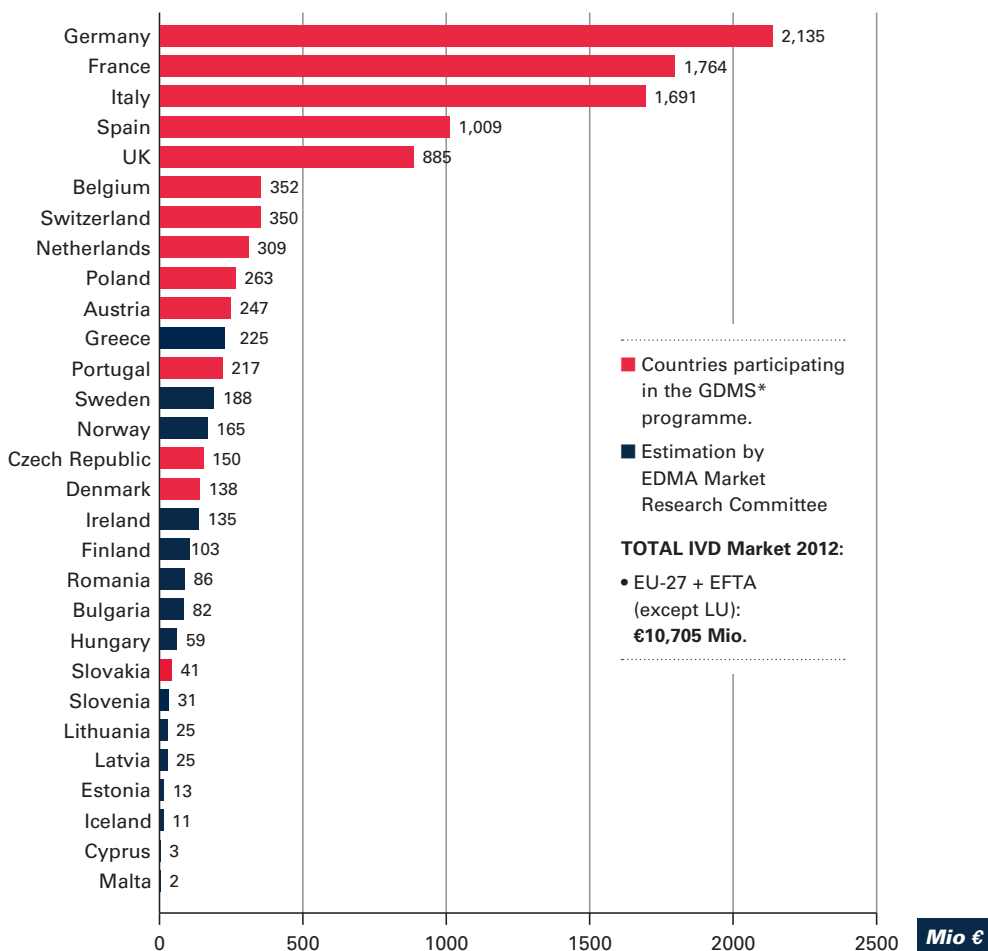


OVERVIEW



The reason for the weakened diagnostic market is primarily associated with the difficult market environment and the austerity measures put in place to contain healthcare costs. This has resulted in consolidation of laboratories, strong price pressures, and payment delays by healthcare authorities, actions that have all affected the IVD market negatively. Additionally, in several countries reimbursement regimes have been tightened. France, Germany, Hungary and Spain are few of the many countries where diabetic patients have received less refund for testing. This development not only challenges the health of European citizens, but may also lead to unequal healthcare, where only the most well-to-do patients will be able to access the best health services. In Germany, Greece, Hungary and Italy, out-of-pocket payments are also increasing.

European IVD Market 2012 (million €)



*GDMS = Global Diagnostic Market Statistics (formerly EDMS)

