



GLOBAL TRANSDERMAL DRUG DELIVERY MARKET TO 2017

STRATEGIC ANALYSIS,
TECHNOLOGIES, COMPETITOR
PROFILES, FINANCIAL EVALUATION,
PRODUCT PIPELINE ASSESSMENT &
SWOT INVESTIGATION

 **KELLY
SCIENTIFIC
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CUTTING-EDGE MARKET INTELLIGENCE

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and SWOT Investigation’**

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1.0 Executive Summary

“**GLOBAL & USA TRANSDERMAL DRUG DELIVERY MARKET TO 2020: Strategic Analysis, Technologies, Competitor Profiles, Financial Evaluation, Product Pipeline Assessment and SWOT Investigation**” by Kelly Scientific Publications is a dedicated report on the transdermal drug delivery industry and its impact on the USA and global markets.

This comprehensive report tackles problems that this vertical growing market faces and evaluates saturated sub-markets. A detailed outlay of its major players is performed including business strategy and future development analysis, merger and acquisition tactics, current product and pipeline entry evaluation and a detailed section on each player’s financial situation. This analysis determines the unmet needs of the transdermal drug delivery industry and specific niche areas of market entry.

The transdermal drug delivery market has substantial associations within the smoking cessation market, analgesics/pain market, generics market, neuropathic pain market and also the women’s health market. In the future it will significantly enter the vaccine and gene therapy markets. Transdermal drug delivery is a complex area that has many driving factors including the unmet need for non-invasive drug delivery systems for pediatric, geriatric and dementia patients.

This report describes the current technologies that are propelling the market space and emerging trials and pipeline agents that will make a significant impact on the industry. It examines the current transdermal delivery systems and how generic competition is allowing penetration of new players in the market and saturation of niche areas.

Financial figures of the drug delivery market and the transdermal drug delivery space are revealed in this report. Forecast projections and future growth rates are provided to give the reader a forthcoming perspective of this growing industry. The study also provides a comprehensive financial, business strategy and product review of key players in the transdermal drug delivery industry. Strategic drivers and restraints of this market are revealed and market opportunities and challenges are identified.

In summary, the transdermal drug delivery market has huge opportunities for growth in the areas of dementia (Alzheimer’s & Parkinson’s Disease), generics, paediatrics and geriatrics. Currently the USA is the most prominent market place, followed by Europe, Asia and Emerging Markets. This report will reveal in-depth analysis of the industry and provide cutting-edge intelligence on the current and future spaces it will penetrate.

1.1 Objectives of Report

This is a comprehensive account of the market size, segmentation, key players, SWOT analysis, influential technologies, and business and economic environments. The report is supported by **320 tables & figures over 280 pages**. This report is presented as follows:

- By **Company** (e.g., JANSSEN, MYLAN, ACTAVIS, GLAXOSMITHKLINE, BAYER, NOVARTIS, NOVEN, LAVIPHARM, PROSTRACKEN, NITTO DENTO)
- By **Geography** (Global, USA)
- By **Parent Market** (Drug Delivery Systems, Advanced Drug Delivery Systems)
- By **Sub-market** (Generics, Women’s Health, Analgesics, Neuropathic Pain)

A wealth of **financial data & business strategy information** is provided including:

- Up-to-date company financials, sales & revenue figures
- Revenue and market forecasts
- Business model strategies for drug delivery, pharmaceutical and biotechnology companies
- Comprehensive account of company products, financials & portfolios

SWOT, Economic & Regulatory Environment specifics include:

- Key strengths, weaknesses and threats influencing leading player position within the market
- Technologies driving the market (e.g., chemical enhancers, microneedles)
- Top fastest growing market segments and emerging opportunities
- Top pharmaceutical companies within the market
- Comprehensive product portfolios, R&D activity and pipeline products
- M&A activity and future strategies of top companies
- High demand and unmet need enhances the market
- Challenges of the transdermal drug delivery market

This report highlights a number of significant companies and gives details of their operations, products, financials and business strategy.

