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WELCOME TO THE FIRST ISDB NEWSLETTER OF 2026

2026 started as strangely as 2025 ended. The world seems in permanent turbulence. Nevertheless – or perhaps because of this - we wish you the best for the coming year.

In 2026 we expect two trends: still a lot of new drugs for niche markets with very high prices; and most drug spending going to anti-obesity drugs, without any mention of the food industry's responsibility for the obesity epidemic. No new advances are expected in the short term for common problems such as pain management, arthritis, depression or antimicrobial use.

For our core activity of providing drug information, the explosion of Artificial Intelligence is the main point of interest. We all continue to invest in critical appraisal, evaluation of benefits and harms of medicines and posing questions about cost-effectiveness. We publish beautiful articles in our drug bulletins. But...where is our information in the messages of CHATGPT, Gemini or Copilot?

The abundant presence of fake news and sponsored information on the internet and algorithms linked to biased information pushes patients towards irrational drug use. But what about health professionals: can we expect busy physicians and pharmacists to easily resist the attractive summaries created by AI, answering whatever question they have and produced in a few seconds?

The trust in AI and threat to independent information has extended to governments that no longer see the need to finance an independent drug bulletin, as you will see from the article on GeneesmiddelenBulletin (GeBu), the national Dutch drug bulletin, in this Newsletter.

What can we do? The most important issue remains our readers' trust in our Bulletins and the added value of reading and understanding a full evidence review. However, it is clear that AI is a serious challenge that ISDB needs to consider. Also, as ISDB we have to look for answers. Looking for partnership is certainly needed, we come back to this in the coming months.

ISDB General Assembly

As you can see from the beautiful pictures in this Newsletter, the General Assembly in Verona was great. A big thanks to Roberta Joppi and her team in Verona for perfect organisation. Very interesting talks and discussions, friendship and of course the best food in the world.

The assembly voted also for a new executive committee. Some very important members decided not to run again for the executive after serving for several terms. Thank you so much to Rita Kessler (La Revue Prescrire) for acting as President, Luis-Carlos Saiz (Boletin de Información Terapéutica de Navarra), as Secretary, and Nuria Homedes (Boletin Farmacos) as board member. Your contributions to ISDB during the last few six years has made a huge difference to the network's survival and growth. Over the last 3-year term, major achievement were the revamp of the ISDB website, organisation of subcommittees on ISDB membership and priorities, and of course the newsletter and AGM.

Luckily enough two members of the former executive have stayed on to assure continuity: thanks to Barbara Mintzes (Therapeutics Initiative and Drug and Therapeutic Bulletins) and Roberta Joppi (Infofarma). New members voted in at the AGM include Thierry Christiaens (Folia Pharmacotherapeutica), Natalia Cebotarenco (Medex), Carlos Duran (Excellensis Ecuador) and Ella Feldman (BUKO Pharma-Kampagne). At the first meeting, Thierry was elected president, Barbara secretary general and Ella treasurer.

After the AGM, Worst Pills, Best Pills put forward Nina Zeldes as a candidate, as a means to provide additional support for ISDB's work. The executive welcomed her unanimously, adding a link to the USA and an enthusiastic additional member. This is consistent with the constitution point 5.2: "An OGM or the Committee may, by a simple majority, appoint a person who is willing to act to be a Committee member either to fill a vacancy or as an additional Committee member, provided that the maximum of eleven is not exceeded."

Ending with good news: Welcome to a new African ISDB member

The African Journal of Primary Health Care & Family Medicine is an international journal that reaches many African countries. Last year, they began to publish a separate "Therapeutic Letter" section within the journal several times a year. This stemmed first from a collaboration to reprint relevant issues of the Therapeutics Initiative (Canada)'s 'Therapeutic Letters' and has extended to include locally produced drug bulletins. We would like to extend a big welcome to them to ISDB as new Associate Members!

