

EUROPEAN IVD MARKET STATISTICS

REPORT 2015

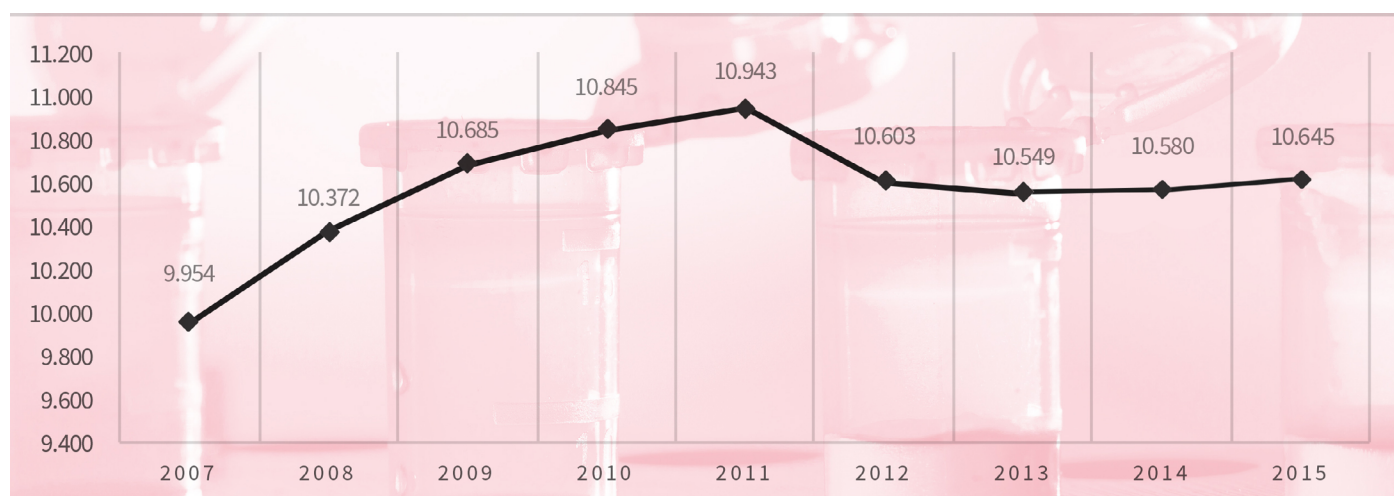


OVERVIEW

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 2015. The EDMA figures include macroeconomic and healthcare data for all 28 member states, including for the first time data for Croatia, as well as the European Free Trade Association (EFTA) members. As in the 2014 report, data from Turkey are included.

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 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, reduced costs and economic growth in the long run.

Despite stagnating or decreasing revenues in four of the five largest European IVD markets (Germany being the exception), overall revenues across EU-28 plus EFTA increased by +0,6% to €10,645 million. However, this remains below the revenues recorded in 2009 (€10,685).



While the IVD revenues in Germany stagnated overall, modest growth was seen. Germany is the only large market to experience growth of +1%, modest growth was seen in both microbiology +2,2% and immunochemistry +2,5%. From the largest five markets, UK is experiencing the highest decrease of -2,9%, due to reduced reagent revenues mainly in Clinical Chemistry rapid test and POC. In Italy the IVD market dropped with -1.3% compared to 2014. After decreasing the previous three consecutive years, in 2015 the French IVD market is in stagnation with a tiny growth of +0,1%.

As in previous years, the continuing economic crises in Greece and Spain saw decreases of -6,1% and -1,6%. On the contrary, Portugal, which also suffered economic turmoil, showed a +4,4 increase in IVD expenditure.

In the newer EU member states, IVD expenditure averages 1,2% of total healthcare expenditure (THE) significantly higher than the 0,7% seen in older member states (EU-15), but in absolute terms the new member states spend only €9 per capita compared to €22,5 in the EU-15. Growth in the newer states at +6.6% compares to a decline of -0,1% in the EU-15 states.