- Actavis
- Actelion
- GlaxoSmithKline
- Bayer
- Mylan Pharmaceuticals
- Novartis
- Upsher-Smith
- Ascend Therapeutics
- AMAG Pharmaceuticals (Lumara Health, KV Pharm/Ther-Rx Corp)
- Janssen Pharmaceuticals
- Noven Pharmaceuticals
- ProStrakan
- Shire
- Hercon Pharmaceutical
- Kremers Urban Pharmaceuticals
- Nitto Denko
- Teva Pharmaceutical Industries
- Endo International
- Teikoku USA
- Boehringer Ingelheim
- 3M
- UCB
- ParPharm

1.2 Data Sources and Methodology

The project leader and principle author of this report obtained her Ph.D. in Molecular Medicine from the Royal College of Surgeons, Ireland, following obtaining M.Sc. Molecular Medicine (Trinity College Dublin) and first class B.Sc. Biochemistry (NUIG). She has extensive experience in the fields of biopharmaceuticals drug delivery including siRNA, proteins and genes, non-viral gene delivery systems, and a variety of drug delivery systems including liposomes, nanoparticle, microparticle and also bioresponsive drug delivery systems. The author has over two decades of experience in medical writing and pharma/biotech analysis.

The senior editor of this research obtained a Ph.D. in Medicine from the Royal College of Surgeons in Ireland, following completion of a M.Sc. in Biotechnology (NUIG) and an honours degree in Biochemistry from Trinity College Dublin. With many years of medical writing and publishing the senior editor also has extensive experience and knowledge of molecular biology, immunology, bioinformatics and diagnostic testing. As a pharma/biotech industry analyst she has significant expertise in laboratory diagnostic testing and instrument and reagent development technology.

Sources of information for this report were collected and compiled from company specific corporate websites, annual reports, press-releases, international scientific and medical journals and news and research reports. Graphical and numerical data have been referenced and sourced accordingly. Specific websites were consulted and referenced throughout the completion of this report. Key data from business databases and literature were analysed for this report. High-impact business and scientific professionals were consulted on certain areas of this document and provided opinions on market forecasts and current market trends. Kelly Scientific Publications has used the most recent statistical and numerical data available. The most reliable of data sources were used in the production of this report, however we cannot guarantee complete accuracy or completeness from secondary information.

1.3 Key Findings and Observations

1.3.1 The Global Drug Delivery Market has a Growth Rate of █%

In 2014, the global drug delivery market (DDM) was worth just under \$█, a significant jump from \$█ in 2010. The market grew steadily within this time period with a compound annual growth interest of █%. By the end of 2016, it is expected to be worth over \$█, and make gains to over \$█ by 2020.

Today the US market holds just over █% share, and within the next five years Asian and Emerging market spaces will increase in size. By 2020, the Asian drug delivery market will surge past █%, compared to over █% in Europe. The US total drug delivery market will continue to maintain its █% share by 2020.

Within the total drug delivery market exists the advanced DDM, which is further segmented into the following niche areas:

- Transdermal
- Transmucosal
- Targeted
- Sustained-released agents
- Prodrugs
- Implants
- Intrauterine devices
- Oral

Targeted drug delivery is the most significant player within this space, and generated \$█ globally in 2014. Currently, targeted drug delivery systems are indicated in specific cancers, diabetes, tuberculosis and also cardiovascular disorders. These ‘nanocarriers’ are forecast to propel the advanced drug delivery space by an estimated \$█ by 2021.

1.3.2 The Transdermal Drug Delivery Market is Growing Vertically

Today the transdermal drug delivery market (TDDM) is worth \$█ globally and is one of the fastest growing segments of the total drug delivery sector and currently holds █% share. This area is set to grow vertically over the next five years, propelled mainly by an unmet need in the market for less invasive and more convenient delivery systems. These delivery systems are paramount within the pediatric, geriatric and dementia market spaces. Transdermal patches are gaining market penetration since primary physicians and patients alike put more trust in easy to use delivery methods. By 2018, the TDDM is forecast to generate \$█ annually.