Further information about the new Associate Member can be found at https://phcfm.org/index.php/phcfm

ISDB General Assembly 2025: Advancing Independent Drug Information for Global Health

From October 1–3, 2025, Verona became the focal point for international dialogue on independent drug information during the General Assembly of the International Society of Drug Bulletins (ISDB). The event brought together bulletin editors and other experts and stakeholders for three days of rigorous debate, methodological reflection, and critical analysis—offering a comprehensive and timely perspective on the evolving relationship between scientific evidence, regulatory frameworks, and public health.

Opening Reflections: Revisiting ISDB's Mission

Gianni Tognoni, one of the ISDB co-founders, inaugurated the Assembly by urging participants to critically examine the network's 40-year trajectory. He underscored a pressing reality: scientific progress increasingly coexists with market forces that exacerbate health inequities. In this context, ISDB must reaffirm its identity and redefine its mission to safeguard independent, evidence-based information.

Adriane Fugh-Berman (PharmedOut) followed with a compelling analysis of pharmaceutical industry influence on medical knowledge—from disease creation to redefinition. Drawing on examples such as menopause, dementia, and gastroesophageal reflux, she exposed strategies that prioritize market logic over patient needs. Her message was clear: independent bulletins must intensify efforts to provide unbiased, evidence-driven counterpoints that serve public health.

European HTA and JCA: Navigating New Regulatory Landscapes

Day two focused on technical developments shaping drug evaluation. Barbara Spix (IQWiG) presented the European Regulation on Health Technology Assessment (HTA) and the launch of Joint Clinical Assessments , detailing:

- Regulatory structure and governance involving 44 HTA organizations,
- Scope covering medicines with new indications and high-risk devices,
- Procedural flow from scoping to endorsement.

A critical challenge lies in constructing PICOs (population, intervention, comparator, and outcomes) that reflect diverse healthcare systems across 27 EU countries under tight timelines.While Joint Clinical Assessments provide a shared evidence base, decisions on therapeutic value and cost-effectiveness remain national responsibilities.

Panelists Jörg Schaaber, Silvio Garattini, and Nicolas Demanet emphasized vigilance to ensure independence and public health orientation in these processes.

Training and Emerging Methodologies

The Assembly featured a dedicated session on emulated trials, led by Viet-Thi Tran (Université Paris Cité), highlighting both the promise and pitfalls of this increasingly adopted approach in observational research. Emulated trials represent an important methodological advance to ensure equivalent follow-up time between comparison groups in observational research.

Confounding, the other key limitation of observational research as compared with RCTs, is addressed similarly to other observational research.

Lessons from the Pandemic

The afternoon session examined Covid-19 vaccine management as a case study in crisis communication. Speakers Tom Jefferson, Nicola Magrini, and Maria Francisca Aldunate Gonzalez addressed systemic weaknesses—limited data access, accelerated regulatory timelines, and political pressure—underscoring the urgent need for transparency in emergencies.

Obesity: Clinical Paradigm Shifts

Stefan Weiler and Staffan Svensson explored obesity's evolving definition and treatment landscape, stressing the importance of clear, evidence-based communication to patients and professionals. Disease-oriented advertising and promotional messages to clinicians increasingly frame obesity as a chronic disease. This is consistent with long-term drug treatment and shifts the focus away from a public health orientation.

ISDB Strategic Outlook

The final day focused on ISDB's internal governance, including committee updates, membership trends, and financial status. The newly elected Executive Committee presented the strategic plan, reaffirming ISDB's commitment to strengthening its global network and promoting equitable access to reliable drug information.

Closing the Assembly, Roberta Joppi highlighted ISDB's vitality and its indispensable role in advancing transparency, fairness, and accessibility in global health—a mission more critical than ever amid accelerating scientific complexity and industrial pressures.

Executive Summary

The ISDB General Assembly 2025 underscored the organization's pivotal role in safeguarding independent drug information against growing industrial influence and systemic challenges. Key takeaways include:

- *Strategic Renewal*: ISDB is redefining its mission to address health inequities and market-driven narratives.
- *Regulatory Transformation*: European HTA and JCA introduce opportunities and risks requiring vigilant oversight.
- *Methodological Innovation*: Emulated trials and pandemic lessons highlight the need for rigorous, transparent evidence.
- *Global Commitment*: ISDB's strategic plan prioritizes network strengthening and equitable access to reliable information.

