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INTRODUCTION

Osteoporosis, **or porous bone**, is a bone disease when the body loses too much or produces too little bone. Bones are a living tissue that is being constantly replaced. Osteoporosis is a condition when the creation of new bone is not equal to the removal of old bone. The results are weakened bones that may break from a fall, or in extreme cases from sneezing or mild stresses.

Osteoporosis is a disease that affects both sexes and people of all ages. However, **older white and Asian women who are past menopause** are most likely to develop osteoporosis.

Common risk factors for osteoporosis include lack of calcium and vitamin D, lack of exercise, low body weight, cigarette smoking, history of rheumatoid arthritis etc. An interesting thing about osteoporosis is that it is a **silent disease**, meaning there are no telltale symptoms until a bone break. In the early stage of osteoporosis, it is very difficult to recognize the disease. But as it progresses, symptoms become more apparent. Some of the symptoms include: **back pain, loss of height over time, stooped posture, injuries**. Regarding injuries, most common are wrist fractures, hip fractures, and fractures of the spine. They can also occur in other bones such as the arms or pelvis.

This research was made to reveal interesting trends, facts and statistics within the EU, and especially for the UK, Germany, France, Netherlands, Switzerland, and Austria. Firstly, a reoccurring theme in the research is **(Bone Mineral Density) BMD**. A BMD test measures how much calcium and other minerals are present in a person's bones. **Measuring the density of minerals such as calcium determines the strength of bones**. Logically, the thicker your bones are, the longer it takes to get osteoporosis.

The research covers all aspects of the disease and its consequences in different societies. Firstly the disease is dissected and how it affects different countries through numbers. Numbers are presented on a general level. It is also explained why it appears, who is affected by osteoporosis, what are major causes and consequences. When consequences are covered, they are separated into two categories: health and financial.

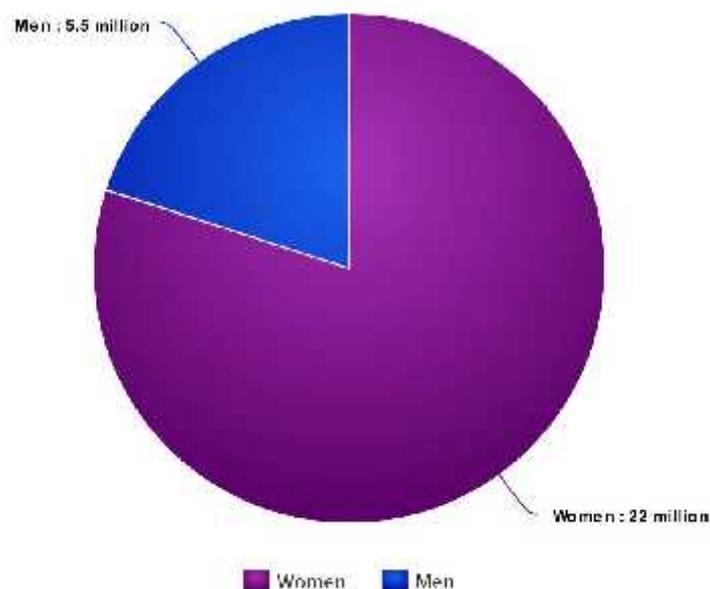
All of the researched countries are highly developed modern countries and each of them has a strategy battling this modern disease. Their cases are dissected one by one covering all aspects of statistics, the financial burden it represents on each of them, how their governments and leading organizations try to educate the public and popularize this not so known disease. The research deals with treatment and coverage, meaning what kinds of

medications are used for prevention in every country and what does the healthcare system do in order to protect and take care of its sick citizens. Also, an important part of the research is the rules and regulations. All the rules, regulations, customs, laws and details are dissected carefully because, after all, the subject is pretty complicated. At the end, **a summary of the key points is given to the reader**. All the most important points are underlined. A detailed explanation is provided.

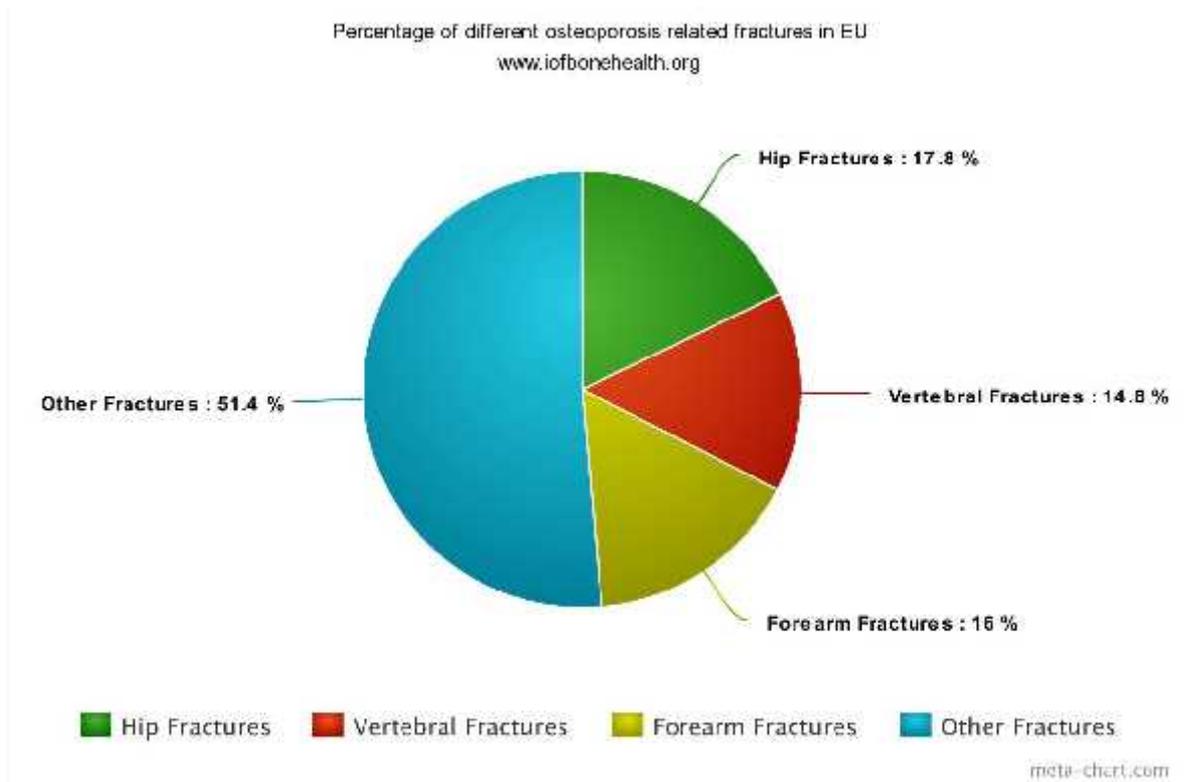
OSTEOPOROSIS STATISTICS AND TRENDS

According to the [International Osteoporosis Foundation](#) (IOF), **approximately 22 million women and 5.5 million men aged between 50-84 years were estimated to have osteoporosis in the EU in 2010**. Due to changes in population demography, the number of men and women with osteoporosis is estimated to rise from 27.5 million in 2010 to 33.9 million in 2025, an increase of 23%. The statistics clearly indicate that **osteoporosis is much more prevalent in females than in males**. According to the [National Osteoporosis Foundation](#) (NOF), there are several reasons why women are more likely to get osteoporosis than men:

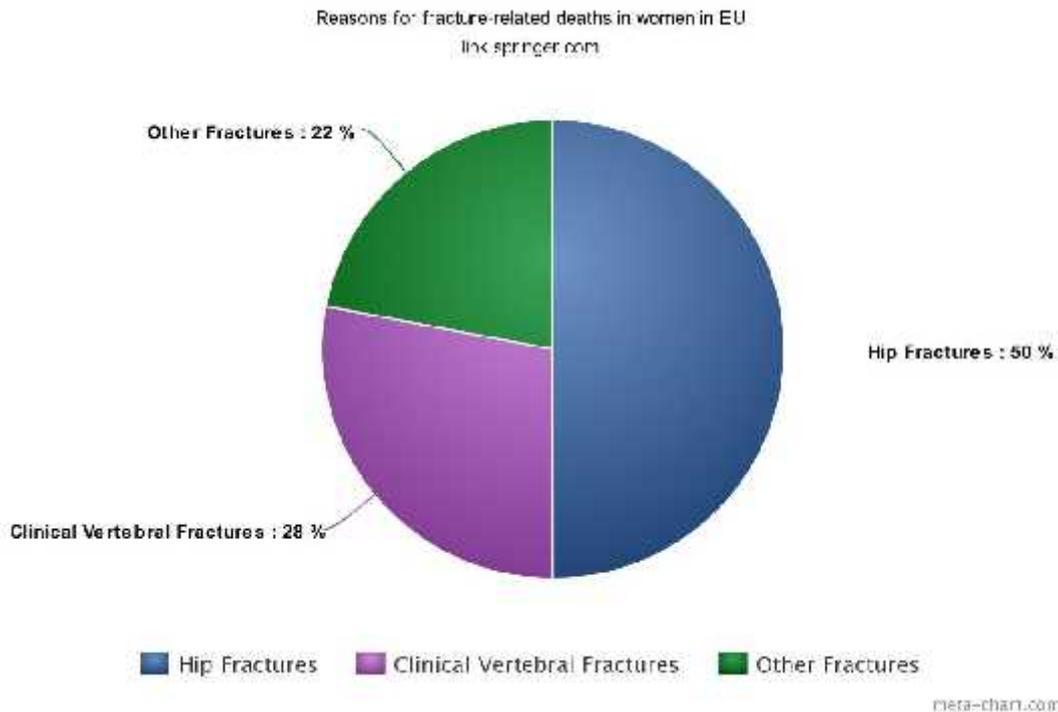
- Women have smaller and thinner bones than men;
- Estrogen, the hormone in women that protects bones, decreases sharply when women reach menopause, resulting in bone loss. This is why the chance of developing osteoporosis increases as women reach menopause.



The number of new fractures in 2010 in the EU was estimated at 3.5 million, comprising approximately 620,000 hip fractures (17.8%), 520,000 vertebral fractures (14.8%), 560,000 forearm fractures (14%) and 1,800,000 other fractures (51.4%).



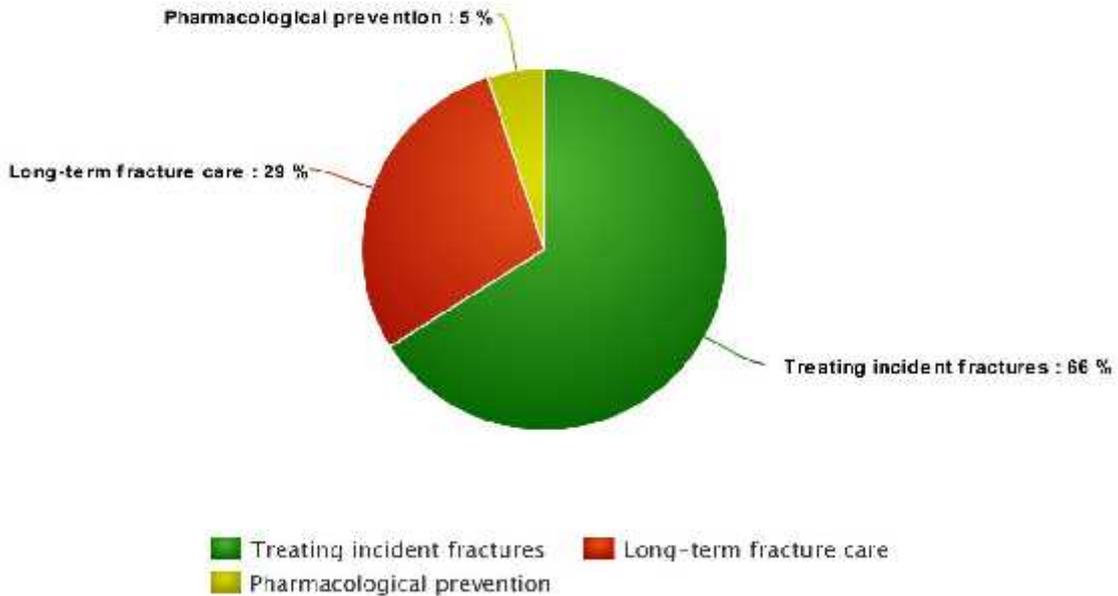
Osteoporotic fractures are a major cause of morbidity in the population. Hip fractures cause acute pain and loss of function, and nearly always lead to hospitalization. Recovery is slow, and rehabilitation is often incomplete, with many patients permanently institutionalized in nursing homes. In the case of hip fracture, most deaths occur in the first 3-6 months following the event, of which 20-30% are causally related to the fracture event itself. The number of deaths causally related to fractures in the EU was estimated at 43,000, and approximately 26,300 life-years were lost in the EU in 2010 due to incident fractures. Approximately 50% of fracture-related deaths in women were due to hip fractures, 28% due to clinical vertebral, and 22% due to other fractures.



The annual number of fractures in the EU is expected to rise from 3.5 million in 2010 to 4.5 million in 2025, an increase of 28%. In Europe, osteoporosis accounted for more disability and life years lost than rheumatoid arthritis, but less than osteoarthritis.

The total health burden of osteoporosis in the EU was estimated at 1,180,000 lost QALYs (Quality Adjusted Life Years) for the EU. The majority of the QALYs lost were a consequence of prior fractures. Assigning a QALY the [value](#) of 2xGDP, the total value of QALYs lost was estimated at €60.4 billion, while the total cost of osteoporosis, including pharmacological intervention, was estimated at €37 billion. Out of these, 66% are Costs of treating incident fractures, 29% are for Long-term fracture care and 5% are Pharmacological prevention.