The bestselling transdermal systems include narcotic analgesics, antihypertensives, Alzheimer’s disease agents, hormone replacement patches within women’s healthcare and nicotine patches for

smoking cessation. Top products within the TDDM include Lidoderm, Duragesic/fentanyl drug delivery system and Exelon. TDS technology has to date been applied to a variety of indications, most recently Migraine, Dementia, Parkinson’s Disease, Depression, ADHD, Chronic Pain and Overactive Bladder.

To that end, the TDDM contributes to the following key markets:

- Smoking cessation market
- Analgesic/Pain market
- Neuropathic Pain market
- Generics market
- Women’s health market

Figure S1: Geographical Breakdown of Global Drug Delivery Market – USA, Europe, Asia, RoW 2014

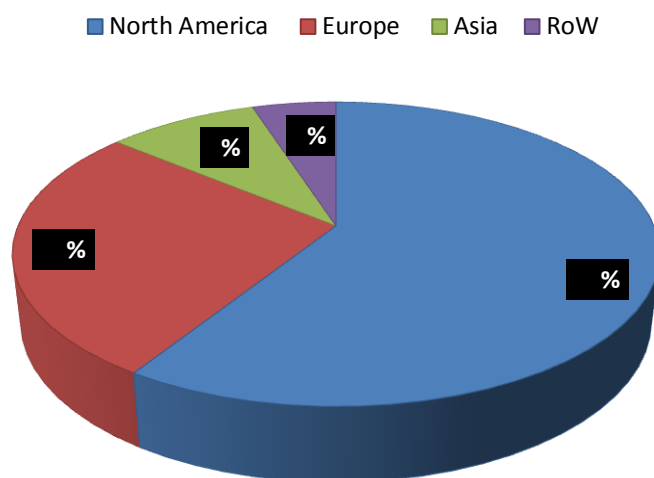
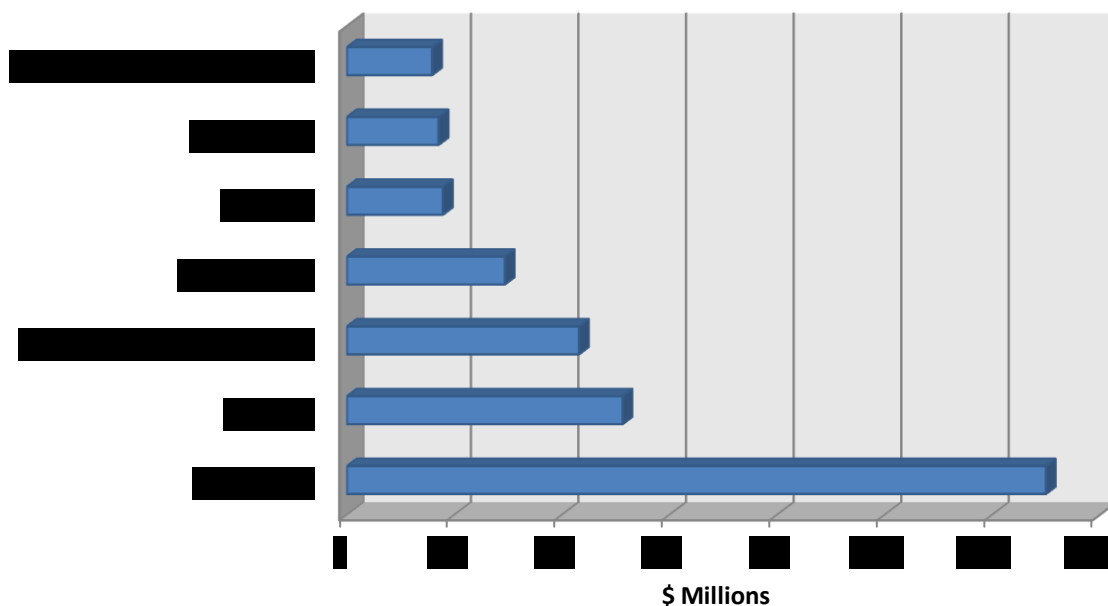