In an era of rapid scientific change and increasing commercial influence, ISDB remains a key initiative supporting transparency and integrity in public health decision-making.

G.A. Gallery

The importance of independent information and the essential role played in it by Ge-Bu

By Marielle AE Nieuwhof

Published on Dicember 22, 2025
Full article available at: 10.35351/gebu.nl.2025.12.33

Translated by Jan Klerkx

Thanks to an amendment to the Dutch government's Interim Budget Report passed by the Dutch parliament, Ge-Bu has been granted another year of government funding, but its continued existence remains uncertain. In the previous year, few parties have shown a willingness to ensure permanent funding for Ge-Bu. Why does Ge-Bu, as a source of independent information, deserve all the help it can get, and why can such information not be found using AI?

Ge-Bu's Indication

What is Ge-Bu's opinion?

- Ge-Bu provides indications regarding the value of treatment with drugs or medical devices based on extensive and independent critical reviews of research.
- Ge-Bu is the only source of information in the Netherlands to have these assessments written and reviewed by care providers who are not allowed to have any ties with the pharmaceutical or medical device industries.
- AI is not suitable for passing independent critical judgements on scientific research; for the time being, it can only be a tool for finding and summarising literature.

Future of Ge-Bu remains uncertain

Ge-Bu can continue to publish independent articles for another year, as the Dutch parliament has passed an amendment to the government's Interim Budget Report. At the time, the existence of Ge-Bu, which is completely dependent on government subsidies, was under threat as the Ministry of Health, Welfare and Sport wanted to discontinue the subsidy. And yet, its continued existence seems more relevant than ever, in view of the abundance of disinformation going around, the ever-present commercial pressure from the pharmaceutical and medical device industries, and the increasingly negative opinions on the value of science. In addition, subsidies ensure that articles are freely available to everybody and do not disappear behind a paywall.

Ge-Bu helps care providers by critically reviewing and summarising scientific research. It is a challenge for care providers in their daily practice to respond to articulate patients who look up everything on Google, and to guide them towards optimised treatment. It is almost impossible to make a relevant selection from the huge volumes of scientific information available. This is precisely the problem for which Ge-Bu provides assistance, and care providers can be confident that this is done in a completely independent way. Why is this independent provision of information so important?

Ge-Bu considers scientific interests

When writing articles, Ge-Bu's sources are exclusively scientific, and it critically assesses the research described. It goes without saying that the pharmaceutical industry mainly wishes to publish favourable information about a drug it has developed. Even if we assume that they have only the best intentions and want to advance patients' health, it is their commercial interests which are their number one priority [1],[2],[3].

Although research sponsored by the pharmaceutical industry is often methodologically sound and hence carries a low risk of bias, this does not mean that there is nothing to criticise [1]. This is because there are various

ways to present the findings of a study in a more favourable light. What are the consciously or subconsciously applied tricks that Ge-Bu pays attention to when reviewing research studies?

Results versus conclusions

Whereas the Results section in a research paper often presents the study findings in a relatively factual manner, the authors can present a more favourably coloured version in the Conclusions section. If through lack of time readers only scan the Conclusions and the Abstract, they will then get an overly favourable impression of the drugs studied.

Favourable results?

Actually, even the Results section can be written in such a way as to present the treatment investigated in a more favourable light. One way of doing this is by leaving out unfavourable findings or by emphasising statistically significant findings from (ad hoc) subgroup analyses that should actually have been interpreted with caution [1].

Research methodology

The way in which a study is designed can increase the probability of getting a result that appears favourable. While readers with little time often skip the Methods section in research papers, Ge-Bu specifically includes this section in its assessment of a study.

Although the methodology of industry-sponsored research is usually not really incorrect, the choices made can often be questioned. One example is that of choosing a suboptimal treatment for the control group. This can for instance be done by choosing a control treatment that does not appear in the relevant guidelines, or by giving the control group too low a dosage [1],[4],[2].