Cost of osteoporosis in EU - €37 billion total
www.iofbonehealth.org



meta-chart.com

Because bone loss occurs with advancing age, the prevalence of osteoporosis increases with age. The table below shows the [prevalence of osteoporosis](#) in the largest countries in the EU in women, using WHO criteria. Approximately 21 %, of women aged 50–84 years are classified as having osteoporosis accounting for more than 12 million women in these countries. With more than 3 million women aged 50-84 classified as having osteoporosis, Germany is the leading country among the EU5, followed by Italy with 2.487 million, France with 2.266 million, the UK with 2,079 million, and Spain with 1,606 million women with osteoporosis.

Number (in thousands) of women with osteoporosis according to age in the EU5 using female-derived reference ranges at the femoral neck

Age group (years)	France	UK	Germany	Italy	Spain	EU5
50-54	135	127	192	128	95	695
55-59	200	175	265	180	126	974
60-64	286	276	328	276	175	1385
65-69	271	308	489	335	215	1672
70-74	364	365	718	464	270	2236
75-79	484	411	672	546	368	2543
80-84	526	417	686	558	357	2612
50-84	2,266	2,079	3,350	2,487	1,606	12,117

GERMANY

According to the [International Osteoporosis Foundation](#), **more than 5 million people aged +50 years have osteoporosis in Germany**. But this is not just sheer numbers. If we think about injuries to the elderly, we can conclude that this implicitly means that the economic burden surrounding these kinds of injuries increases more than 9 billion euros each year. By 2025, the cost for medical expenses will increase by 25% or more than 11 billion euros. Furthermore, according to the [report of the European Commission in 1998](#), in Germany hip fractures are expected to rise from 117 000 in 2000 to 240 000 in the year 2040. [This report on osteoporosis](#) claims that in 2003, 7.8 million Germans, of which 6.5 million women, were diagnosed with osteoporosis. If we look at the numbers more closely and analyze [this research from 2013](#), 104 528 people received a diagnosis of osteoporosis. If we add up these numbers, we can conclude that **885 000 people develop osteoporosis in Germany each year**.

UNITED KINGDOM

Approximately 3 million people in the UK are estimated to have osteoporosis, according to a 2015 publication from the National Osteoporosis Society called “[The Osteoporosis Agenda England](#)”. With the prevalence of osteoporosis being higher in women, it’s estimated that **1 in 2 women and 1 in 5 men above the age of 50 will break a bone**. People in the UK experience more than 300,000 fragility fractures yearly, and these are often caused by just a minor bump or fall. Older people with long-term conditions such as osteoporosis account for nearly 69,000 unplanned hospital admissions in England, or around 70% of all hospital admissions and 70% of total NHS spending. Hip fracture alone cost around £1.5 billion (€1.7 billion) in English hospital costs, without taking into account the high cost of social care.

According to the [2014 survey “Life with Osteoporosis”](#), 42% of the people interviewed said that osteoporosis made them feel isolated, and the same number that has experienced long-term pain believe it will never go away. These numbers clearly state that the consequences are more than financial.

Social Isolation and Unbearable Pain



■ Feeling the consequences ■ Not Affected

INSIGHTS IN MEDICAL SOCIOLOGY AND TREATMENT

Osteoporosis is not a new disease. According to reliawire.com, osteoporosis has been around for at least 4000 years, as Egyptian mummies have been found with the telltale dowager's hump, a deformation that clearly indicates the mummies suffered from osteoporosis. In the 1830s the French pathologist Jean Georges Chretien Frederic Martin Lobstein noticed that some patients' bones had larger than normal holes and he invented the term osteoporosis that literary means "porous bone". But the official recognition of the disease will not come until 100 years later when Fuller Albright of Massachusetts General Hospital defined postmenopausal osteoporosis and begun treating women with the condition with estrogen. But ultimately, **osteoporosis was not officially acknowledged and defined as a disease by the WHO until 1994**. In 1998, the European Commission (EC) issued a report and recommendations for action against osteoporosis in the European Community. The European Foundation for Osteoporosis and Bone Disease (EFFO) and later the [IOF](http://iof.org) assisted in the publication and dissemination of the report. The publication of the report showed disappointing progress in Europe since 1998, so IOF initiated the launch of the European Parliament Osteoporosis Interest Group, which issued a "Call to action" to spur government action against osteoporosis in Europe. The European Parliament Osteoporosis Interest Group is an informal, all-party group of MEP's dedicated to improving national and European policies to prevent osteoporosis and related fractures. In 2002, IOF was awarded a grant from the EC for a policy project entitled "Call to Osteoporosis Action". This project brought together policy makers from the European Union and its member states, and osteoporosis experts, to form and EU Osteoporosis Consultation Panel to implement practical, cost-effective strategies to improve access to diagnosis and proven therapies before the first fracture.

Osteoporosis international, an international multi-disciplinary journal which is a joint initiative between the International Osteoporosis Foundation and the National Osteoporosis Foundation of the USA, has published the "[European Guidance for the diagnosis and management of osteoporosis in postmenopausal women](#)" in 2012, to provide guidance in a European setting for postmenopausal women at risk of fractures due to osteoporosis. They emphasize that although the diagnosis of the disease relies on the quantitative assessment of bone mineral density, which is a major determinant of bone strength, the clinical significance of osteoporosis lies in the fractures that arise. Because a variety of non-skeletal factors contribute to fracture risk, the diagnosis is at the same time an assessment of a risk factor for the clinical outcome of fracture and for this reason, they urge for a distinction to be made between the use of bone mineral density for diagnosis and for risk assessment. Common sites for osteoporotic fracture are the forearm, hip, spine and proximal humerus. The remaining lifetime probability in women at age 50, of a fracture at any one of these sites exceeds that of breast cancer (approximately 12%) and the likelihood of a fracture at any of these sites is 40% more in Western Europe, a figure close to the probability of coronary heart disease.

The objectives of bone mineral measurements are to provide diagnostic criteria, prognostic information on the probability of future fractures and a baseline on which to monitor the natural history of the treated or untreated patient. BMD is the amount of bone mass per unit volume or per unit area, and both can be measured in vivo with the use of densitometry techniques. The [European Guidance for the diagnosis and management of osteoporosis in postmenopausal women](#) has identified a wide variety of techniques to assess bone mineral, the most popular being techniques based on X-ray absorptiometry of bone, particularly dual energy **X-ray absorptiometry (DXA)**, since the absorption of X-rays is very sensitive to the calcium content of the tissue of which bone is the most important source. Other techniques include quantitative ultrasound (QUS), quantitative computed tomography (QCT) applied both to the appendicular skeleton and to the spine, peripheral DXA, digital X-ray radiogrammetry, radiographic absorptiometry, and other radiographic techniques.

DXA is the most versatile bone densitometric technique, as it can be used to assess bone mineral density/bone mineral content of the whole skeleton as well as specific sites, including those most susceptible to fracture.

