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Hampered access to innovative cancer drugs in Spain

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Medical societies, patient associations, and independent experts are pressing for expedited access to innovative cancer treatments in Spain, citing a noticeable lag and lack of alternatives in the process.

Spain faces a “structural problem” when assessing and funding innovative cancer drugs. Between 2017 and 2021, Spanish patients waited an average of 611 days to access innovative therapies – far above the figures for Germany and Denmark, which are 102 days and 145 days respectively.

This report is also available in Spanish.
Experts call for faster access to innovative cancer treatments in Spain

By Berta Pinillos Cardiel | EuroEFE

Languages: Deutsch | Spanish

Access to innovative cancer treatments in Spain must be expedited, medical societies, patient associations, and independent experts have urged, citing concerns over marked delays and a lack of alternatives.

Spain faces a "structural problem" when assessing and funding innovative cancer drugs, with patients waiting an average of 611 days to access therapies between 2017 and 2021, according to a new report presented at a conference in Madrid. These figures contrast sharply with Germany's 102 days and Denmark's 145 days, emphasised Candela Calle, general director of non-profit Fundació Sant Francesc d'Assís and director of the advisory council for OncoLAB, a forum for knowledge exchange in oncology in Spain, backed by AstraZeneca.

The report, titled Solutions Now: Bringing Innovation to the Patient, was commissioned by the advisory council of OncoLAB, which is composed of over 20 scientific societies and patient associations.

Experts stressed the evident lack of agility and alternatives in accessing oncological innovations in Spain, while also calling for more systematic methods and greater transparency in drug pricing and funding. The report highlighted that there is "no public information" on the status, feedback, or claims from different participants in therapeutic positioning reports.

Such delays, experts noted, hinder access to innovative therapies, causing Spanish cancer patients to miss out on potentially life-saving treatments and, consequently, a higher chance of survival.

Additionally, the advisory council believes Spain should prioritise "bringing innovation closer to cancer patients", viewing it as an opportunity from healthcare, economic, and social perspectives.

Calle underscored the significance of investment, citing studies that show every euro invested in innovation can save up to seven euros in care.

The report also mentioned a perceived "stigma" concerning healthcare economics has hindered the timely introduction of new medications.

OncoLAB proposes enhancements in evaluating and funding new therapies, advocating for a "more consistent" definition of pharmaceutical innovation. Experts believe this can pave the way for a consensus on criteria facilitating patient access.

Voices from the EU Parliament

The revision of European pharmaceutical legislation must be expedited, Members of the European Parliament (MEPs) from Spain highlighted during the event, which was moderated by Javier Tovar, EFEsalud director.

Currently, the Parliament and the Council are working on their positions in response to the European Commission's proposal for a new Directive and a new Regulation to revise and replace the existing general pharmaceutical legislation.

Socialist MEP Nicolás González made the case that the legislation has been untouched for "20 years", highlighting the urgency of issues like drug shortages and insufficient drug production in the EU.

European People's Party MEP Pilar del Castillo emphasised the absence of a European industrial policy, made evident during the pandemic when supply chains were found outside the EU. She insisted on the pharmaceutical industry's importance and pressed for reforms before the upcoming European Parliament elections.

Meanwhile, Renew MEP Susana Solís emphasised that European legislation should prioritise patients, eliminate disparities in access to innovation across the EU, and incentivise the biopharmaceutical industry.

Vox MEP Margarita de la Pisa said there's work ahead on the reform, advocating for faster, more accessible treatments. She expressed that the solution might not solely be a European directive.

The event also featured Marta Moreno, director of Corporate Affairs and Market Access at AstraZeneca, who stressed the importance of Europe and pharmaceutical companies collaborating to find alternatives for equitable and efficient access to medical advancements.

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Access to pharmaceutical innovation in oncology is access to the future

By Candela Calle

Languages: Spanish

With the science moving forward in addressing the burden of cancer, access to potentially life-saving treatments needs to be improved through pharmaceutical regulation in Europe and Spain in particular, writes Candela Calle.