Sometimes a study compares a new drug with the right standard treatment, but the authors opt for testing on non-inferiority. The study then does not test whether the drug works better than an existing treatment, but whether its efficacy is comparable. If the non-inferiority margin is set too wide, the article may suggest that the new drug works just as well, while in reality it may still be less effective [5].

Composite or surrogate outcome measures

Researchers use composite or surrogate outcome measures to increase the likelihood of finding a favourable result [1],[6]. Using a composite outcome measure carries the risk that the positive efficacy found is attributable to only one of the outcome measures. This may be an outcome measure that is clinically less relevant than the other measures, on which there may be little or no effect. Combining them makes it seem like all outcome measures have shown improvement. While surrogate outcome measures are an indication of efficacy, hard outcome measures are required to assess the relevance for patients (see box).

Ge-Bu always critically assesses the outcome measures chosen in a study. In 2016, for instance, the media presented jubilant stories about a fantastic new drug against Alzheimer's disease. They even claimed that "there is overwhelming evidence that it works" [7],[8],[9]. Based on the registration study, however, Ge-Bu came to a different conclusion: "While the monoclonal antibodies aducanumab, lecanemab and donanemab do reduce the amyloid load and possibly the amyloid plaques in the brain, this leads to only a very modest delay in the cognitive and functional decline."[10]

Ge-Bu authors are independent

Ge-Bu is a member of the International Society of Drug Bulletins, an organisation which imposes strict requirements regarding independence, which apply to everyone involved in the process of writing and publishing an article. This distinguishes Ge-Bu from other medical journals, as Ge-Bu demands that all those involved, including the authors, have had no paid or unpaid ties with the pharmaceutical or medical device industry in the past three calendar years.

How essential is it that an article is written by fully independent authors? Authors are expected to present their research findings objectively. However, if conflicts of interest are involved, bias may arise in various ways when describing the results. Research has shown that sponsored reviews are more likely to draw conclusions that are favourable to the pharmaceutical industry [11],[1],[2].

Ge-Bu cannot be replaced by artificial intelligence

A recent article in the Dutch journal Huisarts en Wetenschap discusses the applicability of AI as a tool for solving questions in primary care that are not addressed by the guidelines [12]. The authors investigated the suitability of the EvidenceHunt tool, and concluded that it was suitable for summarising the literature, but was too limited to critically review and evaluate a study [12]. It is precisely the latter for which Ge-Bu offers substantial added value. Ge-Bu's articles are written by independent authors and undergo extensive peer review by independent experts on content and methodology. Hence, readers can safely assume that the research discussed has been thoroughly and critically evaluated by peers.

'Garbage in, garbage out'

An additional problem is the increasing number of fraudulent research papers. These articles, produced by so-called paper mills, often use AI to increase their credibility and disguise plagiarism [13]. In turn, these articles find their way back into AI and cloud the scientific results that are searched for by care providers. This is a worrying trend which implies that, for the time being, AI is not yet a suitable alternative to GeBu's critical and independent outlook.

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Your expert, independent second opinion for prescription drug information

FDA Removes Most of the Boxed Warning for Menopausal Hormone Therapy

Article published in the January 2026 issue of Worst Pills, Best Pills News

In November 2025 the Food and Drug Administration (FDA) initiated the removal of most of the boxed warning — the most prominent warning the agency can require — from the prescribing information of all menopausal hormone treatments containing estrogen.[1]

The labeling changes follow an "expert panel" meeting on menopause and hormone replacement therapy for women that the FDA convened in 3uly 2025 and the subsequent submission of public comments.[2] The labeling changes reflect the opinion of FDA Commissioner Martin Makary that the boxed warning overstates the risks of hormone replacement therapy for women.[3]

The changes, which will require discussions with the companies that market the products, will take months to fully implement. Notably, the boxed warning about endometrial cancer for systemic estrogen-alone products will be maintained.[4]

For years, Public Citizen's Health Research Group has advocated for the strong safety warnings for menopausal hormone therapy that are about to be removed. Although we are open to targeted updates to the safety warnings that incorporate recent medical evidence, many of the labeling changes are unsubstantiated. In our September 2025 comments to the FDA, we urged the agency not to update or remove the boxed warnings before additional safety data were obtained and gaps in the understanding of these treatments were addressed.[5]

Rather than advancing women's health, the FDA's rushed actions undermine the agency's credibility. Moreover, the labeling changes may encourage inappropriate off-label prescribing of hormone replacement therapy for unapproved uses, such as preventing cardiovascular disease and cognitive decline.

