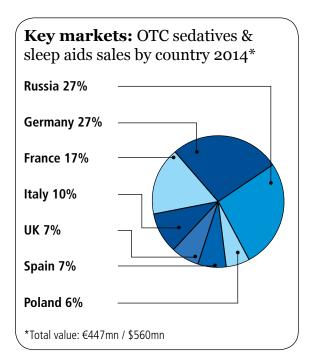
Sedatives & sleep aids: NPD investment boosts topline

AT-A-GLANCE GUIDE: SEDATIVES & SLEEP AIDS 2014

MARKET OVERVIEW: Revenue advanced by 7% overall, with healthy performances across much of the region. Italy was the only market to decline, owing largely to melatonin restrictions introduced in December 2013, although many marketers have since reformulated products. Strong growth in Russia was driven in part by price rises, while NPD and A+P support contributed to impressive results elsewhere. Marketers continued to position brands as effective tools against the stress of a busy lifestyle, while Polish player Adamed extended Nervomix with an option for those feeling irritable while giving up smoking. Doxylamine-based entries are popular, with generic versions making headway in France, while melatonin and valerian are key natural ingredients.



Europe: OTC sedatives & sleep aids 2014

(MSP)	TOTAL (€mn)	TOTAL (\$mn)	INDEX (14/13)	POPULATION (mn)	PER CAPITA SPEND (\$)
France	74.1	92.8	106	64	1.45
Germany	120.1	150.3	107	81	1.86
Italy	43.4	54.4	097	60	0.91
Poland	25.1	31.4	104	39	0.81
Russia	120.1	150.4	112	144	1.04
Spain	31.8	39.9	108	47	0.85
UK	32.5	40.7	107	64	0.64
TOTAL	447.3	559.8	107	497	1.13

All data in this report MAT Q3 2014: *Nicholas Hall's OTC INSIGHT* based on *Nicholas Hall's DB6* OTC database, in partnership with Nielsen, DSM, PharmaExpert and INSIGHT Health in certain countries. Exchange rates: \$/€: 0.80; €/PZL: 4.23; €/Rb: 54.83; €/£: 0.78 based on average figures from 01/11/14-07/11/14 from <u>oanda.com</u>. Owing to changes in channel coverage, data is not directly comparable to last year's *Market Report*



France: Natural options key

• Doxylamine generics compete for share

The topline increased by mid-single digits in the reporting period, with significant NPD and A+P investment from marketers boosting sales, while industry sources also point to the recent negative economic climate as a growth factor by causing stress and anxiety.

Bayer's Euphytose commands around a quarter of category sales, boosted by frequent TV ads which target women and highlight that it relieves various symptoms of stress via a natural formula of four plant extracts. The marketer discontinued the 40-tab pack size in late 2013, with the 120-count option still available.

Donormyl (Upsa / BMS, doxylamine) faces generic competition from Biogaran / Servier, Mylan, Sandoz / Novartis and Teva, all of which are available in 10-count 15mg-strength packs. Versions from Biogaran and Sandoz have been seen in the trade press, with ads for the latter saying, "Doxylamine Biogaran Conseil, son nom déjà sonne comme une berceuse" (Doxylamine Biogaran Conseil, its name already sounds like a lullaby).

Boiron's Sédatif PC, positioned for professional women, benefited from TV ads throughout the reporting period. Meanwhile, the marketer recalled one lot of Kalium Phosphoricum 6DH



Sédatif PC is said to combat sleep problems, irritability and stress

tablets and one lot of Oligostim Lithium tablets in April 2014 as a precautionary measure owing to packaging errors, while in July, the marketer recalled two lots of Passiflora Composé Boiron owing to anomalous results in the appearance of some tablets.

Lehning invested in mass media support for homeopathic sleep aid L72 drops, with ads carrying the tagline, "Faites fuir les troubles du sommeil" (Fend off sleep

problems). Stablemate Biomag Agrumes (citrus fruits, previously called Biomag) was supported by TV, press, online & outdoor ads from October 2013, with promotion highlighting that it relieves stress, minor anxiety and temporary fatigue often associated with a busy work life.