OVERVIEW

| Countries | Population | GDP | GDP / capita | THE | THE / capita | THE as % GDP | IVD mkt. 2015 | IVD mkt. 2014* | IVD mkt. growth rate 15-14 | IVD mkt. / THE | IVD mkt. / capita |
|--------------------------------------|-----------------|-------------------|---------------|------------------|--------------|--------------|---------------|----------------|----------------------------|----------------|-------------------|
| | 1000 | Mio € | € | Mio € | € | % | Mio € | Mio € | % | % | € |
| | Source WHO 2014 | | | | | | Source EDMA | | | | |
| Germany | 80.767 | 2.915.650 | 36.100 | 329.381 | 4.078 | 11,3% | 2.226 | 2.204 | 1,0% | 0,7% | 27,6 |
| France ¹ | 65.835 | 2.132.449 | 32.391 | 246.074 | 3.738 | 11,5% | 1.418 | 1.416 | 0,1% | 0,6% | 21,5 |
| UK ² | 64.351 | 2.007.561 | 31.197 | 182.999 | 2.844 | 9,1% | 859 | 885 | -2,9% | 0,5% | 13,3 |
| Italy | 60.782 | 1.613.859 | 26.552 | 149.248 | 2.455 | 9,2% | 1.635 | 1.656 | -1,3% | 1,1% | 26,9 |
| Spain | 46.512 | 1.032.044 | 22.189 | 93.192 | 2.004 | 9,0% | 982 | 998 | -1,6% | 1,1% | 21,1 |
| Netherlands | 16.829 | 662.770 | 39.383 | 72.224 | 4.292 | 10,9% | 291 | 297 | -2,0% | 0,4% | 17,3 |
| Greece | 10.903 | 177.559 | 16.285 | 14.354 | 1.317 | 8,1% | 186 | 198 | -6,1% | 1,3% | 17,1 |
| Portugal | 10.427 | 173.446 | 16.634 | 16.479 | 1.580 | 9,5% | 235 | 225 | 4,4% | 1,4% | 22,5 |
| Belgium | 11.203 | 389.262 | 34.746 | 41.241 | 3.681 | 10,6% | 375 | 364 | 3,1% | 0,9% | 33,5 |
| Sweden | 9.644 | 403.245 | 41.813 | 48.107 | 4.988 | 11,9% | 194 | 191 | 1,6% | 0,4% | 20,1 |
| Austria | 8.506 | 319.289 | 37.537 | 35.778 | 4.206 | 11,2% | 256 | 254 | 0,8% | 0,7% | 30,1 |
| Denmark | 5.617 | 253.141 | 45.067 | 23.615 | 4.204 | 9,3% | 150 | 145 | 4,0% | 0,6% | 26,8 |
| Finland | 5.451 | 195.766 | 35.914 | 18.950 | 3.476 | 9,7% | 112 | 107 | 4,8% | 0,6% | 20,6 |
| Ireland | 4.605 | 189.046 | 41.052 | 14.714 | 3.195 | 7,8% | 105 | 95 | 11,0% | 0,7% | 22,9 |
| Luxembourg | 549 | 48.535 | 88.406 | 3.367 | 6.134 | 6,9% | 19 | 15 | 28,8% | 0,6% | 34,2 |
| EU-15 | 401.981 | 12.513.623 | 31.130 | 1.289.724 | 3.208 | 10,4% | 9.044 | 9.049 | -0,1% | 0,7% | 22,5 |
| Poland | 38.017 | 411.036 | 10.812 | 26.102 | 687 | 6,4% | 322 | 303 | 6,3% | 1,2% | 8,5 |
| Romania | 19.947 | 150.138 | 7.527 | 8.355 | 419 | 5,6% | 120 | 100 | 20,0% | 1,4% | 6,0 |
| Czech Rep | 10.512 | 148.554 | 14.132 | 11.009 | 1.047 | 7,4% | 154 | 150 | 2,5% | 1,4% | 14,6 |
| Hungary | 9.877 | 102.975 | 10.426 | 7.621 | 772 | 7,4% | 69 | 59 | 16,9% | 0,9% | 7,0 |
| Bulgaria | 7.245 | 42.718 | 5.896 | 3.607 | 498 | 8,4% | 28 | 30 | -7,0% | 0,8% | 3,9 |
| Slovakia | 5.415 | 73.724 | 13.615 | 5.938 | 1.097 | 8,1% | 75 | 72 | 4,2% | 1,3% | 13,9 |
| Croatia | 4.246 | 43.123 | 10.156 | 3.365 | 793 | 7,8% | 57 | 56 | 1,5% | 1,7% | 13,4 |
| Lithuania | 2.943 | 35.970 | 12.222 | 2.357 | 801 | 6,6% | 29 | 26 | 11,0% | 1,2% | 9,8 |
| Latvia | 2.001 | 23.581 | 11.785 | 1.387 | 693 | 5,9% | 23 | 24 | -3,0% | 1,7% | 11,6 |
| Slovenia | 2.061 | 36.351 | 17.637 | 3.357 | 1.629 | 9,2% | 48 | 47 | 0,6% | 1,2% | 23,0 |
| Estonia | 1.315 | 19.395 | 14.749 | 1.237 | 941 | 6,4% | 16 | 15 | 10,0% | 1,3% | 12,4 |
| Cyprus | 858 | 15.946 | 18.585 | 1.175 | 1.369 | 7,4% | 2 | 2 | 0,0% | 0,2% | 2,3 |
| Malta | 425 | 8.106 | 19.073 | 790 | 1.860 | 9,7% | 5 | 5 | 0,0% | 0,6% | 11,8 |
| New MS | 104.862 | 1.111.615 | 10.601 | 76.299 | 728 | 7% | 948 | 889 | 6,6% | 1,2% | 9,0 |
| EU-28 (EU-15 + new MS) | 506.843 | 13.625.238 | 26.883 | 1.366.023 | 2.695 | 10,0% | 9.991 | 9.938 | 0,5% | 0,7% | 19,7 |
| Switzerland | 8.139 | 510.128 | 62.677 | 59.477 | 7.308 | 11,7% | 467 | 460 | 1,4% | 0,6% | 57,4 |
| Norway | 5.107 | 352.944 | 69.110 | 34.305 | 6.717 | 9,7% | 176 | 171 | 3,0% | 0,5% | 34,5 |
| Iceland | 325 | 13.527 | 41.621 | 1.198 | 3.687 | 8,9% | 11 | 11 | 0,0% | 0,9% | 33,8 |
| EFTA | 13.571 | 876.599 | 64.594 | 94.981 | 6.999 | 10,8% | 654 | 642 | 1,9% | 0,7% | 48 |
| TOTAL (EU-28 + EFTA) | 520.414 | 14.501.837 | 27.866 | 1.461.004 | 2.807 | 10,1% | 10.645 | 10.580 | 0,6% | 0,7% | 20,5 |
| Turkey ³ | 76.667 | 581.803 | 7.589 | 31.504 | 411 | 5,4% | 402 | 390 | 3,1% | 1,3% | 5,2 |
| TOTAL (EU-28 + EFTA + Turkey) | 597.081 | 15.083.640 | 25.262 | 1.492.508 | 2.500 | 9,9% | 11.047 | 10.970 | 0,7% | 0,7% | 18,5 |