The FDA also erred ininitiating the changes without convening a formal advisory committee meeting, where independent experts would have offered an impartial and rigorous assessment of the available evidence. The FDA's expert panel meetings are opinion-based and do not follow the rigorous process of advisory committee meetings. Panel members are more likely to offer interest-driven or one-sided views.[6] For instance, the criteria according to which panelists were selected for the menopause expert panel were not made public. At least some panel members had conflicts of interest that were not adequately disclosed and that should have disqualified them from participation.[7]

About menopausal hormone therapy

The FDA has approved the use of standard menopausal hormone therapy — mainly estrogen alone (such as conjugated estrogens [PREMARIN and generics[8]]) and combined estrogen and progestin (such as conjugated estrogens and medroxyprogesterone [PREMPHASE, PREMPRO[9]]) — for the treatment of moderate to severe vasomotor symptoms and moderate to severe vulvar and vaginal atrophy due to menopause. The FDA has also approved some of these medications for the prevention, but not treatment, of postmenopausal osteoporosis (bone thinning), which increases the risk of fractures. The treatments have been available for many years; conjugated estrogens were first approved in 1942.

At present, the prescribing information for all menopausal hormone therapy containing estrogen, regardless of the dose or formulation, includes a boxed warning stating that the therapy may increase the risk of endometrial cancer, cardiovascular disorders, breast cancer and probable dementia. For this reason, the boxed warning also states: "Estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman."[10]

The Text Box below summarizes the FDA's requested changes to the prescribing information.

FDA's Requested Changes to the Prescribing Information for MenopausalHormone Therapy [11]

Changes to the boxed warning for all menopausal hormone therapy (systemic and local vaginal products):

- Remove the language related to cardiovascular diseases, breast cancer and probable dementia
- Remove language related to endometrial cancer except for the systemic estrogen-alone drugs
- Remove the recommendation to use the lowest effective dose for the shortest amount of time

Additional changes to the labeling as a whole for systemic products:

- Add consideration of starting hormone therapy for moderate to severe vasomotor symptoms in women younger than 60 years old or less than 10 years from the start of menopause
- Add Women's Health Initiative data for women 50-59 years old
- Retain the boxed warning about endometrial cancer for systemic estrogen-alone products
- Retain information about cardiovascular diseases and breast cancer warnings

Additional changes for local vaginal estrogen products:

- Condensed safety information, prioritizing the information most relevant for local vaginal formulations

Evidence against the changes to the boxed warning

Menopausal hormone therapy has several documented risks. These differ depending on the patient's specific health risks (such as a history of cancer or heart disease), age at treatment initiation, dose and type of hormone therapy, and the length of therapy. [12],[13]
Unfortunately, high-quality data from randomized controlled trials that could provide clarity on these interdependent risks (and that should have been required prior to removing the boxed warning) are limited, especially for long-term use and newer hormone therapy formulations.

The long-standing boxed warning for menopausal hormone therapy is largely based on the results of the 2002 Women's Health Initiative trial, a large long-term randomized controlled study with several sub-studies.[14]

The boxed warning is supported by more-recent high-quality evidence as well.

For instance, a 2019 meta-analysis showed that the long-term use of all types of hormone therapy (except vaginal estrogen), especially combination (both estrogen and progestin) hormone therapy, is associated with a higher risk of breast cancer.[15] Although this risk was low after less than one year of hormone therapy, there was an increased risk after one to four years of using hormone therapy and progressively greater risks with longer use.