The fight against cancer is one of the most challenging battles of our era. As we advance our understanding of the different pathologies, there is a constant stream of advances in cancer research and treatment development. However, one of the biggest hurdles facing patients is access to these innovations.

In the context of the upcoming pharmaceutical regulation in Europe, currently in the pipeline, it is crucial to reflect on the importance and significance of improved access to new diagnostic techniques and new cancer treatments for the lives of thousands of patients.

Facilitating access to innovative oncology treatments and techniques would not only improve patients’ survival and quality of life but also prolong their life expectancy. Revealing data show that the 1.74-year increase in life expectancy in the first decade of this century in developed countries is 73% directly attributable to the positive effect of new drugs on the health of the population.

In recent months, the need for improvements in the process of evaluating and financing new drugs has become apparent. Improvements that contribute to a more agile, faster access, in a transparent, predictable and, above all, more participatory approach. When a promising new treatment emerges on the horizon, patients cannot afford to wait years to access it because of bureaucratic red tape.

Pharmaceutical regulation must simplify and speed up approval processes to ensure that patients have timely access to potentially life-saving treatments. Cancer does not wait, so the time to lay the groundwork for progress is now.

Moreover, access cannot depend on a patient’s geographic location or financial capacity. European pharmaceutical regulation must ensure equal access for all EU citizens, regardless of their country of residence. This could be achieved through collaborative policies between countries.

Another area of concern relates to the current system of incentives for innovation, as it does not encourage the creation of a competitive environment for industry to increase and extend to all countries of the European Union flexible and equitable access to therapeutic innovation.

To solve the problems of access to innovation, the work must start in the member states themselves, by putting in place effective measures at the national level that are aligned with the European target of reducing access times by an average of approximately 400 to 180 days, listening more to patients, and supporting and evaluating medicines early.

In this process, one aspect is of great importance, the definition of the concept of ‘pharmaceutical innovation’, the basis on which to establish clear criteria to facilitate access for patients.

Pharmaceutical innovation refers not only to the creation of new drugs, but also to the significant improvement in existing treatments; the development of new diagnostic techniques and, in general, the creation of novel therapeutic approaches. These advances can make a difference in patients’ lives and should be recognised as such in regulation.

And in Spain?

The state of patient access to innovative treatments in Spain has worsened in recent years, as shown by the WAIT1 study – published in 2023 – which reports that Spanish patients had to wait an average of 611 days in the period analysed – between 2018 and 2021 – to access innovative therapies already pre-approved by the EMA (European Medicines Agency).

In Germany and Denmark, this period is reduced to 102 and 145 days respectively. Taking these countries as a reference, as well as France, which, although facing the same problem as Spain, has set up early access programmes, the lack of agility and alternatives to the process of access to oncological innovation in Spain is evident.

In the context of the forthcoming European pharmaceutical regulation, it is essential that Spain’s national health system (NHS) advances accordingly and adopts measures that guarantee efficient access to pharmaceutical innovation in oncology. The Spanish NHS has made significant progress in oncology care but still faces significant challenges in terms of access to pharmaceutical innovation.

To this end, the OncolAB Advisory Board, composed of representatives from scientific societies, foundations and professionals in the oncology field and promoted by AstraZeneca, has recently developed and presented the consensus document "Now, solutions: bringing innovation closer to the patient" to contribute to the definition of the meaning of ‘pharmaceutical innovation’ and to the establishment of criteria that facilitate patient access to the most advanced treatments.

As a society, we must commit to unleashing hope and giving patients the best possible tools to beat this serious disease. Pharmaceutical regulation has a key role to play in this mission.

OPINION

DISCLAIMER: All opinions in this column reflect the views of the author(s), not of EURACTIV Media network.
Spanish MEPs hope for ‘balance’ between incentives and access in pharmaceutical reform

By Ana Báez and Desirée Montes | EuroEFE

Languages: Français | Deutsch | Spanish

Spanish MEPs from different political groups hope to find a balance between incentives for industry innovation and equal access to medicines as EU lawmakers work on a revamp of the pharmaceutical legislation.