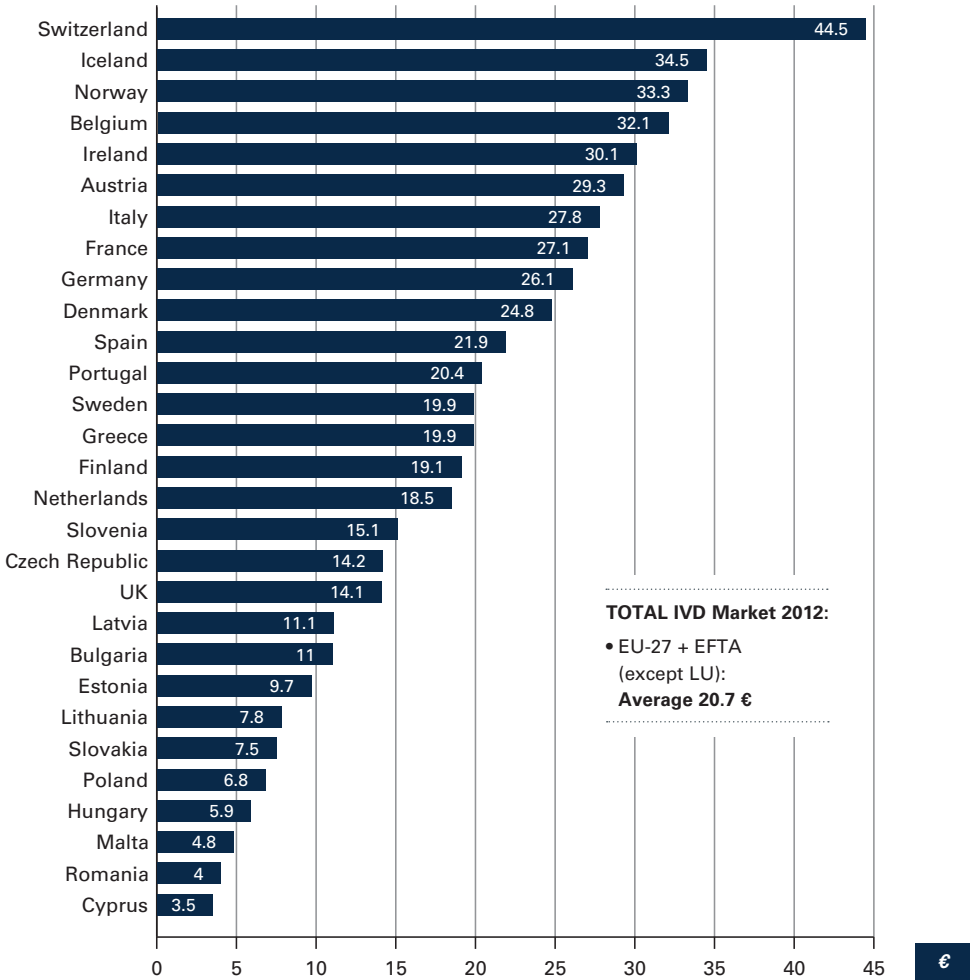


COUNTRY-SPECIFIC DATA



Europe is not a homogenous region and there are big discrepancies in the total healthcare expenditures as well as great differences in access to IVDs (from €3.5 to €44.5 per capita per annum). In Europe, on average €20.7 per person is spent on IVDs. Although Europe overall showed a negative growth rate, revenues grew compared to 2011 in some countries. The greatest market growths were observed in Romania (+7.3%), Norway (+5.0%), Belgium (+3.5%), Bulgaria (+3.5%) and the UK (+3.0%).

IVD Per Capita (€)





GERMANY - FRANCE DATA



Germany

In 2012, the German IVD market dropped 1.6% compared to 2011. Despite this, Germany was able to maintain its position as the country with the largest European IVD market, in part due to having the largest population.

As in previous years, trends varied between the different market segments. Laboratory diagnostics grew by 2.8% in contrast to the rapid test market, which decreased by 7.3%. Glucose self-testing, which dominates the rapid test market, dropped by 8.1%. Germany's legal framework continues to be restrictive. Patients with type-2-diabetes using oral anti-diabetic drugs are excluded from reimbursement by their statutory health insurance. In addition, medical doctors are forced to prescribe low-price test strips for insulin-dependent patients. Positive results were visible for the microbiology market. The growth of 6.5% in 2012 was stimulated by the amendment of the German law for preventing healthcare associated infections.



France

After a decrease of 0.4% in 2011, the unfavourable economic environment affected the total French IVD market negatively, which showed a decline of 1.3% in 2012.

The laboratory market decreased by 0.3%, largely due to significant reduction in IVD sell prices that can be further explained by two reasons. First, there has been an on-going policy of reducing healthcare costs in France for several years; in particular, reimbursement rates for IVDs have been reduced. In private laboratories, for example, the reimbursement of clinical biology expenses has decreased 1.3% in 2012 (compared to a growth of 2.1% in 2011), while the volume of prescriptions has increased by 3.4%. Second, the laboratory consolidation that has been on-going since the implementation of the French reform of clinical biology in 2010 has had an impact on the price reduction.

The decline of 5.5% in the glucose self-testing market is linked to the limitation in reimbursement of glucose test strips for diabetes type 2 that was implemented in 2011, and has continued to affect the market in 2012.

