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Who pays, decides the evidence

What happens to health technology once a country decides to pay for it

2026

At a glance

Health technology has a problem other software does not have: the user is not the buyer and the buyer only pays once you prove something. Germany was the first country to introduce a reimbursement procedure for apps on prescription, and that experiment has now run long enough to learn something from it: well over a million prescriptions, 234 million euros of spending, and more than a fifth of the admitted applications that have meanwhile been taken off the list again. Since February 2026 the rule has been tightened: the price depends in part on measured outcome, and the manufacturer has to supply data every quarter about actual use. Meanwhile the most used form of AI in care is not diagnosis but documentation, and according to randomised research it yields less time saving than everyone assumes. This document describes that shift, with the figures behind it, and names what is not yet settled.

234 million

euros that the German statutory health insurance spent between 1 September 2020 and 31 December 2024 on apps on prescription. Systematic review in npj Digital Medicine, 2025, based on the official reporting.

Foreword

Digital care is usually described from the technology: the sensor, the model, the interface. That is the part that changes fastest and decides least. What decides is whether someone pays, for what exactly, and which evidence that payer demands for it. That part changes slowly, country by country, and it governs every business plan in this sector.

This document therefore looks at the paying side. What has Germany learned from five years of apps on prescription, what changed in those rules in February 2026, how does the Belgian framework work, what does randomised research say about the AI that is being rolled out most broadly today, and which data legislation is coming. The sources are listed per part and are primary where possible: regulations, publications in the official gazette, and peer reviewed research.

It is not an overview of suppliers and not a recommendation. The applications that are named are there as evidence of a shift. Where the evidence is weak, that is stated as well.

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01 The shift: the payer is the market

In virtually every other software category the market validates itself. People use the product or they do not, and the revenue tells you which of the two. In care that mechanism does not work. The user is the patient, the decider is often the doctor, and the payer is an insurer or a government that does not sit in the consulting room. Three parties, three interests, and only with the third is the money.

That makes the usual evidence worthless. Half a million downloads, a score of 4.6 in the app store and an enthusiastic pilot study in a hospital say nothing to whoever has to decide whether they reimburse this for the whole population. That person asks a different question: does the health of this patient group measurably improve because of it, or does care measurably run more efficiently because of it, compared with what we do today.

The shift of the past decade is that a number of countries have formalised that question in a procedure, with an authority, a deadline and a price. With that, digital health has stopped being a consumer market with a medical edge. It has become a regulated product with the same logic as a medicine: market authorisation first, reimbursement separately, and evidence for both.

Germany did that first at scale, with the digital care act of 2019. France followed in 2024 with an early reimbursement procedure. Belgium built a pyramid of its own. The United Kingdom is working on a national showcase with assessment according to the evidence standards of NICE. Whoever builds in this sector therefore does not build for a European market but for a series of national procedures that each ask for their own evidence.

Source: Digitale-Versorgung-Gesetz, Germany, 2019, and the ensuing procedure at the BfArM · PECAN, French procedure for early reimbursement of digital applications, introduced 2024

02 The German experiment in figures

Since September 2020 a German doctor can prescribe an approved digital application as they prescribe a medicine, and the statutory health insurance pays. The target group is roughly 73 million insured and more than 170,000 prescribers. The federal institute for drugs and medical devices, the BfArM, assesses the application in an accelerated procedure of three months.

That procedure has two exits, and there sits the ingenious construction. Whoever can already demonstrate the favourable care outcome goes on the list definitively. Whoever cannot yet do that goes on the list provisionally and gets twelve months to prove it with an evaluation study approved in advance. The country therefore pays for something of which it does not yet know whether it works, on condition that the evidence is being worked on in the meantime. That is the same reasoning applied elsewhere to promising medicines.

> Of every five prescriptions, one is never activated. The doctor was convinced, the patient was not.