Séroxyl (Arkopharma, L-tryptophan, vitamin B6 and valerian) was seen in press and online ads targeting professional women, underlining that it helps combat stress and sleep problems without causing dependency. A competition running from September-November 2013 promoted Sériane Nuit (Naturactive / Pierre Fabre), offering consumers the chance to win a watch, while the brand was also seen in consumer titles including *Top Santé, Prima* and *Avantages* in the same period, with ads stating, "Prenez soin de votre sommeil" (Take care of your sleep).

D-Stress (Synergia) was promoted to pharmacists via trade press ads claiming that it is the No.1 product by value available in pharmacies to treat stress, while also highlighting that it reduces fatigue and helps to restore intellectual performance. The brand was also advertised via counter displays, in addition to spring 2013 TV spots and ads in titles such as *Top Santé*, *Modes & Travaux* and *Avantages*. D-Stress Booster was updated with a peach flavour in November 2013; the unidose powder sachets contain magnesium, several B vitamins and taurine, among other ingredients. This has a similar positioning to D-Stress, while it is also claimed to support normal nervous system function and boost metabolism.

In terms of NPD, Ineldea launched Melatonight Spray (20ml SKU) under the INS Micronutrition banner in September 2013. This is claimed to reduce jet lag and make it easier to fall asleep and gets to work in under 30 minutes via its formula of melatonin 1mg, extracts of lemon balm and orange blossom and vitamins B1 and B6.

The following month, Sanofi's NovaSanté was extended with Novanuit Sommeil, a supplement claimed to have a triple action on sleep: boosting relaxation (passiflora), making it easier to fall asleep (melatonin) and making

Simplifyle 6

sleep less disrupted (extracts of California poppy and lemon balm). This is available in a 30-cap pack and is promoted at <u>novasante.com</u>, while TV ads targeting women carry the tagline, "Pour le sommeil dont vous rêviez" (For the kind of sleep you've been dreaming of). The marketer ran a buy-one-get-one-free offer in November-December 2013. Finally Juva Santé / VivaSanté launched mass market entry Passiflore Rhodiola under the Juvamine Phyto banner in June 2014. This is said to support good mood and emotional wellbeing and is available in a 30-cap pack, which costs around €5.99 (\$7.50).

Germany: Neurexan makes waves

Kava ban overturned

Sales of sedatives & sleep aids advanced by high single digits, driven by strong growth for homeopathic Neurexan (Heel, +14%), which is gaining ground on category leader Baldriparan (Pfizer, +4%). Mass market entries still contribute a significant percentage of sales, but generally underperformed, while private labels fell by 23%. Internet sales (not included in our topline) grew by over 70%, equivalent to just under 20% of revenue generated through traditional channels.

Future category performance may improve following the Cologne Administrative Court's June 2014 decision to overturn a ban on the calming herb, kava. BfArM had previously recalled registration for kava-based products in 2002 on the basis of potential liver-related complaints, although the court ruled that the risks did not outweigh the ingredient's benefits.

A less positive development was the August 2014 recall of a number of batches of passiflora products, following the discovery of increased levels of aflatoxin in tablets and capsules. Brands affected by the recall included Kytta Sedativum (Merck KGaA), Hoggar Balance (Stada), Lioran (Niehaus) and Abtei Baldrian Plus Passionsblume (Omega), although *Apotheke Adhoc* reported that pharmacies were restocked rapidly.

Baldriparan's growth was driven by its 30-tab Stark für die Nacht sleep aid (valerian), which generated around half of brand revenue. TV ads in autumn 2014 highlighted its strength, claiming that, "Schon ein Dragee genügt" (One tablet is enough). Alongside 60, 90 and 120-count versions of the sleep aid, the line also features Zur Beruhigung sedative (lemon balm and hops), which accounts for 17% of turnover.