Figure S.2: Top Seven Transdermal Drug Products By Sales



1.3.3 Who are the Leading Players in the Market?

KellySciPub has analysed the following key companies within the transdermal drug delivery market with regards their business strategy, financial accounts and current and pipeline products:

- Actavis
- Actelion
- GlaxoSmithKline
- Bayer
- Mylan Pharmaceuticals
- Novartis
- Upsher-Smith
- Ascend Therapeutics
- AMAG Pharmaceuticals (Lumara Health, KV Pharm/Ther-Rx Corp)
- Janssen Pharmaceuticals
- Noven Pharmaceuticals
- ProStrakan
- Shire
- Hercon Pharmaceutical
- Kremers Urban Pharmaceuticals
- Nitto Denko
- Teva Pharmaceutical Industries
- Endo International
- Teikoku USA
- Boehringer Ingelheim
- 3M
- UCB
- ParPharm

1.3.4 Neurodegenerative Disorders Such as Alzheimer's and Parkinson's Disease Will Propel the Future Market

The Alzheimer's disease TDDM submarket is gaining market penetration and is now worth over \$ [REDACTED] globally per year. This is set to increase dramatically as the numbers of diagnosis are registered. Another major advantage of a TDD for geriatric Alzheimer's patients is its lack of invasiveness and steady drug pharmacokinetics.

KellySciPub forecasts that other neurodegenerative and progressive disorders such as Parkinson's Disease (PD) will become key indications for TDD in the near future once approvals are granted. Currently a number of companies are in the process of trialling rotigotine, lisuride and apomorphine TDD systems for Parkinson's and Restless Leg Syndrome (RLS) patients

1.3.5 Why is the Transdermal Drug Delivery Market so Promising?

It has several advantages over traditional oral and iv routes such as:

- Drug delivery unaffected by food or gastrointestinal problems
- It is not invasive
- Avoids first-pass metabolism in the patient's liver
- Diminished likelihood of hepatic induction
- A means of administering drugs to patients unable to take oral medications
- High potential within pediatric, geriatric and dementia markets
- Higher patient compliance

- More successful patient outcome
- Reduction in healthcare costs due to higher compliance & more effective treatment

1.3.6 What are the Main Drivers of the Market?

One of the driving factors of this industry is the convenience and home use appeal for patients. Not only is first generation transdermal delivery safe and effective, it also has the benefit of being low-cost. The use of physical enhancers may require electrical hand-held devices and so are more expensive, however they have the advantage of being able to deliver macromolecules and vaccines.

As with most fast paced markets, advances in technology is a major driving force and the transdermal drug delivery market is no exception. The development of microneedles to enhance absorption has opened up market opportunities for transdermal peptide and vaccine delivery. An added advantage is the ability of microneedles to be incorporated in a single-use patch that is low cost and does not require an electrical current. A disadvantage of this method is that it is more invasive and so raises health and safety concerns.

In saying this, Kellyscipub believes that the use of microneedles in TDD will revolutionise how vaccines are administered in the future. This technology would lend itself to infant vaccine programs, and also annual influenza vaccines which are particularly important in the geriatric and immunocompromised markets.

Disadvantages of using the skin as a primary delivery receptacle include rash, sensitization and allergy. Drugs most likely to provoke allergic response are clonidine and estradiol.

TDS technology must be amenable to systemic administration of the active agent, this report gives significant information on the characteristics required, and the pitfalls associated with certain formulations. Currently, a number of active agents are regulatory approved for TDS delivery, including sumatriptan (migraine), buprenorphine (chronic pain), oxybutynin (overactive bladder), rivastigmine (dementia), selegiline (depression), methylphenidate (ADHD), rotigotine (Parkinson's Disease) and fentanyl (post-operative pain). Lidocaine is one of the original active ingredients used for transdermal delivery and is a major player within the local analgesic market.

1.3.7 First, Second and Third Generation Drug Delivery Systems

Over the years, transdermal drug delivery has evolved with technological advancements, and today three generations of delivery systems exist. The majority of TDDs on the market are 1st generation systems, and work by passive diffusion alone. This generation of TDDs is efficient at delivering small lipophilic agents such as nicotine, testosterone, scopolamine and estradiol.