According to [patient.info](#), risk factors for osteoporosis are:

- Women are at a greater risk than men, especially women who are thin or have a small frame, as are those of advanced age.
- White and Asian women, especially those with a family member with osteoporosis, have a greater risk of developing osteoporosis than other women.
- Women who are postmenopausal, including those who have had early or surgically induced menopause, or abnormal or absence of menstrual periods, are at greater risk.
- Cigarette smoking, eating disorders such as anorexia nervosa or bulimia, low amounts of calcium in the diet, heavy alcohol consumption, inactive lifestyle, and use of certain medications, such as corticosteroids and anticonvulsants, are also risk factors.
- Rheumatoid arthritis itself is a risk factor for osteoporosis.
- Having a parent who has/had osteoporosis.

TREATMENT OF OSTEOPOROSIS

Treatment of osteoporosis focuses on slowing down or stopping the mineral loss, increasing bone density, preventing bone fractures, and controlling the pain associated with the disease. emedicinehealth.com identifies several medications used to treat osteoporosis:

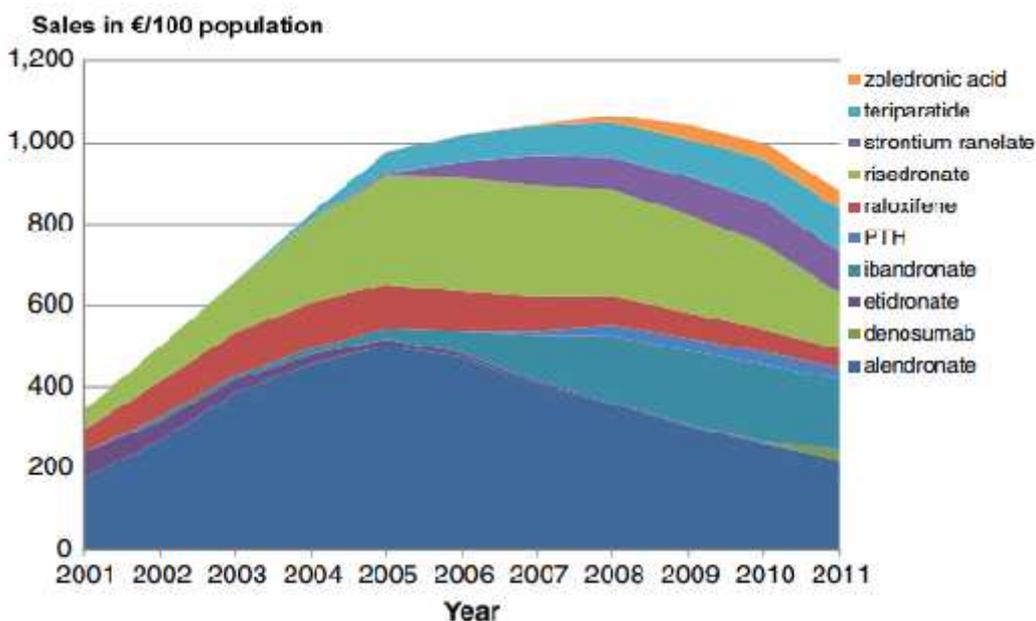
- **Estrogen** – most commonly used to treat newly menopausal women as a way to prevent bone loss, or at least slow down the process. Many women choose estrogen replacement therapy because of its proven usefulness, but recent studies question the safety of long-term estrogen use. Prolonged estrogen intake increases the risk for developing certain cancers and although it was once thought that estrogen protects the heart and blood vessels, recent studies have shown that estrogens cause an increase in coronary heart disease, stroke, and venous thromboembolism (blood clots). Besides the risks, estrogen also produces side effects in women (breast tenderness, weight gain, and vaginal bleeding).
- **SERMs** – For women who are unable to take estrogen or choose not to, selective estrogen receptor modulators (SERMs) offer an alternative. For example, many women who have first-degree relatives with breast cancer will not consider estrogen.
- **Calcium** – Calcium and vitamin D are needed to increase bone mass in addition to estrogen replacement therapy.

- **Bisphosphonates** are hormone therapies that slow down bone loss and in some cases, they actually increase bone mineral density. Doctors can measure the effects of these drugs by obtaining DXAs every year or two and comparing the measurements. To take these drugs, patients must have sufficient calcium levels in the blood and well-functioning kidneys.

According to “[Osteoporosis in the European Union: medical management, epidemiology and economic burden](#)”, a 2011 report prepared in collaboration with the International Osteoporosis Foundation (IOF) and the European Federation of Pharmaceutical Industry Associations (EFPIA), alendronate (a bisphosphonate) is the most commonly prescribed agent, accounting for approximately a quarter of the total value of sales. Other common drugs are denosumab, etidronate, ibandronate, parathyroid hormone (PTH) 1–84, raloxifene, risedronate, strontium ranelate, teriparatide and zoledronic acid. There are a number of pharmacological options available in the European Union for the treatment of osteoporosis. The table below shows the year of introduction in Europe (EMA marketing authorization) for the agents indicated for osteoporosis. The bisphosphonates were the first group of drugs to be approved, followed by the SERM raloxifene in 1998. In the 2000s, additional bisphosphonates, as well as novel groups of drugs, have become available. The patent of alendronate expired and generic versions of the drug became available in Europe in 2006. Risedronate has been also available in generic formulations since 2010.

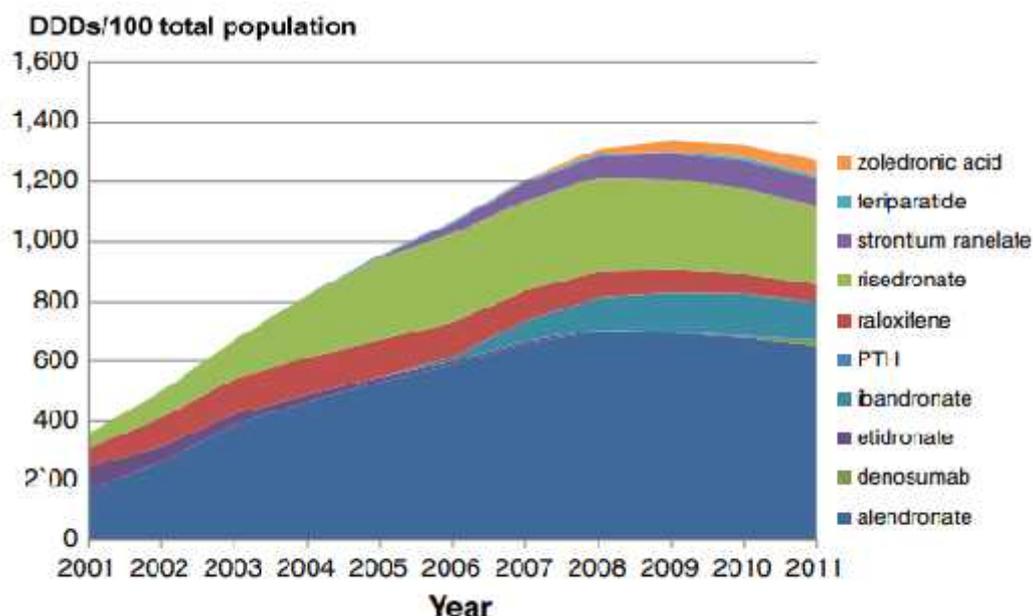
Year of first introduction in Europe	
Medications	Year
Bisphosphonates	
• Alendronate	1995
• Etidronate	1980
• Ibandronate	2005
• Risedronate	2000
• Zoledronic Acid	2005
SERMs	
• Raloxifene	1998
Parathyroid hormones	
• Teriparatide	2003
• PTH (1-84)	2006
Strontium Ranelate	2004
Antibodies	
• Denosumab	2010