The French Law on Strengthening of Health Protection for Medicinal and Health Products ("Loi RSS") was published on 29 December 2011. It aims to reinforce transparency within the healthcare sector. A decree (No 2012-744, published on 9 May 2012) specific to IVDs outlined rules for all types of advertisement (including via the Internet) that target the general public or healthcare professionals. To increase the transparency further in May 2013, the French government released a decree ("The French Sunshine Act") that requires companies to publicly announce any benefits and gifts granted exceeding €10 settled with healthcare professionals or other actors in the French healthcare sector.



THE: Total Healthcare Expenditure
GDP: Gross Domestic Product



ITALY - SPAIN DATA



Italy

The second half of 2012 was influenced by the impact of the public Healthcare Budget 2012-2014 on Medical Devices and Related Provisions (Stability Law 2013). The government has responded to the situation in the health service by introducing various measures between July 2011 and the present time. State funding will be reduced by €14 billion over the three-year period between 2012-2014, including around €8.5 billion (about 0.5% of GDP) in 2014. Assobiomedica, the Italian trade association for IVDs, estimates that the budget manoeuvre could reduce state spending on IVDs and other medical devices by 33% over the period. The imposed measurements already influenced the 2012 IVD market negatively, which showed a decline of 2.3% compared to 2011.

In 2012, the situation of late payments was still critical, although the Italian government is considering possible solutions to resolve the problem. The Decree no. 35 on "Paying the Debts of the Public Administration" was converted into a law (Law no. 64, dated 6 June 2013), that applies to those debts of the public administration accumulated up to 31 December 2012 due for payment. Although the public administration has recognised the serious situation faced by its creditors, doubts remain whether the measures implemented can solve the problem. Firstly, because of the limited funding made available (€14 billion over two years, against a health sector debt of more than €40 billion) and, secondly, because of the possible difficulties to comply with the deadlines set by the decree. These measures cannot be expected to result in drastic reductions in payment times, which in Italy still remain among the longest in Europe.



Spain

In 2012, Spain was still in a deep crisis and exposed to an uncertain economic environment. The unfavourable situation affected the IVD market, which fell by 5.8% compared to 2011.

There are serious budgetary restrictions in Spanish health provision and the IVD market is suffering strong price pressure. The practice of "aggregated purchasing" by autonomous regions is used as a tool to keep prices low, and has become a general rule for IVD procurement. The long tender procedures of about 3 or 4 years contribute to the static market. Additionally, as laboratories are becoming bigger and bigger, there is an increased market demand for laboratory automation, which makes it expensive for laboratory suppliers to fulfil tender requirements. Another challenge for the Spanish IVD industry is late payments. Payment delays recovered the first half of the year, but after a disappointing evolution in the second semester, the average delay has reached almost 300 days. The situation in Spain has put pressure on the patients as well: diabetic patients, for example, have experienced a tight control of number of tests and POCT monitoring.



THE: Total Healthcare Expenditure
GDP: Gross Domestic Product



UK - BELGIUM DATA



United Kingdom

The total IVD market has grown by 3.0% in 2012, which is level in real terms. The National Health Service (NHS) target remains to reduce the pathology laboratory budget by £500m. With the switch from commissioning of health services by Primary Care Trusts to Clinical Commissioning Groups (mainly GP-led) by 1 April 2013, there may be shifts in pathology service commissioning once these new bodies become more established. However the main dynamics in the market are currently being determined by the continuing consolidation of laboratory provision and tendering of pathology services. The author of the Carter Report (Lord Carter of Coles), which recommended these changes, recently expressed disappointment at their slow progress.

Private sector involvement continues to increase slowly. No change to the block contract commissioning is yet envisaged, so pathology testing continues to be a budgeted cost rather than a price-per-test related reimbursable service. Although "demand management" is much discussed to try to relieve pressure on stretched resources, it is obvious that the savings demanded can only be achieved by reductions in staff and overhead costs, not by reduced testing. The hope remains that the new commissioning organisations will be able to overcome some of the barriers to introduction of innovative diagnostic tests caused by "silo budgeting" and reach the savings and efficiencies in healthcare pathways with the help of an effective use of IVD tests.