The volumes: by the end of 2024 more than a million prescriptions had been written, of which roughly 81% were actually activated by the patient. The cumulative spending of the health funds amounted to 234 million euros between 1 September 2020 and 31 December 2024. The average price per prescription was roughly 541 euros in 2024, with a spread of 119 to 2,077 euros per use, usually for ninety days and in some cases up to a year.

Put those numbers side by side and you see at once where it chafes. An average of 541 euros for ninety days of software is not an app price, it is a therapy price. And of every five prescriptions one is never activated, which is to say that the doctor was convinced and the patient was not. That is a problem no clinical study measures, because in a study everyone activates.

Source: Systematic review of care effects and strength of evidence of reimbursed digital applications, npj Digital Medicine, 2025 · Data-driven analysis of the German market for digital applications, Journal of Medical Internet Research, 2024

03 What the experiment taught about evidence

The most interesting outcome of five years of reimbursement is not how many applications got in, but how many flew out again. Since the first inclusion in September 2020 more than 75 applications have appeared on the list. Slightly more than 20% lost the reimbursement again in the meantime, roughly 15% is on it temporarily awaiting assessment, and roughly 65% is definitively included.

Of the eleven applications that were removed at some point, six disappeared because the favourable care outcome could not be demonstrated, one because the study did not get finished, and four at the request of the manufacturer itself. That last figure deserves attention. Four companies chose to leave before the measurement sent them away, and that is the quietest form of negative evidence there is.

The quality of the evidence itself remains contested. The systematic review in npj Digital Medicine establishes that the BfArM does not make its assessment of the risk of bias in the admission studies public, so that outsiders cannot judge the strength of the underpinning. Earlier research in BMC Health Services Research found that the official list itself does not suffice to check which evidence has been delivered, and ran in one case into results in the list that did not correspond with the study report.

The recurring technical problem in those studies is dropout. High dropout in the intervention group means that the people who ought to use the product stop with it, and that is worse in real care than in a study. Whoever works in this sector knows that this is the actual product problem: adherence is not a marketing question but the active substance itself. An application that is clicked away after three weeks has no effect to measure.

Source: Systematic review, npj Digital Medicine, 2025 · Analysis of the evidence requirements of definitively included applications, BMC Health Services Research, 2023 · Overview of inclusions and removals, published February 2026

04 The price becomes a variable

On 29 January 2026 an amendment appeared in the German official gazette to the regulation that governs the procedure, with effect from 1 February 2026. Its core is that paying for admitted software no longer suffices: the manufacturer has to demonstrate what happens in practice.

Concretely, an accompanying success measurement is coming. Manufacturers have to collect data about real use, about the satisfaction of the patient and about the health status reported by the patient, via standard questionnaires that are attached as an annex to the regulation. Participation by the patient is voluntary. From the third quarter of 2026 those data have to be generated every quarter and submitted anonymised and aggregated to the BfArM every six months. The first submission falls no later than 15 April 2027 and contains the third and fourth quarter of 2026. Every quarterly package also states how many prescriptions and how many follow-up prescriptions were redeemed.

In addition the pricing shifts. From 2026 at least a fifth of the price is tied to performance, and the procedure is opened up for devices in a higher risk class. For those who know the model from the world of medicines: this is a price-volume agreement, applied to software, in a sector that was used to a licence being a licence.

The consequences for the product architecture are larger than the consequences for the accounting. A product that has to report every quarter about use and outcome has to have that measurement built in, with consent, with a questionnaire at the right moment, with a data processing that survives the check. That is not a reporting layer you build on afterwards. That is a design requirement, and companies that start on it today have roughly a year.

Source: Amendment of the German regulation on digital health applications, published in the official gazette on 29 January 2026, in force on 1 February 2026 · Analysis of the new reporting obligations, Inside EU Life Sciences, 3 February 2026

05 Belgium: a pyramid and a handful of care processes

Belgium chose a different construction. The platform mHealthBelgium orders applications with a CE marking as a medical device in a pyramid of three levels. Level M1 means that it is a certified medical device. Level M2 means that an admissible application for reimbursement lies with the RIZIV. Level M3 is the funding itself, and that level falls apart into M3-min, where funding is temporary while the socio-economic value is still being demonstrated, and M3-plus, where that value is proven and the funding definitive.