The graph below shows an estimated population-adjusted total sales and market shares for the time period 2001 through 2011 as sales in Euros. In terms of value, sales increased rapidly from 2001 to 2005; grew at a slower pace until 2008 and thereafter decreased. Over the entire period, the value of sales in the EU27 increased from approximately €344/100 persons aged 50 or above in 2001 to €883 in 2011.



The next graph shows an estimated population-adjusted total sales and market shares for the time period 2001 through 2011 as sales in DDDs (Defined daily dosage). In terms of volume (DDD per 100 person-years aged 50 or above) sales increased almost linearly until 2010 decreased slightly in 2011. The discrepancy between the development of sales in terms of value and volume was predominately driven by the decreased price of generic alendronate.

WWW.



Estimated sales per product in 2010 measured both as DDDs and in Euros along with market shares are shown in the table below. A comparison of market shares measured as sales and volume shows a substantially higher market share in terms of volume than in sales for alendronate, reflecting the low price of generic alendronate. Conversely, the effect of high price is seen with PTH and teriparatide, which have higher market shares in sales than in volume.

Estimated sales in EU27 and market shares in 2010 based on IMS Health data

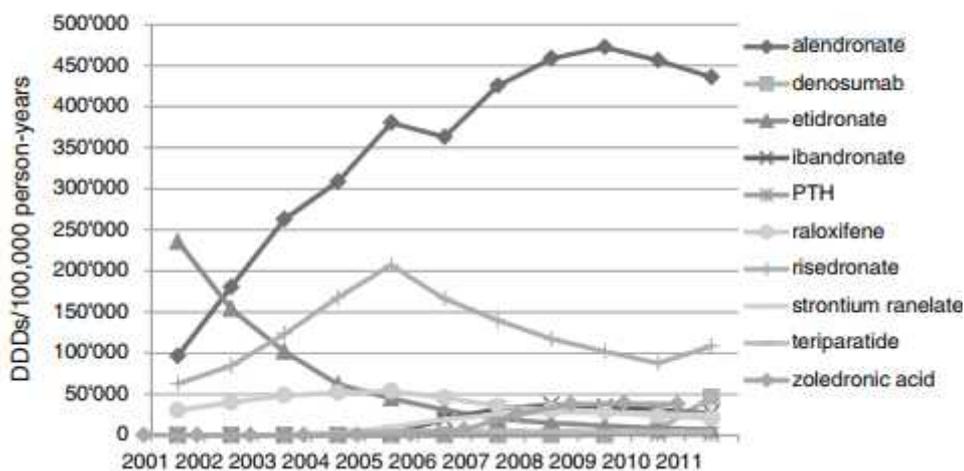
	Estimated sales in 2010 (DDDs per 100 persons aged 50 years and above)	Estimated sales in 2010 (Euros per 100 persons aged 50 years and above)	Estimated market share 2010 (DDDs)	Estimated market share 2010 (Euros)
Alendronate	679.8	261.3	51.3%	26.1%
Denosumab	1.4	1.8	0.1%	0.2%
Etidronate	3.8	2.7	0.3%	0.3%
Ibandronate	140.7	190.6	10.6%	19.0%
PTH	0.8	30.2	0.1%	3.0%
Raloxifene	68.3	54.9	5.2%	5.5%
Risedronate	281.7	210.5	21.3%	21.0%
Strontium ranelate	94.3	105.5	7.1%	10.5%
Teriparatide	10.1	101.7	0.8%	10.2%
Zoledronic acid	43.7	41.4	3.3%	4.1%
Total	1,324.7	1,000.5	100%	100%

Alendronate is the most commonly prescribed agent, accounting for approximately a quarter of the total value of sales. In terms of DDDs, alendronate represents almost half of all DDDs used to treat osteoporosis in the European Union. The treatment uptake of osteoporosis drugs has increased considerably during the study time, however, recently a slight decrease has been observed. The volume in terms of value of sales has decreased

more than the volume in terms of DDDs in the two most recent years, mostly due to the decreasing price of generic bisphosphonates.

GERMANY

The health sector in Germany is one of the most advanced in Europe. According to the [Report on Osteoporosis in the European Community](#), the availability of hospital beds is good and the demand for more beds for the treatment of osteoporotic fractures will be moderate. One of the most popular ways of fighting osteoporosis is adding calcium in food and beverages. With the exception of UK, adding calcium to foods is not compulsory in any country. But [for example](#), **calcium is added to cereals, milk, juices, soy drinks and sweets in Germany**, to milk in Greece and Netherlands and breakfast drinks in Austria. According to [Osteoporosis in the European Union: medical management, epidemiology and economic burden](#), the most popular osteoporosis drug in Germany is Alendronate. Other popular drugs in Germany are Risedronate, Denosumab, Etidronate, Ibandronate, PTH, Raloxifene, Strontium ranelate, Teriparatide and Zoledronic acid. The table below shows treatment uptake in Germany (Defined daily doses [DDDs] per 100,000 persons aged 50 years or above). The proportion of persons over the age of 50 years who were treated increased from 1.59 % in 2001 to 2.67 % in 2011.



The 2010 annual drug cost for each of these drugs is presented in the table below.

	Annual drug cost (€)
Alendronate	245
Risedronate	509
Etidronate	475
Ibandronate	576
Zoledronic acid	562
Raloxifene	540
Strontium ranelate	611
Parathyroid hormone	7,853
Teriparatide	7,700

It's interesting to note that while Alendronate is the most used osteoporotic drug, it's also the cheapest. This is due to the surge of generic versions of the drug, which drove its price down.

Because the medication Strontium ranelate is rarely prescribed by doctors, the [manufacturers of the drug have announced](#) that it will no longer be available after August 2017 anywhere in the world. The decision was made following concerns about the drug connected to cardiovascular risks which have led to its limited use.

UNITED KINGDOM

In 2008, the UK National Osteoporosis Guideline Group (NOGG) produced [a guideline on the prevention and treatment of osteoporosis](#). This is a guideline for prevention of fractures in postmenopausal women and men older than 50. This includes lifestyle measures, pharmacological advice, therapy and post fracture cares.

This all helps people, but one of the biggest problems is finances. For example, [according to this research](#) 30% of people reached think that their disease presents a financial burden to them. They mostly spend money on extra support, medications, therapy and such.