A 2023 systematic review and meta-analysis noted that several observational studies found that menopausal hormone therapy reduced the risk of Alzheimer's disease and all-cause dementia.[16] However, in randomized controlled trials (which are considered to provide higher-quality evidence than observational studies) of postmenopausal women aged 65 and older, the risk of dementia appeared to be higher with combination hormone therapy than with placebo.

A 2019 systematic evidence review requested by the FDA showed that low-dose vaginal estrogens (without concomitant progestogen) for vulvar and vaginal atrophy in menopausal women did not increase the risk of endometrial cancer.[17] Similarly, a federally funded systematic review published in 2024 comparing hormonal treatments and vaginal moisturizers for vulvar atrophy in postmenopausal women reported a low frequency of serious adverse events with these treatments.[18]
However, the authors of both reviews stated that longer-term data is needed to confirm their findings because many of the randomized controlled trials were small and none followed participants for more than one year.

The long-standing boxed warning specifically states that neither estrogen-alone therapy nor estrogen-plus-progestin therapy should be used for the prevention of cardiovascular disease or dementia. This warning is supported by a 2022 review of clinical trials by the U.S. Preventive Services Task Force (USPSTF) — a federally funded, independent, voluntary panel of experts that makes evidence-based

recommendations about clinical preventive services.[19] The USPSTF found that although some evidence shows that estrogen-alone therapy lowers the risks of diabetes and fractures, it also increases the risks of gallbladder disease, stroke, blood clots and urinary incontinence. Likewise, the USPSTF found that combined estrogen and progestin therapy lowered the risks of colorectal cancer, diabetes and fractures but increased the risks of invasive breast cancer, gallbladder disease, stroke and blood clots in postmenopausal women. The USPSTF also concluded that estrogen-plus-progestin therapy probably increased the risks of dementia and urinary incontinence.[20] For these reasons, the task force has consistently recommended against hormone replacement therapy (assigning it a grade "D" recommendation) for the prevention of chronic conditions in postmenopausal women.

What You Can Do

Be aware that the FDA's decision to remove most of the boxed warning for menopausal hormone therapy was based on opinion, not more safety data.

If you experience moderate to severe menopausal symptoms, discuss with your clinician whether menopausal hormone therapy is an option for you. Also discuss with your clinician other potential treatments. If hormone treatment is planned, take these medications for the shortest period necessary to ensure that the treatment's benefits outweigh the possible risks.

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Ataluren in Duchenne muscular dystrophy: a critical review of the regulatory process

By Erviti J, Saiz LC, Gutiérrez-Valencia M - 13 December, 2025.
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Summarised by Roberta Joppi and Barbara Mintzes

Introduction

Duchenne muscular dystrophy (DMD) is one of the most serious neuromuscular diseases in children, characterized by progressive muscle degeneration and the absence of curative therapies. In this context, the arrival of ataluren, developed for patients with nonsense mutations, had raised considerable expectations. The drug promised, at least in theory, to restore dystrophin synthesis through a mechanism of "read-through" of the genetic mutation. However, subsequent clinical and regulatory evaluation revealed a much more complex picture.

Clinical evidence: inconclusive and inconsistent results

Analysis of the main clinical studies conducted on ataluren shows a substantial lack of efficacy.

Study 007, the first reference trial, showed no significant difference compared to placebo in the 6-minute walk test, the primary endpoint used to assess motor function. A subsequent post-hoc analysis suggested a potential benefit in a subgroup of patients, but this observation was not predefined and could not be considered conclusive.

Study 020, designed to test this hypothesis, confirmed the absence of a relevant clinical effect. Study 041, the largest and most recent study, also failed to produce favorable results.