The platform started in 2018 as a federal initiative after the then minister of health had funded 24 pilot projects to examine the added value of mobile health applications. Three public authorities each worked out one level: the medicines agency for M1, the eHealth platform for the ICT criteria of M2, and the RIZIV for the funding at M3. At the end of 2023 the cooperation with the RIZIV came to an end. Since then the platform has been continued by the sector federations beMedTech and Agoria, without public support.

The difference with the German model sits in the unit of payment. In Germany the application itself is prescribed and paid. In Belgium the funding runs via care processes: the platform mentions among others telemonitoring of patients with COVID-19 at home, rehabilitation after a knee or hip prosthesis, telemonitoring and therapy guidance with chronic heart failure, holter recording for cardiology patients, telemonitoring of cancer patients and telemonitoring with sleep apnoea. The app is not the product that is paid. It is a part of a trajectory that is paid.

That distinction determines your whole strategy. In an app model you sell to an authority that assesses your effect. In a care process model a care process first has to exist that your application fits into, and if it is not there, the question is not whether your product is good but whether someone is prepared to open the nomenclature. That is a trajectory of years, with different interlocutors, and it is the reason why Belgian companies in this sector often go knocking in Germany first.

Source: mHealthBelgium, validation pyramid, funding and overview of the care processes, consulted 17 July 2026 · RIZIV, regulatory framework for the funding of mobile health applications, in force since January 2021

06 Documentation, not diagnosis: where AI in care really lands

If you read about AI in care over the past years, it was about diagnosis. In practice the fastest rolled out application of generative AI in hospitals worldwide is something far more prosaic: a system that listens along with the consultation and makes a report of it. No decision, no risk class, no clinical claim. Just typing.

That choice is economically logical. Administration is the biggest time consumer and a documented cause of burnout among doctors, the error of a report is correctable, and no notified body is needed for it. The question is what it yields, and that has meanwhile been examined in a randomised way instead of polled.

> The fastest rolled out AI in care makes no diagnosis. It types the report, and it wins 0.8 minute per consultation.

In a pragmatic randomised study with three arms in a large academic care system in California, carried out between 4 November 2024 and 3 January 2025 with 313 ambulatory doctors and published in NEJM AI in December 2025, two systems were compared with the ordinary course of things. The effect was modest but positive: less time in the report with one of the two systems, and less exhaustion and less perceived task load with users of both. In a prospective time measurement study in JMIR Medical Informatics from 2026 the measured gain amounted to 0.8 minute per consultation, the duration of the consultation stayed unchanged, and the total throughput time stayed equal too.

The authors themselves draw the conclusion the sector does not like to hear: no higher throughput or a larger patient volume may be expected from this technology. What it does do is lighten the load and restore the eye contact, and that is a real outcome for whoever is trying to keep staff. But it is a different business case from the case that is sold. Time saving that does not exist, you cannot invoice as saved consultation time.

Source: Lukac et al., Ambient AI Scribes in Clinical Practice: A Randomized Trial, NEJM AI, December 2025 · Prospective observational time measurement study with an AI scribe, JMIR Medical Informatics, 2026

07 The data layer that is coming

The third piece of the puzzle is the data, and that piece is meanwhile law. Regulation (EU) 2025/327 on the European health data space was adopted on 11 February 2025, published on 5 March 2025 and entered into force on 26 March 2025. It governs three things: rights of the patient to their own data, a procedure for the secondary use of health data for research and policy, and a product regime for systems that manage electronic patient records.

The calendar is long and that is no detail. The general application falls on 26 March 2027. The rules on secondary use and the first categories for cross-border exchange, with patient summaries and electronic prescriptions, apply from 26 March 2029. Images, laboratory results and discharge letters follow on 26 March 2031. Whoever builds a product today that counts on that infrastructure builds for the second half of this decade.