The European Parliament has been debating the proposed revision of the European pharmaceutical strategy the Commission presented in April. The European Parliament has been debating the proposed revision of the European pharmaceutical strategy the Commission presented in April.

The deadline for delivering amendments to the Committee on the Environment, Public Health and Food Safety is 13 November for the regulation and 14 November for the directive.


On this issue, Margarita de la Pisa of the European Conservatives and Reformists Group for Vox, argued that it makes no sense to improve accessibility by “conditioning the incentive,” because if this issue is neglected, “patients are left unattended.”

“Disincentivising innovation is to disincentivise the possibility of treatments for diseases that do not exist today,” she said.

De la Pisa argued that with this new incentive scheme proposed by the Commission, there is a concern about a possible decrease in the development of new medicines in Europe and a transfer of that innovation “to other places.”

Currently, Europe is governed by a system of regulatory data protection for innovative drugs of eight years plus two years of market protection, with the possibility of a further extension, which ultimately gives a period of protection of 10 or 11 years before the entry of generic drugs.

The new regulation proposes a minimum period of regulatory protection of eight years, which includes six years of data protection and two years of market protection.

Additional periods of protection are given for those that meet certain criteria, such as introducing medicine in all member states, addressing unmet medical needs, or conducting comparative clinical trials. Overall, this can increase the total period to up to 12 years.

But according to De la Pisa, the proposal of extending the protection based on these criteria is “open to interpretation” and therefore “provides legal uncertainty” when developing a drug.

“There is a lot more work to be done to ensure that this pharmaceutical legislation is the tool we need in Europe,” she said, stressing that it should favour patients, “those with a vocation for research,” and the industry so that it can develop and not be dependent on third parties.

The acting Spanish health minister, José Manuel Miñones, acknowledged on 23 October that during the six-month Spanish presidency, there would not be enough time to achieve a breakthrough on pharmaceutical reform, given the “complexity” of the matter.

Montserrat said that health “has not been one of the main priorities” for the Spanish presidency. “If it had been, the pharmaceutical legislative review would probably have more chance to succeed.”

“We want to have all the amendments to the text in November and be able to vote on it in the penultimate plenary session of the term (...) but considering the complexity of this legislation of more than 400 articles, the timetable is very tight,” said Solís from Renew Europe.

For her part, Montserrat also said that it was in her group’s interest that “the package comes out in this legislature”, but clarified that the European Parliament needs the Presidency of the Council of the EU, currently held by Spain, to also “be pushing it”.

The four interviewees agreed that their respective political groups will present the amendments to the pharmaceutical legislative review in time for the penultimate plenary session of the current term next April, given that the European elections will be held from 6 to 9 June.

However, they all said that the European Commission proposal arrived with many delays, which meant the European Parliament had to work to a tight schedule and with the possibility of not finalising the revision in this mandate.
Ana Rodríguez, OncoLAB coordinator: We must speed up innovation to help patients

By Berta Pinillos Cardiel | EuroEFE

Languages: Spanish

More and more innovative drugs and biomarkers for cancer are being developed, which is why the coordinator of the OncoLAB Advisory Board, Dr. Ana Rodríguez Cala, assures that “we need to hurry up” to introduce the new treatments into the healthcare system to benefit patients.

In an interview with EFEsalud, Rodriguez analyzed the objectives of OncoLAB, a space for analysis and sharing of knowledge in the field of oncology in Spain, formed by 20 scientific societies and patient associations, which have the support and collaboration of AstraZeneca. But it also emphasizes the importance of research, early detection, and the need to shorten the time it takes for patients to access new therapies.

Rodriguez, who was director of Strategy and Projects at the Catalan Institute of Oncology, stresses that OncoLAB was created to put cancer on the political agenda and work, above all, on innovation in this field.