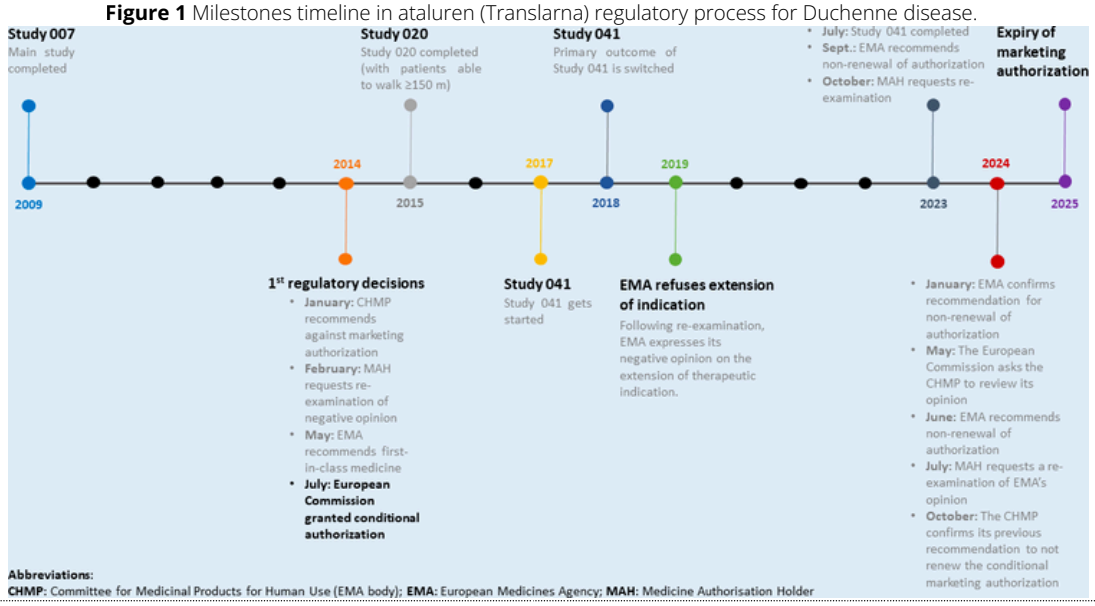
During the conduct of the study, the primary endpoint was modified, a methodologically questionable choice that did not, however, lead to positive evidence. Overall, none of the trials demonstrated a clinically significant benefit.

The European regulatory process: between scientific assessments and external pressures

Despite the weakness of the evidence, in 2014 the European Commission granted conditional authjorization for ataluren, departing from the initial negative opinion of the EMA's Committee for Medicinal Products for Human Use (CHMP). Since then, the drug's regulatory path has been marked by numerous reviews, requests for reassessment by the manufacturer, and growing public involvement.

A particularly critical moment occurred in 2024, when the European Commission overturned a negative opinion from the EMA, an unprecedented event in the regulatory history of the EU. This decision required a new scientific evaluation, which nevertheless confirmed once again the drug's lack of efficacy. It was not until March 2025, after eleven years on the market, that the authorization was finally withdrawn.

Figure 1 Milestones timeline in ataluren (Translarna) regulatory process for Duchenne disease.



The Spanish case: an example of misalignment between evidence and political decisions

The Spanish situation is a prime example of how political decisions can diverge from scientific assessments. Despite a national decision not to reimburse the drug, many regions chose to fund it anyway. This choice was not supported by new evidence, but by media pressure, awareness campaigns, interventions by patient associations, and local political dynamics. According to the authors, this behavior highlights the risk that emotion and social pressure can influence decisions that should be guided by criteria of effectiveness, equity, and sustainability.

Withdrawal of authorization: a belated conclusion

The withdrawal of authorization in 2025 brought an end to a long and controversial regulatory process. The authors emphasize that keeping the drug on the market for over a decade, despite the lack of solid evidence, fueled unrealistic expectations in patients and had a significant economic impact on European healthcare systems.

Implications and recommendations

The story of ataluren offers broader insights into the drug evaluation and authorization process, particularly for rare diseases. The authors highlight the need to:

- strengthen the link between conditional authorizations and timely confirmatory studies;
- ensure that regulatory decisions remain anchored in solid and reproducible evidence;
- promoting independent studies and national registries to monitor the real-world effectiveness of drugs;
- protecting decision-making processes from political and social pressures;
- ensuring the responsible use of public resources.

According to the authors, only a rigorously evidence-based approach can guarantee fairness, sustainability, and transparency in therapeutic decisions, preventing similar cases from recurring.