- The applied exchange rates are the 2015 annual average exchange rates published by Oanda (www.oanda.com). Applying a single exchange rate to both 2014 and 2015 sales data eliminates possible fluctuations of market size and market growth due to exchange variations.
- During the data collection of 2015 year's figures the 2014 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 2014. The growth rate between 2014 and 2015 has been calculated using the re-estimated figures.
- The data regarding population, GDP and healthcare expenditure are the latest available from the World Health Organisation (WHO).

1 France data includes only the Central Laboratory IVD Market.

2 UK data does not reflect the market share of companies which do not participate in GDMS.

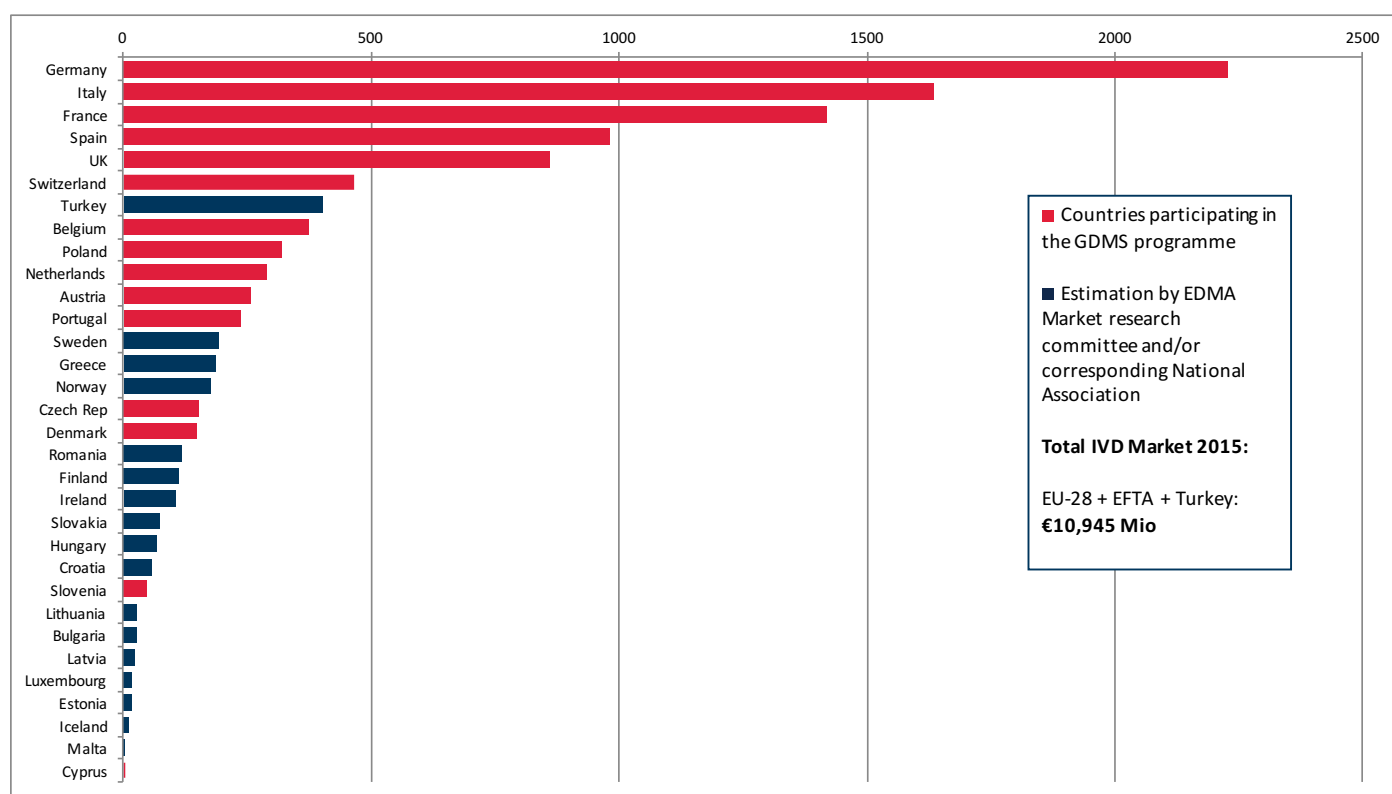
3 Turkey figures, exceptionally, are calculated by using the corresponding 2014 and 2015 exchange rates upon the request of ARTED.