This is where [Fracture Liaison Service \(FLS\)](#) comes into play. This is a model for fragility fracture prevention. Usually targeted people are osteoporosis patients older than 50. With this tactics, it is estimated that up to 25% of hip fractures in the UK (20 000 a year) can be prevented. Every "FLS" is run by a nurse specialist that works with [NHS England](#), [Public Health England](#), and other organizations. The idea is to link every hospital in the UK with "FLS".

Furthermore, according to the article [Osteoporosis in the UK at...Breaking Point](#) there are two types of prevention - primary and secondary. The bisphosphonate alendronate is used as first-line treatment for both primary and secondary prevention, followed by risedronate and etidronate as a second-line treatment. Strontium ranelate, raloxifene or teriparatide were recommended in specific circumstances.

The British Orthopedic Association and the British Geriatrics Society founded the [Blue Book](#), which serves as a manual for the care of patients and coordinated services and standards for hip fracture care. The book specifically emphasizes the importance of the [National Hip Fracture Database \(NHFD\)](#), a web audit to promote best practices, care, and prevention of hip fractures.

PUBLIC AWARENESS

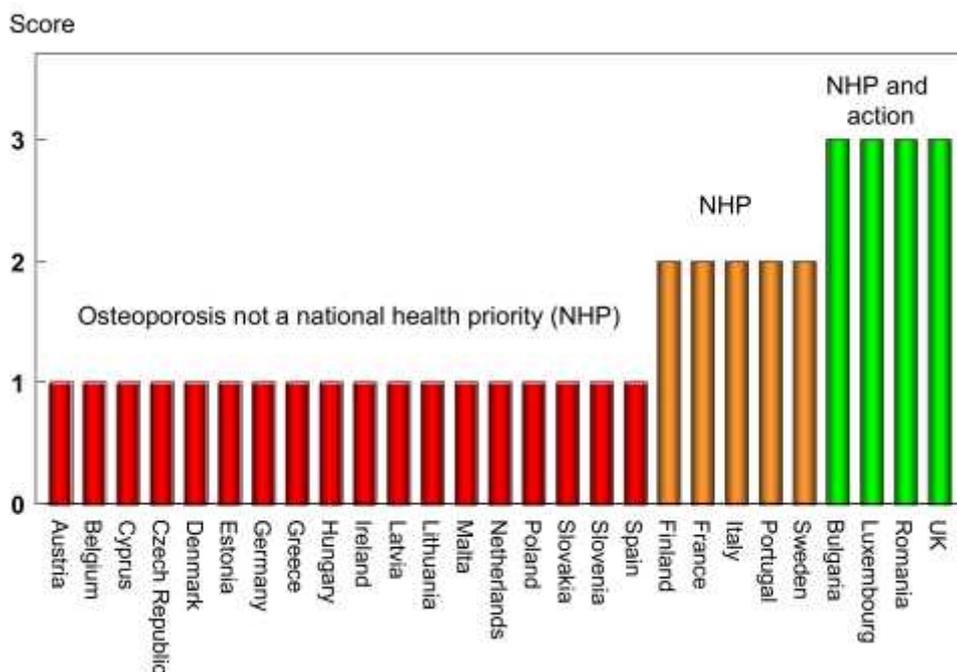
Called the “silent disease”, osteoporosis usually doesn’t show signs or symptoms until a fracture has occurred. This characteristic of the disease raises the need for wider public awareness. Osteoporosis represents a major non-communicable disease of today and is set to increase markedly in the future. According to the [National Center for Biotechnology Center \(NCBI\)](#), there is underutilization of the measures available to combat the disease and therefore a need for assessment of best practices in prevention and treatment, since the adoption of these across countries can potentially result in significant reductions in the burden of this disease. Osteoporosis and resulting fractures can often be prevented, they are not “just a part of old age”, as many people wrongly believe. The chairman of the European Parliament Osteoporosis Interest Group has stated in an [article](#) that effective treatments are widely available in Europe for the management of osteoporosis, but, despite this, the majority of individuals at high risk (up to 80%) who have already sustained at least one osteoporotic fracture are neither diagnosed nor treated to prevent further fractures. Although there have been achievements in the past 10 years and the number of fractures per year is stabilizing, there is still a long way to go, according to the [2013 SCOPE report – or Scorecard for Osteoporosis in Europe](#), published by international experts working in cooperation with the IOF. More than 100 national osteoporosis and bone-related societies in Europe are members of the International Osteoporosis Foundation- and many participated actively in the compilation of the Scorecard.

The aim of the report is to compare, measure, and present how the 27 different countries within the EU care for people with osteoporosis.

Several of the key findings of the Scorecard are:

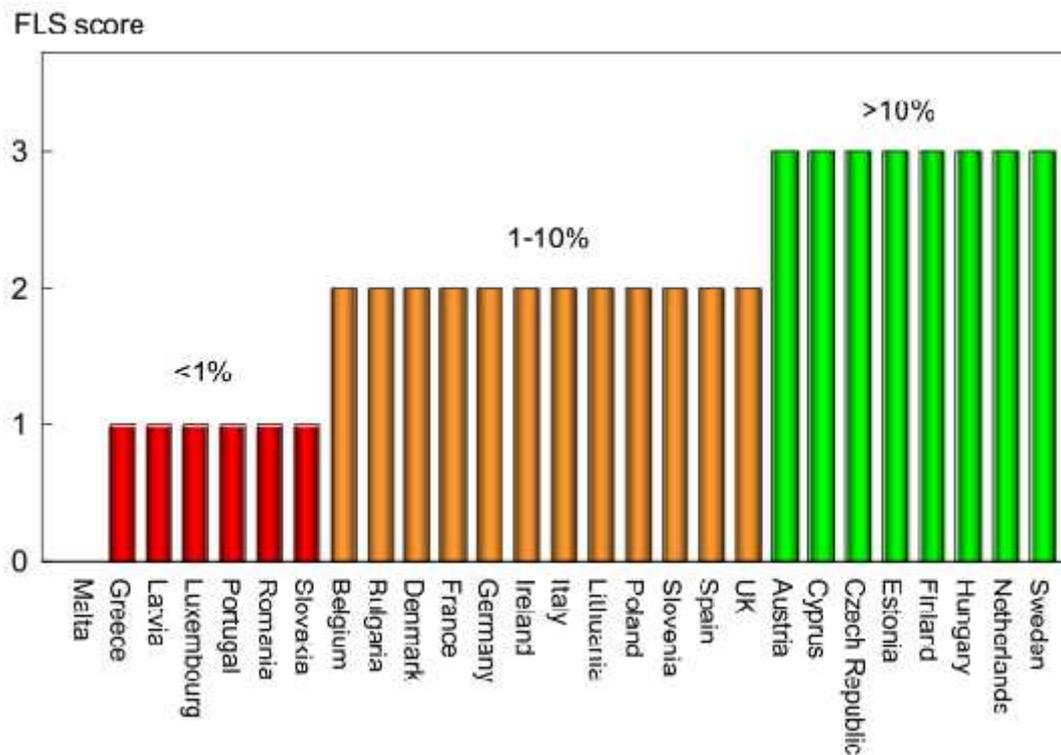
1. The majority of high-risk individuals remain untreated. Less than half of women at high risk of fracture are treated despite the high cost of fractures and the availability of effective medications.