“As in biomarkers, in new products that are coming out, in some way, we have to incorporate them, so that patients can benefit,” said Dr. Rodriguez.

Rodriguez referred to the document “Now, solutions: bringing innovation closer to the patient”, which OncoLAB made public a few weeks ago and which, among other aspects, points out that “the lack of agility and alternatives to the process of access to oncological innovation in Spain is evident.”

In addition, the document considers that Spain “faces a structural problem” in terms of the procedure for evaluating and financing innovative cancer drugs.

“In the document, different points are evaluated and one of them is basically, above all, to bring or improve everything related to innovation, to bring innovation and treatments to the population,” said Rodriguez, adding that they will present the work to Spain’s Ministry of Health so that they can evaluate it.

She stressed the need to support research into new diagnostic methods since there is increasing talk of precision medicine and early diagnosis.

“In this sense, it is very important to support the digitization of genetic and clinical information of patients. And also to use artificial intelligence,” said Ana Rodriguez, who is also currently a CSR and Quality consultant.

As for the delay in the approval of innovative drugs in Spain, she points to the bureaucracy that “slows everything down,” whereas in other countries the processes are more agile. She is therefore in favor of analyzing whether it is possible to “shorten some links in the chain.”

She also points out that this requires political will.

Another of the contributions proposed by OncoLAB, Rodriguez said, is that just as the organization has an advisory council made up of 20 scientific societies and patient associations, Spain’s Ministry of Health should also have a similar one.

“There should be a cancer advisory council within the ministry that would be made up of different experts, “of a multidisciplinary nature,” with oncologists, hematologists, anatomo-pathologists, and radiologists, among others, Rodriguez explained.

She points out that the ministry already has a commission that advises on the pharmaceutical service of Spain’s National Health System, which also includes different profiles.

“Society is moving very fast. And we are all moving very fast. I mean that in some way they should speed up, because more and more innovative drugs, more biomarkers are coming out, so we have to hurry up to be able to introduce these innovative treatments that are going to benefit patients,” she said.

In addition to flexibility and agility, Rodriguez also stresses the importance of early diagnosis, because if cancer is detected at an early stage the type of treatment the patient will receive is very different, which would be cheaper for the healthcare system as a whole.

Although in Spain there are screening programs, such as for breast cancer, in which 85% of women participate, there are others, such as for colon cancer, where the participation rate is less than 60%.

“The most important thing in any disease is to catch it in time because the treatment will be very different and the cost will also be very different,” the OncoLAB coordinator said.

And investment in research and innovation is “extremely important,” said the expert, who believes that all the steps that have been taken to advance the fight against cancer have been thanks precisely to that.

“Investing in innovation and research is an important step forward and in the medium term people’s health is above all going to recover, we are going to improve their quality of life at all levels. We must always keep it in mind and we should invest more,” she said.
Pharmaceutical reform poses challenges for innovation in undiagnosed diseases

By Lucía Leal | EuroEFE

The European Commission’s proposed pharmaceutical reform could impact innovation in treating rare or undiagnosed diseases in Europe, industry representatives and patient associations told EFE.

Daniel De Vicente had to wait until he was 36 to be diagnosed with a condition that had troubled him since he was six months old: acid sphingomyelinase deficiency (ASMD), a rare and degenerative disease for which there is still no approved treatment in Spain.

For the last six years, he has been part of a clinical trial for six years, which has allowed him to “reverse” the progression of his disease, benefiting four other Spanish patients as well.

“Spain is among the European countries where a large number of clinical trials are conducted, but then there’s not good access to treatments compared to other European countries. It’s a bit of an inconsistency,” De Vicente, who is a board member of the Spanish Federation for Rare Diseases (FEDER), explained in an interview with EFE.

Henna Virkkunen is a Finnish lawmaker with the EPP Group.

Languages: Spanish

Only about 58% of drugs approved by the European Medicines Agency (EMA) are marketed in Spain, compared to 90% in Germany, with a 629-day delay in Spain, according to the ‘Indicator of Waiting Time for Access to Innovative Therapies’ (WAIT) report.