EUROPEAN IVD MARKET

Although there are variations in healthcare systems, reimbursement policies, etc. from country to country, healthcare cost containment is a constant across the various countries in this report. Besides budget restrictions, greater centralization both in the public and private laboratory sectors has increased the power of purchasing organizations.

While Days Sales Outstanding (DSO) showed some improvement during 2014, the situation overall in 2015 remains unsatisfactory.

European IVD Market 2015 (million €)

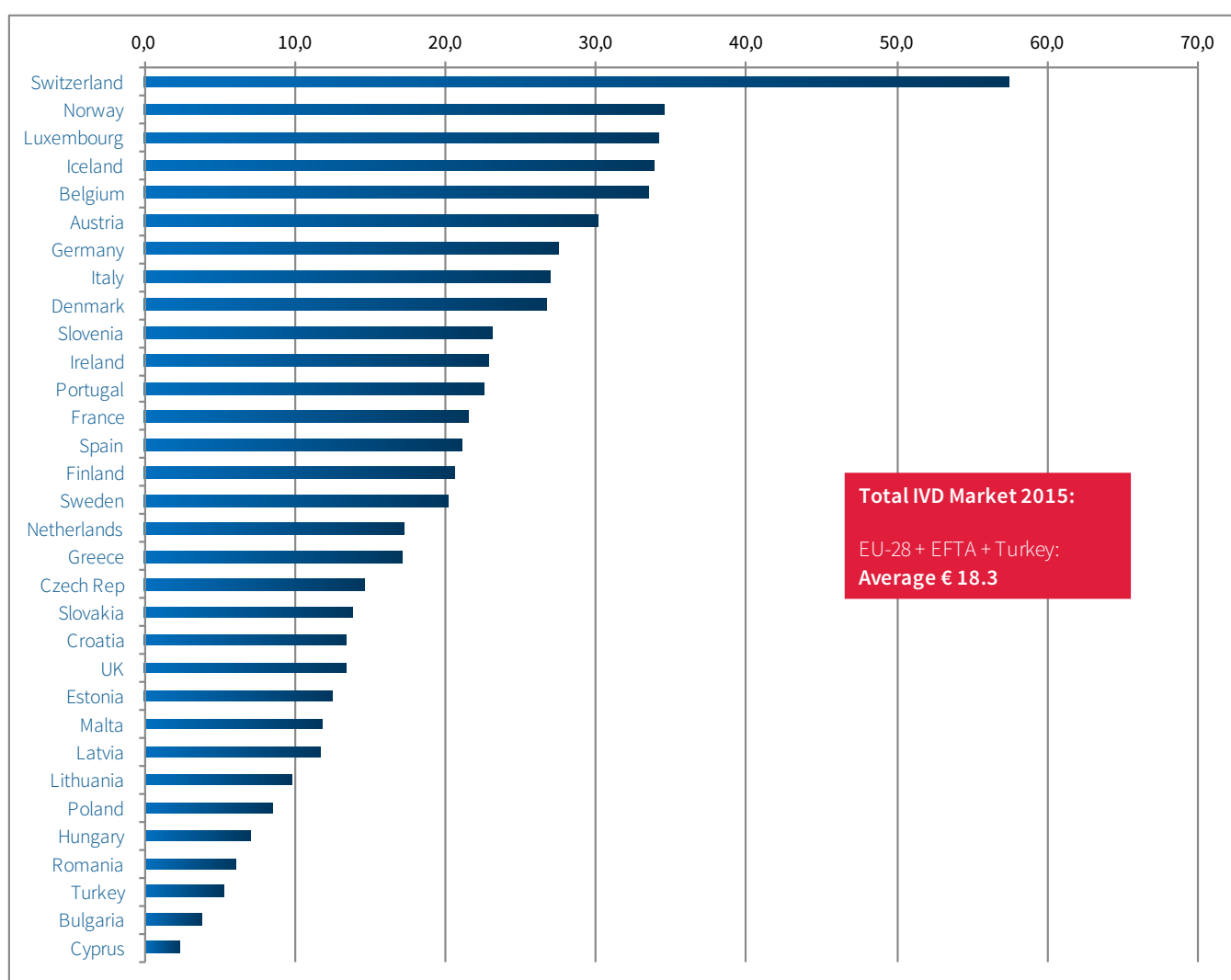


GDMS = Global Diagnostic Market Statistics (formerly EDMS)