2. Despite the huge economic and health burden, Osteoporosis is not a National Health Priority (NHP) in many EU countries. UK, Romania, Luxemburg, and Bulgaria have recognized the disease as NHP and have begun to take action to implement better prevention and treatment practices. Sweden, Portugal, Italy, France, and Finland have recognized osteoporosis as NHP, but are yet to implement changes and take some meaningful action. The rest of the EU member states such as Spain, Slovenia, Slovakia, Poland, Netherlands, Malta, Lithuania, Latvia, Ireland, Hungary, Greece, Germany, Estonia, Denmark, Czech Republic, Cyprus, Belgium, and Austria has not yet made osteoporosis their National Health Priority.



3. Facilities and access to testing for osteoporosis, as well as utilization of fracture risk algorithms, are inadequate in the majority of countries. The graph below shows scores allocated by country on the availability of fracture liaison services in hospitals, also known as osteoporosis coordinator programs and care manager programs. **Fracture liaison services are offered in more than 10% of hospitals in 8 countries:** Sweden, Netherlands, Hungary, Finland, Estonia, Czech Republic, Cyprus, and Austria. In 11 countries the proportion of hospitals that have a scheme in place was from 1-11%: UK,

Spain, Slovenia, Poland, Lithuania, Italy, Ireland, Germany, France, Denmark, Bulgaria, and Belgium. The rest of the EU27 (Slovakia, Romania, Portugal, Luxembourg, Latvia, Greece, and Malta) have less than 1% of hospitals who have some kind of an osteoporosis care program in place.



4. In some countries individuals with osteoporosis are restricted from accessing effective treatment options;
5. Access to drug treatment that can help prevent fractures varies significantly from country to country;
6. Fracture incidence is poorly documented in the EU; **national hip fracture registries for both sexes are available in only 12 of the 27 member states: Belgium, Denmark, Finland, Germany, Hungary, Ireland, Latvia, Netherlands, Portugal, Slovakia, Sweden, and the UK.**

	Incidence of hip fracture		Established National Fracture Registries		Score
	Quality ^a	Sample ^b	Present	Data ^c	
Austria	G	N	No ^d		3
Belgium	G	N	Yes	Hip	3
Bulgaria			No		0
Cyprus			No		0
Czech Republic	G	N	No		2
Denmark	G	N	Yes	Hip+	3
Estonia	P	R	No		1
Finland	G	N	Yes	Hip+	3
France	G	N	No ^d		2
Germany	G	N	Yes	Hip+	3
Greece	P/F/G	R	No		1
Hungary	G	N	Yes	Hip+	3
Ireland	G	N	Yes	Hip	3
Italy	G	N	No ^d	Hip+	2
Latvia		R	Yes	Hip+	3
Lithuania	F	R	No		1
Luxembourg			No		0
Malta	G	N	No		2
Netherlands	G	N	Yes	Hip+	3
Poland	F	R	No		1
Portugal	G	N	Yes	Hip+	3
Romania	G	N	No		2
Slovakia	G	N	Yes	Hip+	3
Slovenia	F	N	No		2
Spain	F/G	R	No ^d	Hip+	1
Sweden	G	R	Yes	Hip	3
UK	G	R	Yes	Hip	3

Responses derived from questionnaire to National Societies

^a Quality: *G* good; *F* fair; *P* poor [2]

^b Catchment: *N* national; *R* regional

^c *Hip* Registration of hip fracture only. *Hip+* Registration of hip and other fracture outcomes

^d Regional registers available

7. There is a nearly three-fold range of hip fractures throughout the EU ranging from 198 per 100,000 people in Romania to 574 per 100,000 in Denmark.

The Scorecard has revealed that countries with a higher risk of fracture and incidence of osteoporosis do not always make the largest investment in fracture reduction and treatment. This indicates that services are not aligned or operating efficiently enough to reduce the risk of fractures. It is hoped that the scorecard will help to inform a Europe-wide strategy for osteoporosis that aims to reduce fractures, costs and the burden in the population.

Besides the Scorecard, which was a call for policymakers at all levels to develop Europe-wide strategies and parallel national strategies to raise awareness of the disease and provide coordinated osteoporosis care, osteoporosis foundations are continuously making efforts to inform the public about the disease and its impact on the society.

GERMANY

On the international level, there are a few groups involved in the subject of osteoporosis such as **the European Commission Working Group on Osteoporosis** and **The European Foundation for Osteoporosis (EFFO)**. According to the research [conducted by the EFFO](#), osteoporosis self-help groups in Germany are thriving, with **more than 425 in existence**. Most of them are organized by the [Bundesselbsthilfeverband für Osteoporose \(BFO\)](#), and the other 88 are organized by a variety of volunteer associations. Under the BFO, there is also a Federal Association with full-time managing and board of directors. There are also **11 national associations in BFO** functioning in different parts of the country.

UNITED KINGDOM

According to the "[The Osteoporosis Agenda England](#)" report, only 25% of adults are familiar with the term "osteoporosis", and one fifth of women with fragility fracture will suffer 3 more fractures before being diagnosed with osteoporosis. This is why the existence of organizations that deal with this specific subject is crucial to raising awareness. [The National Osteoporosis Society](#) is committed to helping people live and prevent osteoporosis. They provide help in various ways. Firstly, they have formed a charity by donating at least UK£3. Furthermore, they have a media center where they regularly update news about the disease, how to cope with it and cures. The UK is definitely one of the countries with a big number of organizations. [The report on osteoporosis claims](#) that **in the United Kingdom there are 82 self-help groups** organized by the "National Osteoporosis Society."

Furthermore, in the UK there is an [All-Party Parliamentary Osteoporosis Group \(APPOG\)](#), an informal parliamentary group that consists of Westminster MPs and other Peers. Their main objective is to inform and raise awareness through presentations, speeches, and similar activities.