Belgium

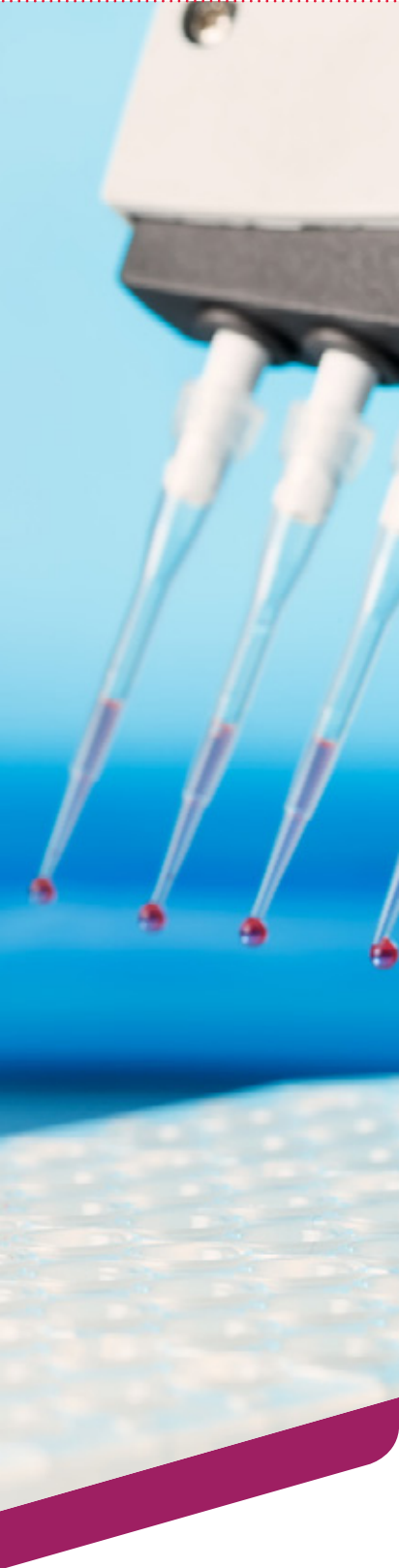
In 2012, the Belgian IVD market grew by 3.5% (reagents revenues increased by 2.9%). The government planned major savings through changes in reimbursement and an awareness campaign. However, these savings have only been partially realised. Since 1 August 2012 there is no longer reimbursement for screening of prostate cancer. The decision is partly based on the conclusions of the US Preventive Services Task Force (USPSTF) and is expected to have a budgetary impact of €2 million. Additionally, there is no budget for innovation. As for other European countries, there is a trend of consolidation of laboratories. Furthermore, international private hospitals and lab chains are acquiring private Belgian laboratories.



THE: Total Healthcare Expenditure
GDP: Gross Domestic Product



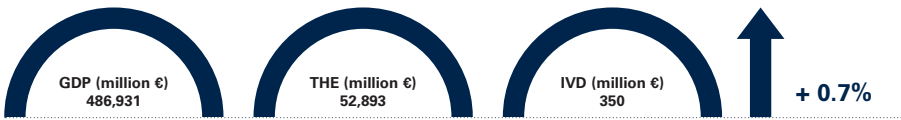
SWITZERLAND - POLAND DATA



Switzerland

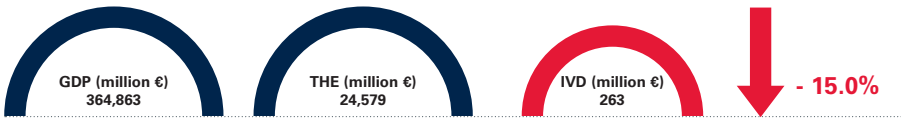
In 2012, market growth was low (0.7%). Price erosion and the implementation of the Diagnosis-related group (DRG) 1 January partly explain the market development. The DRG, which classifies hospital cases into different groups for reimbursement purposes, is expected to promote transparency and efficiency, in addition to controlling healthcare costs.

Moreover, the highly decentralised healthcare sector in Switzerland – with too many small acute care/primary care hospitals – is costly and inefficient from a medical viewpoint, as well as challenging for the IVD industry. There is a consolidation process underway, mainly at the cantonal level. However, due to political sensitiveness, it has been very slow.



Poland

There were two opposing forces acting on the IVD market in Poland in 2012: while the laboratory market increased by 6.6%, the reimbursed market for glucose test strips decreased by 42%. The total IVD market, as a result, fell by 15% in 2012. The large decline in the reimbursed market was connected to the altered reimbursement scheme of glucose test strips that was implemented in January 2012. The decrease was expected to be exceptionally high in 2012, as there was an unusual increase (+19%) in the last quarter of 2011 before the new reimbursement came into effect.



THE: Total Healthcare Expenditure
GDP: Gross Domestic Product



GREECE DATA

Greece

The recession in Greece reached 6.4% in 2012, exceeding 21% in total in five years, while the IVD market dropped by 10% compared to 2011.