Neurexan's impressive performance may have been helped by continued A+P support, with TV ads featuring a woman walking on the beach, ending with the tagline, "Bringt das innere Gleichgewicht zurück" (Restores your inner balance). Print ads in summer 2014 assured women that the product eases constant work, family and household stress. Internet sales of the homeopathic increased by 76%.

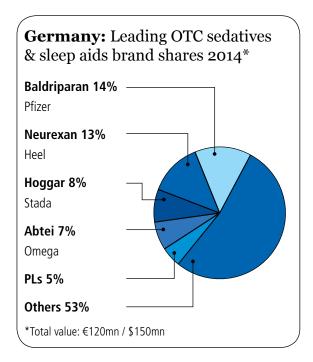
Hoggar (doxylamine) claimed the No.3 spot following 25% growth, supported by TV & print ads in Q4 2013 backing efficacy in easing sleep disturbances caused by jet lag, exam anxiety, shift work and general stress. Mass market entry Abtei and Lasea (Schwabe) jostled for the No.4 spot; the former advanced by low single digits and won a "very good" score from consumer watchdog Ökotest for its valerian-based sleep aid in October 2013. Lasea (lavender oil) grew by 9%, enjoying Q4 2013 print ad support which highlighted that the product does not lead to dependency or cause side-effects.

Outside the Top 5, Bach flower remedy range Bach Original Rescue (Nelsons) advanced by 13%, while sales of July 2012 launch Lioran (Niehaus, passiflora) more

Press ads for Neurexan state, "Entspannen am Tag. Schlafen in der Nacht" (Relax in the day. Sleep at night)







than doubled. The latter wins significant recommendation from healthcare professionals, with 159 pharmacists voting it among the Top 3 new OTC entries of 2013 in a survey by management consultant firm Sempora, on account of its efficacy and tolerability.

In the mass market, Nervenruh (Klosterfrau, valerian) fell by single digits, while Bad Heilbrunner's line-up of the same name grew a little below the category average, supported by winter 2013/14 print ads promoting the natural range of teas including Bad Heilbrunner Gute Nacht (hops and lavender). Kneipp (Hartmann) proved the most dynamic mass market entry, managing double-digit growth on the back of strong sales of its Baldrian Nacht product (valerian).

Italy: Marketers adjust to melatonin restrictions

· Pineal and Sedivitax star

Sales fell by 3% in Italy following the Ministry of Health's decision to cut the maximum daily dose of melatonin in dietary supplements to 1mg, which caused a number of marketers to withdraw products with a higher formulation (mainly 3mg-5mg strengths). Versions containing 2mg are available as medicines from pharmacies, although only

with a prescription. The Ministry delayed the restrictions — originally planned for October 2013 — until 31 December 2013, following pressure from industry association Federsalus. The measure affected sales of a number of mid-tier entries as marketers struggled to adjust, although several leading brands prospered.

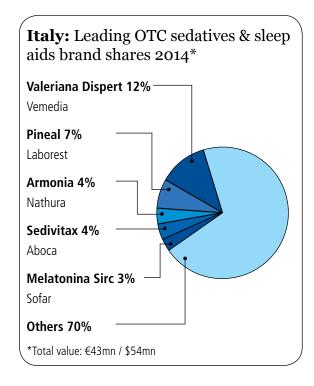
Valeriana Dispert led the way with 9% growth and accounts for over 10% of the topline. TV ads in spring 2014 underlined its efficacy in relieving stress and anxiety and allowing untroubled sleep. The ads also highlighted the marketer's spring relaunch of Melatonina Dispert 1mg (originally 3mg), using 0.5mg to induce sleep and the other 0.5mg to ensure lack of disturbance.

Meanwhile, stablemate Valdispert (-34%) struggled to hold on to its Top 5 position following the 55% decline of its melatonin-based Special version, relaunched in 2014 in a 1mg strength (previously 5mg) with added zinc and magnesium. The marketer ran a campaign between spring-autumn 2014 under the banner "6 secondi contro ansia" (6 seconds against anxiety), encouraging consumers to send in 6-second videos explaining what anxiety is and how to overcome it. Winning contributors received iPhone 6 smartphones.