Country Specific Data

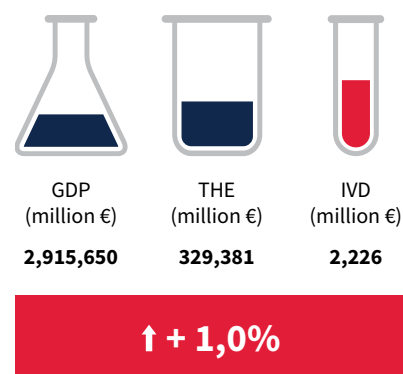
The differences in total healthcare expenditure, both in relative terms to GDP and absolute amounts, demonstrate the wide variation in access to healthcare across the thirty-two countries in this report. Relative to GDP, Sweden is the leading country at 11,9% while Switzerland, Luxemburg and the Scandinavian countries are the top countries in absolute terms. The per capita expenditure also shows a wide variation from a low of €2,3 in Cyprus to €57,4 in Switzerland, which remains the leading country in per capita expenditure on IVD.

IVD Per Capita (€)



Germany

“The German IVD-Market grew slightly around +1,0% in 2015. This indicates a slight recovery from the results of 2014 vs 2013 of -0,1% and versus the previous years. Compared to 2014 the changes in market size differ stronger in the individual market segments. Laboratory diagnostics (reagents and instruments) increased by +1,5%, which indicates a stronger growth compared to 2014 versus 2013 of +0,7%. The rapid test market made a turnaround in 2015. While this market segment decreased in the range of -1,5% in 2014 versus 2013, it grew by +0,2% in 2015.

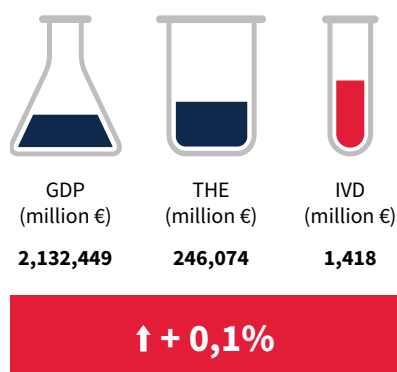


Sales in the glucose self-testing market, the largest segment in the rapid testing market, decreased about -0,6%. While the decline was weaker than in 2014 versus 2013 of -3,2%, this market segment still suffers from the restrictive legal framework that forces medical doctors to prescribe generic, low-priced test strips to keep their respective budget.

Overall, as in 2014 the floating quota percentage for laboratory service fees, that remained unchanged in 2015, still caused strong price pressure on the IVD market in Germany. However, some market segments continued to grow, despite the restrictive legal framework. The sales in the market segment microbiology reagents rose by +2,2%. Even stronger, immunochemistry grew by +2,5%.” - VDPH, German IVD industry association.

France

“The Central Laboratory IVD Market in France is estimated at 1.418 billion €, in stagnation with a tiny growth of +0,1%, compared to 2014. This follows decreases of -0,4% in 2014 and of -0,3% in each of 2012 and 2013.”- SIDIV, French IVD industry association

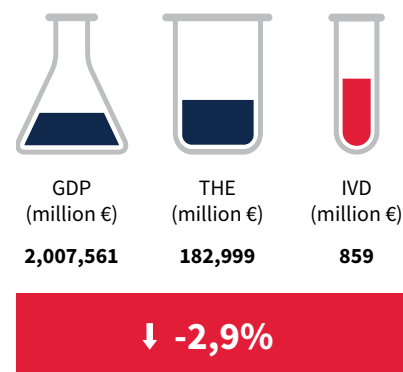


United Kingdom

“The total IVD market dropped by -2,9% (£21,8m) in 2015 according to the BIVDA market audit. This was due to reduced reagent revenues of -£24m, and of these -£25m due to Clinical Chemistry rapid test and POC. This is almost entirely due to reduction in reported revenues for glucose test strips (-£25m) which may reflect in part increased share by non-participating companies in the audit.

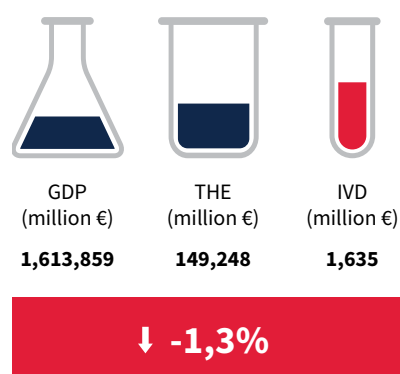
The National Health Service (NHS) target remains to reduce the pathology laboratory budget by £500m. The main dynamics in the market continue to be determined by the consolidation of laboratory provision, tendering of pathology services and the increasing proportion of IVD revenues generated through Managed Service Contracts. The author of the Carter Report (Lord Carter of Coles) which recommended the consolidation of laboratories and set the £500m savings target has recently published an additional report ‘Operational productivity and performance in English NHS acute hospitals: Unwarranted variations’ in which he points to savings of £4m and 70 WTE staff by the formation of Surrey Pathology Services from two pathology providers which incorporate four former hospital laboratories.