RULES AND REGULATIONS

[The European Union](#) (EU) is now a trading bloc comprised of 28 countries in Europe. All Member States adopt common external trade policy and measures. As it is stated in [Trade Regulations of the EU](#) one of the most important aspects of the EU trade policy is that the EU is a customs union. The same import duties are charged on imports from third countries regardless of the country of entry into the EU. The main principles of customs law are regulated at EU level, although the customs authorities of the EU Member States are in charge of their application. However, many of the EU member states maintain their own list of goods subject to import licensing. As an example, we will take Germany's import list (Einfuhrliste) that includes goods for which licenses are required, their code numbers, any applicable restrictions, and the agency that will issue the relevant license. The Import List also indicates whether the license is required under German or EU law. Second important part of the rules and regulations of the EU is Importing Documentation, [The Single Administrative Document](#). The SAD describes goods and their movement around the world and is essential for trade outside the EU, or of non-EU goods. Goods brought into the EU customs territory are, from the time of their entry, subject to customs supervision until customs formalities are completed. Goods are covered by a Summary Declaration which is filed once the items have been presented to customs officials. The customs authorities may, however, allow a period for filing the Declaration which cannot be extended beyond the first working day following the day on which the goods are presented to customs. Speaking about pharmaceuticals, all medicines in the EU [must be approved](#) at national or EU level before being placed on the market. The safety of a drug sold in the EU is monitored throughout its life. If it is dangerous, swift action is taken; sales are suspended, or the marketing permit is withdrawn. The European Commission, the national authorities, and the [European Medicines Agency \(EMA\)](#) in London all play a part in this system. The EMA helps national regulators by coordinating the scientific assessment of medicines' quality, safety, and efficacy.

GERMANY

Almost all goods can be imported into Germany. For medicinal products, it applies the [Medicinal Products Act \(Arzneimittelgesetz\)](#). Medicinal products are monitored by customs officers in accordance to the Medicinal Products Act.

They make sure that products have the required permits, the products are approved, have labels and include a package leaflet in German. **The final decisions concerning medicinal product legislation are made by regional authorities.**

According to [the official site of German customs](#), when importing medical products, companies need **an import permit and a certificate from the country of origin**, or an appropriate certificate from a medicinal authority from the municipality where your business is established.

Since 2004, patients can order pharmacy medicines in Germany. Generally, all rules and regulations that apply for a retail pharmacy apply for online pharmacies. But, if we take a closer look at the [German Institute for Medical Documentation and Information](#), there have been a couple of changes in recent years. Since June 2015, a new section of the German Drug Law came into power. This is part of the national implementation of the European “falsified medicines” directive. In accordance with this new regulation, every web site that sells pharmaceuticals has to display a common security logo and has to be on the national register. This register only includes pharmacies that have an official permit for mail order of medicines for Germany. Entities need to be in the “German Register of Online Medicine Retailers” and possess a security logo that [DIMDI](#) provides. The German register includes pharmacies that have an official permit to mail products to Germany.

UNITED KINGDOM

The leading governing body in the UK is the [Regulatory Agency \(MHRA\)](#) which regulates medicines, medical devices, and equipment. They are the guards of public’s health. They ensure that medicine meet the standards of safety and quality, promote international standardization to make sure biological medicine are safe etc. The general rule is that medicines need to be licensed before being allowed in the UK. [According to the Medicines and Medical Devices Regulation](#), the MHRA works closely with the European regulator, the European Medicines Agency (EMA), and is recognized as a trusted source of expertise. They also collaborate with the US Food and Drug Administration (FDA), UK government agencies and other international regulators. So, the MHRA does its monitoring with: **regular inspections reports from healthcare professionals, annual routine sampling, publishing standards of ingredients, review of products, assessment of misleading and incorrect information, managing the General Practice Research Database (GPRD) and enforcing regulations and obligations.**

Furthermore, EU is a big market with many potential customers and suppliers. This market is generally easily accessible because unitary regulations and standards apply in all of the 28 countries. So, for most products, if you fulfill UK requirements you will meet EU requirements. According to this [article about import regulations](#), you will need at least one more license to trade medicines.

But with the [Registration, Evaluation, and Authorisation of Chemicals \(REACH\) legislation](#) if a company imports more than a ton of chemicals per year, it must register with the **European Chemical Agency**. If there are restrictions, they can be product specific or trade specific. Product specifics face certificates, licenses, and documentation. If an import has restrictions or limitations, this means you will have to [pay anti-dumping duties](#).

Online selling and buying of products are permitted in the UK. But from July 1, 2015, customers can easily check if their seller is legit or not. According to the [General Pharmaceutical Council](#), all entities selling medicines via the internet **must be registered with the Medicines and Healthcare Regulatory Agency (MHRA)** as a registered online seller. They also need to possess a new EU common logo.

Companies can apply to register with the General Pharmaceutical Council (GPhC) as a pharmacist if they:

- have a [UK-recognized pharmacist qualification](#);
- are a European Economic Area ([EEA](#)) national with an [EEA pharmacist qualification](#);
- an overseas ([non-EEA](#)) qualified pharmacist, or a non-EEA national with an [EEA pharmacist qualification \(other than a UK pharmacist qualification\)](#).

Registration forms and information varies depending on which country the pharmacists gained their qualifications in:

- [UK-recognized pharmacist qualifications](#) for pharmacists who completed their training in England, Scotland, Wales or Northern Ireland;
- [EEA-qualified pharmacists](#) for nationals of EEA countries who qualified as a pharmacist in an EEA country other than the UK;
- [Overseas \(non-EEA\) qualified pharmacists](#) for pharmacists who qualified overseas (non-EEA) or nationals of non-EEA countries with an EEA pharmacist's qualification (other than a UK pharmacy qualification);
- [Renewals](#) for those already registered but wishing to renew their registration.

SUMMARY

Based on the WHO diagnostic criterion approximately 22 million women and 5.5 million men aged between 50-84 years are estimated to have osteoporosis in the EU (2010 figures).

Due to changes in population demography, the number of men and women with osteoporosis will rise from 27.5 million in 2010 to 33.9 million in 2025, corresponding to an increase of 23%.

The number of new fractures in 2010 in the EU was estimated at 3.5 million, comprising approximately 620,000 hip fractures, 520,000 vertebral fractures, 560,000 forearm fractures and 1,800,000 other fractures (i.e. pelvis, rib, humerus, tibia, fibula, clavicle, scapula, sternum, and other femoral fractures). Two thirds of all incident fractures occurred in women.

In 2010, the number of deaths causally related to fractures was estimated at 43,000: In women: approximately 50% of fracture related deaths in women were due to hip fractures, 28% to clinical vertebral and 22% to other fractures. In men: corresponding proportions were 47%, 39% and 14%, respectively.

In 2010, 3.3 million individuals aged 50 years or more had sustained a prior hip fracture (prevalence of prior hip fracture). The corresponding number of men and women with prior clinical vertebral fractures was estimated at 3.5 million.

Incidence rates of hip fractures were available for most, but not all, countries of the EU whereas information on country-specific incidence rates of forearm, clinical vertebral fractures and other osteoporotic fractures was scarce.

In **Germany**, more than 5 million people aged +50 years have osteoporosis, and the cost for medical expenses is expected to increase by 25% or more than 11 billion euros by 2025.

In the **United Kingdom**, it's estimated that 1 in 2 women and 1 in 5 men above the age of 50 will break a bone. People in the UK experience more than 300,000 fragility fractures yearly, and these are often caused by just a minor bump or fall. Hip fracture alone costs around £1.5 billion (€1.7 billion) in English hospital costs, without taking into account the high cost of social care.

***The sample contains only information for Germany and the United Kingdom**