No.2 entry Pineal grew by 27%, helped by the Q1 2014 introduction of Pineans, formulated with melatonin, hawthorn, valerian, passiflora, griffonia and rhodiola, and available in 20-tab packs, said to combat anxiety. Pineal Tens, positioned for stress, tension headaches and overexertion proved the most popular format (+27%), contributing almost half of brand revenue. The line-up

Valdispert TV ads highlight that the line comprises options to combat stress and sleep problems





also features several aids under the Pineal Notte banner (melatonin and valerian), which compete more directly with other category entries. Outside the Top 5, Laborest also fields Fisioreve (+3%), available as melatonin-based drops and capsules for sleep, as well as a Tens powder sachet version with added tryptophan magnesium and niacin, strongly positioned for women. Laborest launched laborest.com in September 2014 for consumers and HCPs to increase the profile of its supplements range.

Armonia followed at a distance, falling by 17% owing to the melatonin restrictions and Nathura's subsequent discontinuation of the 40-tab (3mg) and extra-strength Pulse products (5mg). However, sales could be boosted in 2014/15 by the Q1 2014 introduction of a fast-absorption Oro sublingual tablet version (melatonin 1mg). The line also features Armonia Fast drops and tablets for immediate sleep relief and a 120-tab slow-release option. Print and online ads throughout the reporting period promoted all three versions, carrying the tagline, "Perche non abbiamo tutti lo stesso sonno" (Because we don't all sleep the same).

Sedivitax challenged Armonia for the No.3 spot, posting 58% growth. Its paediatric syrup proved the most dynamic

format, although the tablet versions with valerian, passiflora and lavender still generate the majority of brand turnover. Melatonina Sirc and Valdispert competed closely for the No.5 position, although sales of the fomer dropped by 52% owing to the melatonin restrictions.

Poland: Adamed targets irritable smokers

· Nervomag renamed as Extraspasmina

The category topline expanded by 4%, with double-digit growth for mid-tier entries Nervomix (Adamed) and Extraspasmina (Herbapol Lublin / Polpharma, previously called Nervomag) offsetting more modest performances elsewhere in the rankings.

NeoPersen (Lek / Sandoz, owned by Novartis) continued to lead with a 12% share, although sales fell slightly in the reporting period. The line comprises core NeoPersen, NeoPersen Forte and NeoPersen Noc (night), all of which are registered as supplements. The Forte version was the best performer, growing by double digits and generating around 80% of total brand sales. However, sales of core NeoPersen almost halved, bringing down overall brand performance. Lek-Am's melatonin generic claimed the No.2 spot (9% share) although also failed to generate growth. Press ads supported this in late 2013, targeting women and ending with the tagline, "Melatonina Lek-Am. Czas na spokojny sen" (Melatonina Lek-Am. Time for a restful night's sleep).

Labofarm's Tabletki Uspokajajace (sedative tablets) and Farmak's Validol battled closely for the No.3 spot, each garnering a share of around 8%. The latter brand was promoted via press ads highlighting that a combination of menthol and methyl valerate help to relieve anxiety and nervous tension.

Little separated Valerin (Aflofarm), Nervomix and Valused (Hasco Lek) in sales terms, with each brand garnering a 6% share. Nervomix recorded the best performance of the three, driven by strong double-digit growth for Nervomix Control (lemon balm, magnesium amino acids chelate,





Nervomix Control is claimed to relieve nervous tension and annoyance, while also promoting wellbeing

hawthorn fruit, lavender flower and vitamin B6) and Nervomix Sen (L-Theanine and extracts of lemon balm and hops). Sales may be further boosted in 2014/2015 following the November 2014 launch of a TV and online ad campaign for Nervomix Control, with ads showing two female friends discussing stress in their work and home lives and the difficulty of balancing the two. The line is promoted at nervomix.pl and was extended with Nervomix dla rzucajacych palenie (for smoking cessation), which is said to help prevent stress and irritability associated with giving up smoking. The supplement contains sorbitol, vitamin C, extracts of lemon balm and mint leaves and magnesium stearate, among other ingredients.