Second generation TDDs enhance the delivery of molecules that already have suitable properties such as low molecular weight and high lipophilicity. Chemical enhancement, and physical methods such as iontophoresis and non-cavitational ultrasound are the most prevalent second generation TDDs to date. Two significant players in the second generation TDD market are Synera, an iontophoretic lidocaine patch and Ionsys, an iontophoretic fentanyl patch.

Third generation delivery systems employ a slightly more invasive approach such as microneedles and electroporation for delivery of macromolecules with the creation of tiny microchannels. Larger agents such as vaccines (Macroflux), insulin and lidocaine/tetracycline (S-caine) can be delivered in this manner.

1.3.8 The Niche Market of Commercially Available Skin Models

This report also delves into key characterization tools that are required to evaluate the performance of transdermal systems. One of the most important investigating tools is in vitro drug releasing tests

including the static Franz diffusion cell and side-by-side cells. Commercially available skin models include MatTek's patented EpiDerm™ System which consists of normal, human-derived epidermal keratinocytes (NHEK) which have been cultured to form a multilayered, highly differentiated model of the human epidermis.

1.3.9 Transdermal Drug Delivery Technologies are Providing the Market with Niche Spaces

A number of local application formulations are now available on the market including liquid crystals, microemulsions, nanoemulsions, transdermal gels and the Biphasix system. The market has expanded to date due to the introduction of vesicular transdermal carriers, such as liposomes, transferomes, ethosomes and elastic vehicles.

Technology evolution of the transdermal patch system has led to the generation of the h-Patch™ controlled release micropump system and metered-dose transdermal system. Drug delivery via electroporation, electrotransport, cryoelectrophoresis and Iontophoresis are leading to cutting-edge evolutions of traditional drug delivery methods.

Currently the industry is evolving further to the use of microneedles as delivery vehicles for larger macromolecules such as peptides and vaccines. To date a number of technologies are available including biodegradable, dissolvable and ceramic microneedles, and also microneedle transdermal chips and arrays.

Painless injections and needlefree delivery systems are also a key area within the larger market, this subsection includes the PharmaJet Stratis, MicroJet, Sumaval DosePro and Nanoliter-volume pulsed microjets.

1.3.10 Nanotechnology is Transforming Transdermal Drug Delivery

The use of nanotechnology applications for the transdermal drug delivery market is having a positive impact on the space and key players within this niche market include GlaxoSmithKline, Aphios, and Protiva. To date nanoparticles, nanoemulsions and nanopatches are all leading the way. Current studies are examining the use of stable nucleic acids such as siRNA and aptamers in tumor biology and also viral antigens within HIV vaccine studies.

1.3.11 Can Transdermal Drug Delivery be Applied to Cancer Vaccination?

Intradermal delivery of vaccines using adenoviral vectors is currently being examined as a potential method of vaccination. Recombinant *adenoviruses* (Ad) are extremely efficient at delivering DNA to target cells, can infect both dividing and quiescent cells, have a large capacity for incorporation of cDNA expression cassettes, and have a low potential for oncogenesis as they do not insert their genome into the host DNA. Ad is being considered as a cancer vaccine as it can induce immune responses to tumour antigens following intradermal immunization.

Peptide cancer vaccines also have potential, and utilize the WT1 (Wilms tumour 1) gene. WT1 is overexpressed in many cancers especially solid tumours and haematopoietic tumours and possesses oncogenic functions. To date successful responses have been observed in the cases of breast cancer, renal cancer, ovarian cancer, glioblastoma and lung cancer. The vaccine will be administered transdermally by use of an adhesive tape which comprises of an adhesive layer containing WT1 and a suitable induction promoter.

1.3.12 Gene Therapy Advancement Using Transdermal Delivery

Transdermal drug delivery is being developed in conjunction with gene therapy to locally and systemic sites in vivo and is an exciting development within the gene therapy space. To that end the TriGrid™ Delivery System and CELLECTRA device are cutting edge technologies in this area.