Regional News

ISDB members participate in events held by their colleagues in their regions

In-person meetings of ISDB members at conferences are an important stimulus for network development in the different regions. On the sidelines of the ISDB General Assembly in Verona (Italy) 1-3 October 2025 an agreement was reached for ISDB representatives to participate in the regional conference of clinical pharmacologists from the CIS countries in Almaty, Kazakhstan, which took place on October 30-31, 2025. Representatives from Kazakhstan, Russia, Belarus, Kyrgyzstan, Ukraine, Uzbekistan, and Moldova took part in the conference.

As expected, the time difference between Sydney, Almaty, and Washington D.C. is one of the biggest obstacles to effective communication with conference participants.

Despite the difficulties of overcoming time zones and internet issues, ISDB representatives were able to speak online and present their perspectives, highlighting pressing issues around rational drug use.

The congress participants listened to the presentation on "Promotion and Prescribing" by Adriane Fugh-Berman MD from Georgetown University Medical Center with great attention.

A key theme in Adriane's presentation was that "Drugs can save lives and improve health when used appropriately," but "Promotion interferes with appropriate drug use."
Research shows that promotion influences prescription rates, but doctors don't believe that they are affected.
Doctors are often unaware of pharmaceutical marketing campaign strategies and are happy to "meet with drug sellers only for drug samples."

The real purpose of samples: To get access to physicians; To encourage physicians to prescribe specific drugs; Patients are grateful for free samples and Physicians and staff use drug samples themselves.

The next revelation for the listeners was information about the Doctor-Opinion Leader "Key Opinion Leaders - KOLs". The key idea – KOLs Sell Diseases, NOT Drugs – came as a bolt from the blue for most congress participants. Physicians paid by pharmaceutical companies may not know that they are spreading marketing messages. KOL messages usually indicate that a disease is common, but underdiagnosed, undertreated, or more serious than people know. KOLs do not promote specific drugs.

Following the presentation, participants discussed the need for such incisive presentations, especially at congresses of clinical pharmacologists, who are often key opinion leaders.

Barbara Mintzes, Professor, School of Pharmacy, Charles Perkins Centre & School of Pharmacy, University of Sydney made a presentation "Menopause and hormones: treatment advance of the 21st century or an old story told again and again?" Barbara Minzes's presentation was interesting from a practical perspective, namely that doctors are actively promoting hormonal treatment during menopause.

The underlying message of recent press and social media reports is that women are suffering and not being taken seriously; menopause is attributed to a wide range of symptoms, including depression and confusion, in addition to hot flashes; women need hormone treatment, but doctors are often reluctant to prescribe it.

Barbara presented the history of how menopause and use of hormones to treat it have been represented, including the description of postmenopausal women as "estrogen deficient" in the 1950s and 1960s. In 1975 estrogen found to cause endometrial cancer and sales plummeted. In 1979 an NIH Consensus Conference concluded that estrogen only effective for hot flashes and vaginal dryness. In 1980s estrogen-progestin products were launched as 'hormone replacement therapy (HRT) and in the 1990s HRT was widely promoted for long-term disease prevention.

A systematic review "Long-term hormone therapy for perimenopausal and postmenopausal women" Marjoribanks J., Farquhar C., Roberts H., Lethaby A., Lee J was published in 2017 in the Cochrane Database of Systematic Reviews, Issue 1. Art No.: CD004143, synthesizing long-term randomized controlled trial data including thousands of women, assessed outcomes of hormone therapy from one to six years. This Cochrane review found greater harm than benefit from long-term estrogen-progestin use for disease prevention, due to increased risks of heart attacks, stroke, blood clots in the lung or legs, breast cancer, death from gallbladder disease and probable dementia. The key benefit was decreased risks of fracture, but this benefit is outweighed by risks of harm.

Barbara sent a key message to the participants of the conference: Most women navigate menopause without the need for medical treatments. Over-medicalization of menopause can lead to disempowerment and over-treatment.

All conference participants in Kazakhstan noted that the international participation of experienced ISDB members undoubtedly enriches the work of regional conferences and allows for a clear direction for future cooperation.