Private sector investment 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 further 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.”- BIVDA, British IVD industry association.



Italy

“The Stability Law 2015 provided a reduction of the National Health Service (NHS) budget; Regions were expected to reduce their healthcare expenditure, and specific financial caps were set for medical devices. In particular, the overall public expenditure for medical devices should not exceed the 4.4% of the NHS budget, no matter if such a limit is much lower than the actual public expenditure for medical devices (about 5.1% of the budget).



In order to balance the overspending (around 700 million euro each year in the period 2015-2017), the government introduced the so called “payback”, i.e. a mechanism according to which companies will have to pay back to regions (pro quota) half of the overspending. Such mechanism was intended to be applied on a regional basis, but the technical decrees are not yet defined and hence the mechanism is still on standby.

Beyond that, the reduction of the number of laboratories and the strengthening of the centralized bids continues.

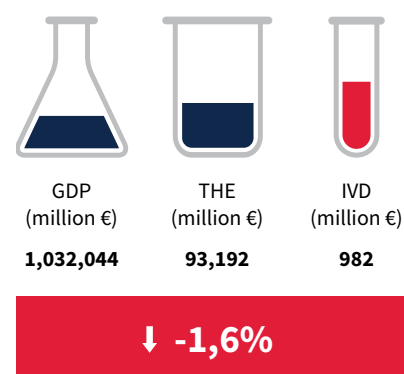
Related to late payments, the DSO decreased and reached a level close to 6 months of delay on average at national level in 2015, a level which is still disappointing.

Into the above framework, the 2015 IVD market (1.635 million euro) decreased by -1.3% compared to 2014.” - ASSOBIMEDICA, Italian IVD industry association

Spain

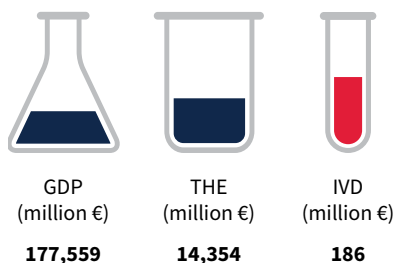
“The IVD market in Spain remains declining slightly year over year -1,6% mainly due to the crisis and also the continuous laboratory consolidation. We expect the market to recover in the coming years, but not to the previous levels prior to the euro crisis.

The rapid testing market and POC -mainly diabetes test strips- decreased -2,4%, in spite of a stable or even growing number of determinations, due to centralized purchasing and price pressures. Introducing new parameters, especially if those represent a budget increase are difficult for budgetary reasons but also due to the very long tender cycles that limit introduction of new tests during this period. The DSO of 145 days improved versus previous years thanks to special governmental paying plans but is still far from the legal frame.” – FENIN, Spanish IVD industry association.



Greece

“Year 2015 ended, for the eighth consecutive year, with recession in Greece, reaching -0,3% vs 2014. The cumulative recession of the last eight (8) years reached -28% since 2008. Capital controls have been implemented since June 2015 and in Autumn 2015 the 3rd bailout program, at the level of €86 billion, has been agreed and implemented. The IVD market in Greece decreased an additional year by -6,1%, reaching a size of €186M.



↓ -6,1%

In the public sector, which accounts for approximately 65% of the total IVD market in Greece, the Hospital Operating Expenses were reduced by -10% in 2015 vs 2014, bringing the overall relevant reduction to 52% in six years (2009-2015). At the same time the public health expenditure was shrunk by 14% year over year in 2015, having been reduced by -60% cumulatively, through the years 2009-2015.

Public procurement, based on tenders and negotiations, is dictated by the Observatory of Prices of the MoH, which continuously pushes prices down, regardless of technical specifications, volumes or methods.

The private sector – accounting for approximately 35% of the total IVD market in Greece – is also under a lot of pressure and has contracted by more than 30% since 2009. Private healthcare providers have been constantly suffering great losses annually, since 2013, in the form of clawbacks and rebates towards the main insurance provider EOPYY. Hence several of them have been pushed out of business while the remaining healthcare providers are trying to pass these losses over to their suppliers.

Most of the IVD suppliers still suffer from the losses imposed to them in 2012 by the trim of the governmental bonds that were given to them as payment for the public sector purchases for the period 2007-2009.

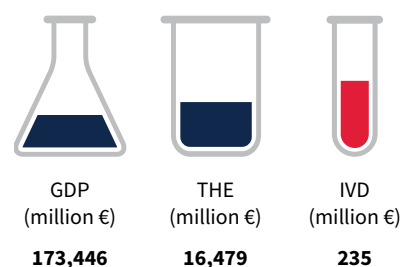
These losses have not yet been recovered and left a lasting impact on the IVD market in Greece. The DSO increased from 350 days at the end of 2014 to 440 days at the end of 2015.” – SEIV, Greek IVD industry association.