The practical meaning for a company sits in the second pillar. From 2029 researchers, governments and companies can apply via national access bodies for pseudonymised health data for well defined purposes. That is precisely the infrastructure that is missing to prove digital care: today every manufacturer has to buy its own study population, while the data about the same patients already exist in hospital systems nobody may query.

There is a reverse side to it that you have to factor in already. Manufacturers of devices that generate or process health data get obligations of their own to make those data available. The regulation therefore gives access and imposes a supply duty at the same time. For whoever

regards their dataset as their most important asset, that is no technical detail but a question about the business model.

Source: Regulation (EU) 2025/327 on the European health data space, published 5 March 2025, article on the phased application

08 What it changes for companies in the sector

The first change is that the evidence plan has become a product plan. Whoever built an application in 2020 and looked for a study afterwards could still get in. Whoever does that today ends up at most on a provisional list with twelve months to deliver what they never prepared. The comparative study in a well defined patient group is the most expensive item and the longest lead time in the whole project, and it determines whether the rest is ever worth anything.

The second change is that use is measured. From 2026 the German model settles up with you on redeemed prescriptions, on follow-up prescriptions and on what the patient reports themselves. With that, adherence becomes a financial parameter instead of a quality concern. An application with a strong effect among the people who persist and a dropout of half is worth less in this model than an application with a moderate effect that everyone reaches. That turns the usual product priorities around.

The third change is that the market is not European. The same application needs a BfArM procedure in Germany, a place in an existing care process in Belgium and an early reimbursement application in France. The underlying CE marking is European, and that is precisely the trap: the device may be on the market everywhere and is paid almost nowhere. A rollout plan that ranks countries by order of population instead of by order of procedure will fail.

The fourth change is the time horizon of the data layer. The secondary use rules of 2029 and the exchange of images and lab results in 2031 are too far away to build on today and too close to ignore, above all for whoever needs clinical evidence that only becomes hard with population data. The sensible position is a product that works with its own data today and can connect tomorrow, and not a product that waits for the infrastructure.

Source: Amendment of the German regulation on digital health applications, 29 January 2026 · Regulation (EU) 2025/327, phased application · mHealthBelgium, funding framework per care process, consulted July 2026

09 What does not add up yet

Four things in this story are systematically presented too favourably. The first is the size. Five years of German reimbursement yielded cumulatively 234 million euros of spending, in an insurance system that spends hundreds of billions a year. That is not an upheaval in health financing. It is a test plot, and in decks it is systematically presented as a market.

The second is the lack of published counter-evidence. The supervisor does not make its assessment of the study quality public, the official list does not suffice to check which evidence was delivered, and in at least one case the published results did not correspond with the study report. As long as that is so, nobody from outside can say how strong the evidence behind the definitively included applications really is. That is not an indictment, it is a gap, and it is filled by both camps with whatever suits them.

> Five years and 234 million euros is not an upheaval in health financing. It is a test plot presented as a market.

The third is the skewed distribution. The applications that make it through the procedure cluster in a limited number of domains where a validated questionnaire is an accepted outcome measure, and that is not by accident mental health. Where the outcome is a hard clinical event, the study is larger, more expensive and longer, and therefore rarer. Supply thus follows measurability and not necessarily the care need, and that is a system effect nobody chose.

The fourth is the promise of time saving. The most broadly rolled out AI in care yields, according to measured research, 0.8 minute per consultation, without effect on the duration of the consultation or on the throughput time. Dropout and load do fall. Whoever sells that as capacity gain sells something the studies do not find, and the payer who measures this themselves within two years will notice. In this sector the measurement is always the end of the promise, and that is precisely the intention of the system.

Source: Systematic review, npj Digital Medicine, 2025 · Analysis of the evidence requirements of definitively included applications, BMC Health Services Research, 2023 · Prospective observational time measurement study, JMIR Medical Informatics, 2026

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SOURCES

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