The delay is even longer in Eastern European countries like Poland and Romania, particularly for orphan drugs, which treat rare diseases, according to the report, published in April by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Addressing Access with Incentives

To address this, as part of its pharmaceutical reform proposal, the European Commission suggests incentives for manufacturers who offer their product in all 27 member states within the first two to three years.

“We want to create a single market for medicines in Europe, and a central element of this is more equal access to medicines for all patients, no matter where they live. We cannot have second-class patients. Everyone deserves to have access to existing treatments for their disease,” a Commission spokesperson told EFE.

Currently, the company that has developed a new drug is the only one allowed to use the data from its clinical trials for the first eight years. Other companies cannot sell their generic derivatives until another two years have passed, making the total period of exclusivity 10 years, or up to 11 years in some cases.

If the Commission’s proposal is successful, which still needs to be debated and approved by the European Parliament and member states, this period would be reduced to eight years.

It can be extended in particular cases: if medicines are launched in all EU countries (+2 years), if they address unmet medical needs (+6 months), or if comparative clinical trials are conducted (+6 months).

For rare disease medicines, the standard duration of market exclusivity will be nine years. Additional years of protection will be applied if companies address a high unmet medical need (+1 year), launch the medicine in all EU states (+1 year), or develop new indications for an already authorised orphan medicine (up to 2 extra years).

Icíar Sanz de Madrid, international department director at FarmaIndustria, argued that meeting the Commission’s new requirement is “impossible” due to the complexity and fragmentation of the EU’s pharmaceutical market.

“Incentives won’t change access as it is national procedures that govern access, pricing, and reimbursement conditions,” she told EFE.

From the Spanish Association of Orphan and Ultra-Orphan Drug Laboratories (AELMHU), Beatriz Perales shared similar concerns. “The Commission’s proposal doesn’t reflect the reality of marketing drugs in Europe,” she told EFE.

“It does not reflect the existing differences between each member state in terms of financing an orphan drug, nor the difficulties it would pose for small and medium-sized enterprises to market their drugs across the entire EU in a short period of time.”

Simone Boselli, public affairs director at the European Organisation for Rare Diseases (EURODIS), stressed that “in rare diseases, if you don’t do it across borders, you don’t get more patients” for the investment to be worthwhile for the laboratory, because these kinds of illnesses have a prevalence of fewer than five cases per 10,000 people in the EU.

The Commission argues its system will expand access to “about 70 million more people” in the EU, maintaining one of the “world’s most generous” incentive systems and a faster EMA authorisation process.

Unmet medical needs

Another aspect of the reform that concerns EURODIS, AELMHU, and FarmaIndustria is the introduction of two concepts associated with greater market protection: “unmet medical needs” and “high-priority unmet medical needs”.

The first concept refers to innovative drugs that treat life-threatening or “severely debilitating” diseases, provided their approval signifies a “significant reduction in the morbidity or mortality” of the condition and there is no existing product in the Union market to treat it, or if there is, it poses too many risks.

The second category is reserved for rare diseases where the introduction of such treatment would represent an “exceptional therapeutic advancement”.

These concepts are too strict, in Boselli’s words. He warned that “very, very few of the therapies that we have are transformative or curative”, fearing the loss of incentives depending on the interpretation of this requirement.

FarmaIndustria’s Sanz de Madrid pointed out that they “advocate for a much broader definition” which includes, for example, diseases that significantly deteriorate the quality of life.

Amendments proposed in the European Parliament’s Public Health Committee (ENVI) follow this line, but it is too early to predict the Parliament’s final direction as the debate is expected to extend well beyond the June 2024 European elections.

If the proposal is passed without changes, the FarmaIndustria representative believes it would send a “clear signal to foreign investors” that pharmaceutical innovation in Europe is going to be “unprotected”.

“We have calculated that by 2030, the market share in research would be 54% in the United States and 25% in the European Union” if the reform is approved, she warned.
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