Portugal

“During 2015, the Portuguese IVD market had an increase of +4,4%. The main reasons were blood glucose strips market growth and DAAs positive impact on Hepatitis C virus NA reagents.

During 2015, which had a decrease on the payment terms, we started with 619 days outstanding and we closed with an average of 502 days at the end of the year. We see an improvement, but is not at the level we expect.

The private lab market continued the trend of consolidation.” - APIFARMA, Portuguese IVD industry association.



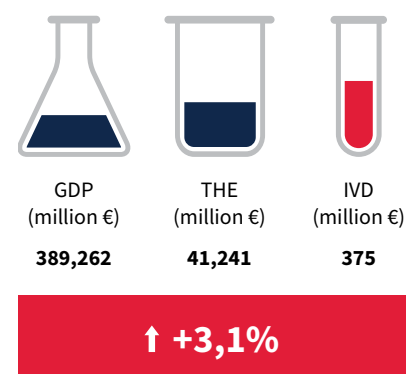
↑ +4,4%

Belgium

“In 2015, the IVD market grew by +3,1%, whereas reagent revenue growth was +4,0% and instruments, consumables, software decreased by -4,5% Within the total national healthcare budget 2015, the IVD expenditures increased by +3,6% compared to 2014. IVD expenditures 2015 equalled €1,289 million. The average annual increase of the budget for clinical biology is +4% for the last 10 years, however looking at the last 5 years this has dropped to an average of 2,3% per year.

The main factors affecting the national IVD market are:

- Reimbursement dossiers still on hold.
- No budget for innovation due to the postponement of the revision of the current nomenclature and the silo budgeting. Standstill. Lack of transversal view on healthcare.
- Increasing power of purchasing departments and an increasing degree of purchasing centralization.
- Consolidation of laboratories
- Centralization of laboratories and procurement/tenders are associated with decreasing price levels.
- Evolution to 'cost per reportable' tests (CPR).



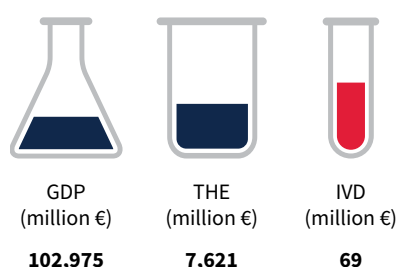
At the end of 2015, the minister of health started discussions with beMedTech regarding a 'Future Pact' with the industry.

The pact also ensures that the industry receives funds for the next few years and can operate in a stable budgetary framework so that it can continue to invest in the development of innovative technology. The minister will present this plan end of 2016.

The 'Oncology horizon scanning project' was finalized in June 2015. This project was initiated by the Vlerick Business School in cooperation with all medical, industry and governmental stakeholders, including beMedTech. This project will provide the Belgian health regulatory and payment authorities, actors and influencers with recommendations on how to ensure and possibly improve patient access to precision medicine, i.e. targeted therapeutics and their companion diagnostics in the near future (within 5 years) in the field of oncology." - beMedtech, Belgian IVD industry association.

Hungary

"An extraordinary factor contributed to the sharp increase of the total IVD market. The modernization of a number of hospitals supported by the EU were completed in 2015. A large quantity of IVD instruments were purchased in the frame of this project valued 2500 Million HUF. It was a once in a lifetime event. Neither before nor after there were or will be IVD instruments purchased in considerable value.



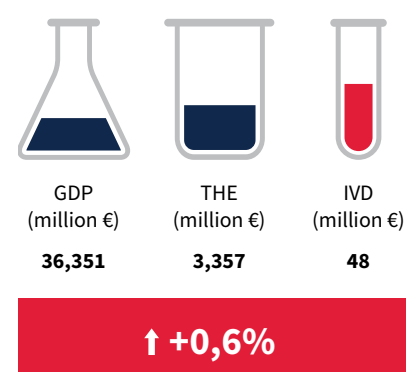
↑ +16,9%

The private laboratory service market –out of pocket payment- had a healthy growth of +11,5% with the total value of 2300 Million HUF. The reimbursement of laboratory services has been frozen since 2002, and it generates a considerable conflict between supply and demand." - HIVDA, Hungarian IVD industry association.

Slovenia

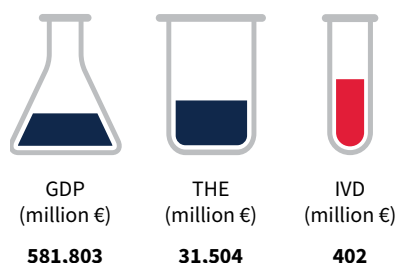
"In 2015, the IVD market experienced a slight increase of +0,6 % versus 2014. Despite growth for the second consecutive year (last year was +4,7%), the value of the market continues to be below the value prior to the economic crisis.