Aflofarm launched Positivum in September 2014, a supplement positioned to support emotional balance, reduce irritability and nervousness and promote restful sleep. It contains extracts of lemon balm, hops and cultivated crocus (saffron). The product is seen at positivum.pl, while TV ads advise consumers to "save" themselves from bad nerves. Elsewhere, Walmark registered Valben tablets (valerian 125mg, lemon balm 112.5mg and passiflora 80mg) in September 2013, although this is not yet available.

Russia: Afobazol leads

• Strong A+P support

Value sales of sedatives & sleep aids grew by 12%. Afobazol (OTCPharm / Phamstandard, +21%) was advertised heavily to consumers via a TV campaign with the tagline, "Give up the habit of stress", which began in H1 2013 and continued in the reporting period. The



Humorous TV ads for Persen Forte highlight that it relieves everyday stress

brand was also promoted on health.passion.ru, with ads directing consumers to afobazol.ru. Advertorials targeted professional women and mothers, highlighting the risk of constant stress and anxiety and underlining the effectiveness of Afobazol to help cope with irritability, worry and disrupted sleep.

Novo-Passit (PGT; +5% value, - 5% volume) and Valocordin (Krewel Meuselbach; -4% value, -14% volume) occupied the No.2 and No.3 spots respectively. Meanwhile, Novartis' Persen advanced by 18% (+5% volume), while Persen Forte (+4% value, -8% volume) was supported by a TV ad showing people stuck in a traffic jam with their bodies jumping on springs to symbolise stress. The ad highlighted Persen Forte's natural efficacy, ending with the tagline, "Naturally quick relief from stress".

Tenoten (Materia Medica) completed the Top 5 and performed strongly (+29% value, +20% volume), while the paediatric version did even better (+47% value, +39% volume). The marketer promoted the former via press ads showing professional women alongside the text, "Tranquility and working capacity at the same time". Valoserdin (Pharmamed; +0% value, -10% volume) and Melaxen (Unipharm; +38% value, +25% volume) competed closely in the mid-tier.

Elsewhere, Nelsons supported homeopathic Bach Rescue Remedy with advertorials in *Zdorovie*, highlighting its positioning as an emergency remedy for overcoming everyday worry and stress, while also claiming that it is natural, effective, safe, allergen-free and non-addictive.

Corvalol generics (peppermint oil and phenobarbital) from a number of local players accounted for more than 10% of total sales. Pharma Start's entry led the pack, although sales fell by 10% (-15% volume).

Spain: Wealth of NPD drives growth

Doxylamine-based entries prove popular

Spain's sedatives & sleep aids category advanced by high single digits, helped by strong growth from NPD outside the Top 5. Leader Dormidina (Pensa / Esteve, doxylamine) grew at the category average to claim around 30% of the topline, backed by TV ads throughout the reporting period demonstrating the frustration of sleeplessness and carrying the tagline, "Que nada te quite el sueño" (So that nothing robs you of sleep). The brand's website also features a tracklist of sleep-related tunes compiled by streaming service, Spotify, to help consumers drift off.

Established valerian entries struggled, although NPD may lead to improved performances in 2015. Kneipp Valeriana (BI for Hartmann) fell by low single digits, despite TV & print ads featuring Spanish actress Isabel Ordaz in spring 2014 underlining efficacy. Valdispert (Vemedia, including Valerian Complex with added passiflora) fared less well, although sales could improve in 2014/15 following the spring 2014 launch of Valdispert Stress for relief of mental stress, formulated with valerian 200mg and hops 68mg. The marketer also introduced Meladispert tablets



in December 2013 for general use, combining melatonin 1mg with vitamins B3 and B6, and extended the brand in 2014 through Forte tablet and 30ml solution versions.