In 2012, instead of receiving payments for supplies provided to public hospitals (as far back as 2007, equalling 1400 days), IVD manufacturers experienced a drastic cutback in the state bonds they had received. Additionally, all interest accumulated on the outstanding debt was forced to be waived, resulting in an actual loss of 80% of the face value for the suppliers. Nevertheless, the suppliers had already paid VAT to the State on the entire amount that was originally invoiced, which was never returned to them. This had a huge impact on the liquidity of companies, especially as the bonds were utilized as collateral to ensure access to credit.

Further reduction of public health expenditure and spending on IVDs remained a central political objective in 2012. Although the main criterion for the procurement of IVDs has always been the lowest price, the Observatory of Prices was used through 2012 as a price-control mechanism to set price caps regardless of technical specifications, volumes, method, reagent rental on tenders and contracts. This cost-containing mechanism has even been applied retrospectively, for invoices issued as back as in 2010. At the same time, the bad practice of late payment continues (average 595 days sales outstanding at the end of December 2012).

In the future, centralised procurement and e-procurement are expected to become more important, and the relevant legal framework has already been established to this end. Public hospital mergers are also ongoing, with an aim to reduce their number from 131 to 80. This has led to layoffs and a 30% reduction in the number of public hospital beds. The recession has also taken its toll on the private healthcare sector, where financial constraints have resulted in less investment and increased price pressure.



THE: Total Healthcare Expenditure
GDP: Gross Domestic Product

PORTUGAL - ROMANIA - HUNGARY DATA



Portugal

In Portugal, the government has issued economic restrictions for the healthcare sector, including a reduction in the number of reimbursed tests, and prescription control through the introduction of electronic prescriptions (end of 2011). These measures, combined with the increased consolidation of laboratories and price pressure, resulted in a 10.3% drop of the Portuguese IVD market in 2012 and means that the market has fallen around 20% the last three years (2010-2012).

Just as in other countries in southern Europe, a major issue for the IVD industry is late payments. Although there was a decrease by 25% in 2012 (in comparison with end 2011) the days sales outstanding continues to be high (499 days).



Romania

Although there is a tremendous pressure to decrease healthcare expenditure in Romania, the IVD revenue grew by 7.3% in 2012. One explanation for this may be an increased focus on prevention over treatment. Other developments seen in Romania are patients' growing preference for private laboratories, and that laboratories are favouring brands with a strong reputation.



Hungary

The budget for the reimbursement of laboratory services has been frozen since 2002. The share of reagents in the cost structure of laboratories is declining. The most dynamic segments include self-testing, especially glucose test strips (up 15%) for which no cap has been applied for reimbursement, and the private laboratory service, paid out of pocket, where the increase was 110%. In total, the Hungarian IVD market grew by 1.4% in 2012.



THE: Total Healthcare Expenditure
GDP: Gross Domestic Product



2013 IVD Outlook



According to the IVD industry flash report – the Management Information System (MIS) - the European IVD market will come out with a negative figure for 2013. Until September 2013, the revenue decline was -2.1% when compared to 2012. The largest market declines are observed in Finland, Greece, Portugal, Slovenia and Spain. Its important to note that large IVD countries, including Germany, Italy and the UK are experiencing a downturn in the market. The largest revenue growths are seen in the Czech Republic and Poland.

To learn more about the MIS programme, visit

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

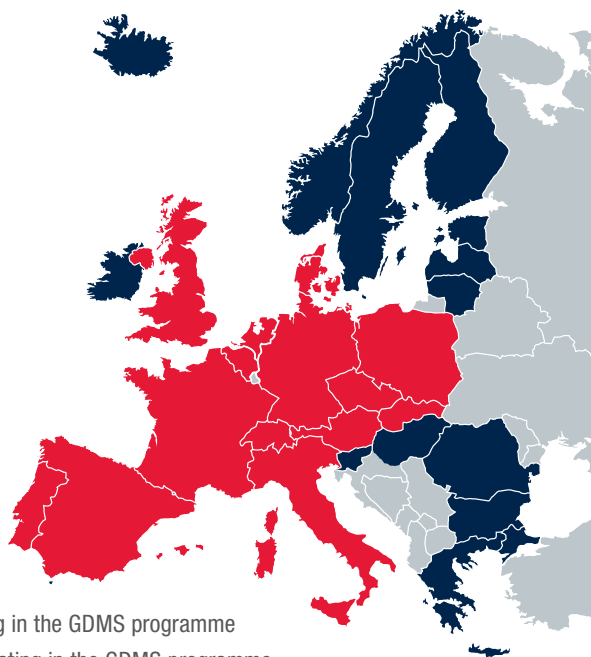


DATA GATHERING

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



- Participating in the GDMS programme
- Not participating in the 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.

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DIAGNOSTICS FOR HEALTH