In general, growth is driven by the laboratory market (clinical chemistry +1,0 % and immunochemistry + 4,2 %) and a decline was in POC - 0,8 % and diabetes testing -0,6 %." - SIEDMA, Slovenian IVD industry association.



Turkey

“In 2015, Turkey kept experiencing price erosion due to increasing bargaining power of public payers driven by consolidation of public hospitals under public hospital unions, as well as full service tender concept which resulted in single digit growth. On the other hand, strong test volume growth especially due to Syrian refugees and the healthcare policies continued; which resulted in market growth of +3,1% (which equals to +6.9% in local currency). Government financial support for university hospitals continued to weaken which prolonged the payment terms.



↑ +3,1%

Private healthcare service utilization has kept surging due to the increasing number of private hospitals providing healthcare services to patients reimbursed by public funding. Meanwhile, Turkey's Ministry of Health's PPP program's first wave of hospitals have come close to launch. Even though the exact number of hospitals to be built are not yet finalized, the estimation stands at 36-40 hospitals with a total bed capacity of 30,000.

Turkey has continued to become an important player in healthcare tourism driven by government policies and the growing number of private hospitals.

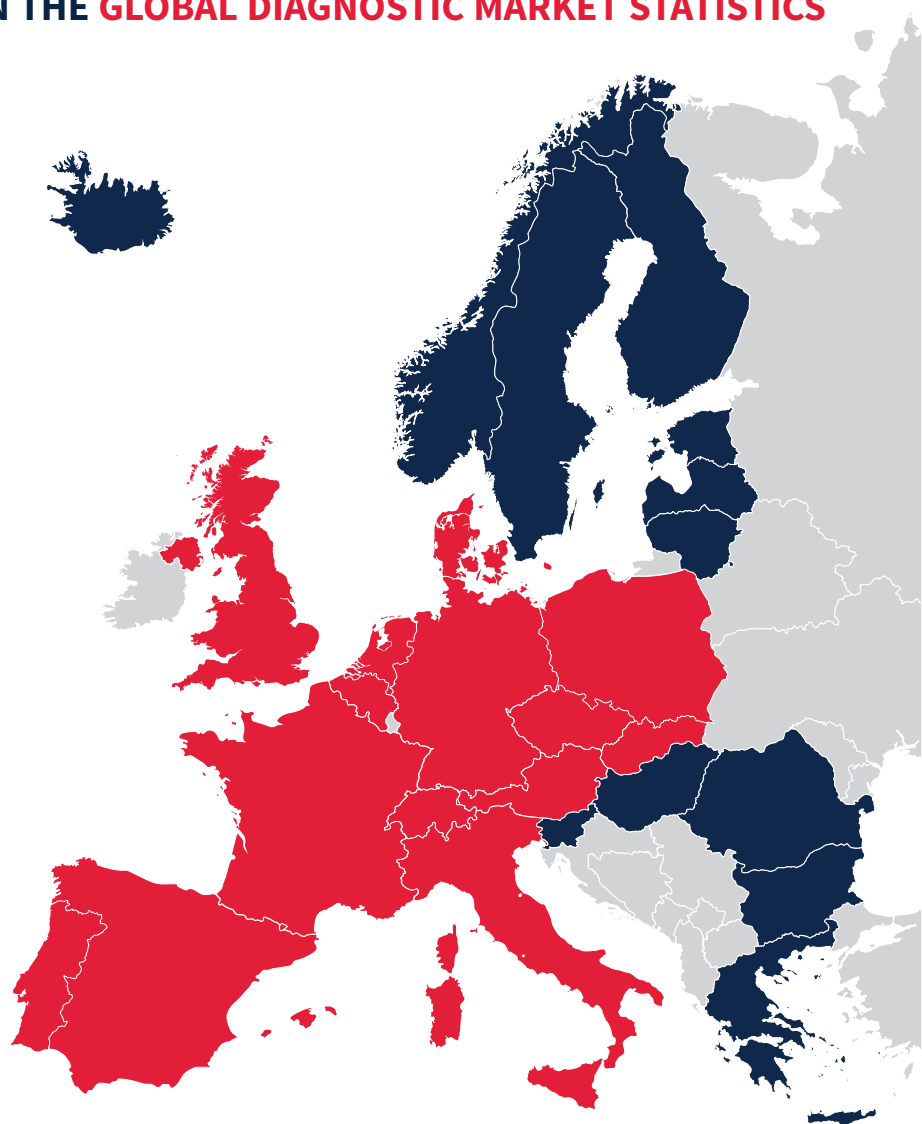
In 2015, Turkish Lira weakened dramatically against foreign currencies, which negatively affected the companies in the IVD market. As the long-term government tenders are in Turkish Lira, it has not been possible to reflect the FX changes to the existing contracts, which resulted in an even harder year for the Diagnostics industry.” - ARTED, Turkish IVD industry association.

DATA GATHERING

The results presented above are based on individual estimates made for 28 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, Croatia, 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.

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.medtecheurope.org

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