Meladispert was extended with strawberry-flavour drops Just outside the Top 5, Angelini's Valeriana Leo (valerian, passiflora and hawthorn) dropped by double digits, although print ads in autumn 2014 promising calm throughout the day could lift its performance. Sales may have been cannibalised by the January 2014 launch of Valeriana Forte (valerian 450mg), available in a 15-tab pack and claimed to help reduce stress and anxiety and promote healthy sleep. Angelini's sleep aids range also includes Valeriana Tri, with valerian, passiflora and L-tryptophan, but turnover here is modest.

Several other mid-tier entries competed closely, with Soñodor (Urgo / VivaSanté, diphenhydramine) falling slightly, while Melamil (Milte / DMK, melatonin) and Dormirel (Cinfa, doxylamine) advanced by double digits. In June 2014, Cinfa introduced Ns Valeriana Complex tablets for anxiety and disrupted sleep, formulated with valerian root, California poppy, vitamin B6 and L-tryptophan, to be marketed under the Ns Nature System range alongside Cinfa's other sleep aid, Ns Melatonina.

Generics marketer Kern Pharma has also entered the fray, launching first Dormikern (doxylamine 25mg) in July 2014 for occasional insomnia, and then Somnolin in October 2014. The latter is the company's first dietary supplement and is said to help establish and normalise sleep rhythms. Formulated with melatonin, Somnolin is available in orodispersible sticks with a menthol flavour.

UK: Leading brands grow

Kalms Sleep now Kalms Night

The category recorded a healthy result, growing by 7%. Herbal remedies, available for self-selection in the mass market, generate the majority of sales (over 55% in the reporting period). Both these and medicated remedies (P-only, behind the counter) advanced in line with the topline in value terms, although the latter segment's performance was skewed by revenue growth for leading brand Nytol (Omega; diphenhydramine 25mg and 50mg caplets) following a price rise in early 2014 when the SKU size of both versions increased from 16 to 20 (total value growth for Nytol was around 12%, with units increasing by around 5%).

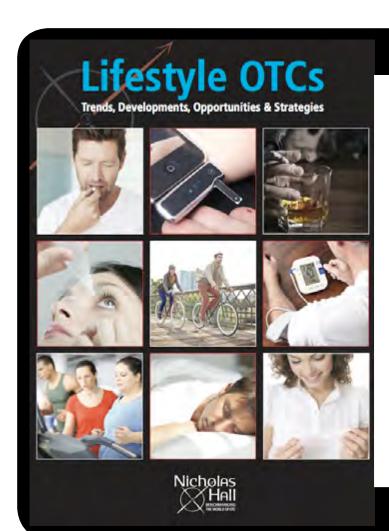


Nytol has been advertised consistently on TV over the past year, with Omega continuing the spot featuring an animated female character explaining to women that the brand is a safe and effective treatment for occasional sleeplessness. A herbal version formulated with hops, valerian and passiflora garnered almost 20% of sales. While not included in our topline, brand awareness may have increased following the launch of an anti-snoring spray in 2013.

Kalms (Lanes Health) grew by around 4%. Kalms Sleep was discontinued in spring 2014 and replaced by Kalms Night, bringing it in line with sub-range stablemate Kalms Night One-A-Night (Kalms Night contains smaller tablets than One-A-Night; up to four can be taken in one night if necessary). The brand is also available in daytime anti-stress versions Kalms and Kalms Day Pocket Pack, the latter positioned especially for on-the-go use. All versions are formulated with valerian.

Calming and sleep aid versions of Bach Rescue homeopathic (Nelsons) grew by a combined 6%. The chewing gum format was extended with a spearmint flavour in October 2014. Promotion for the brand includes sampling and prize giveaways, managed through the brand website and, since February 2014, a Facebook page. Fans of the brand can sign up to receive regular product updates and promotions via e-mail. Press and online banner ads in the reporting period featured cleverly-presented headings such as "I can't switch off", with the "switch off" written in bolder text than the "I can't", to emphasise the before and after effect of the brand.

The other brand of note, Sominex (Actavis), performed well from a low base. Heavy discounting for the herbal version sees it on sale at considerably less cost than even Boots' private label (30-count SKUs). For this reason, volume sales outstripped value in the reporting period.



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