Smart Pharma CONSULTING

Value of Established Pharma Brands

BEST-IN-CLASS SERIES

How to get the best of it?

POSITION PAPER

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1, rue Houdart de Lamotte – 75015 Paris – France
Tel. +33 6 11 96 33 78
Email: jmpeny@smart-pharma.com – Website: www.smart-pharma.com

Smart Pharma Consulting has recently conducted a study re. best management practices of established brands, based on desk research, its own expertise and senior executive interviews

Context, objectives & approach

Context and objectives

- Established brands play different roles, depending on the structure of pharma companies' portfolio
- For big pharma companies having a dynamic pipeline of innovative products, they represent an essential source of cash
- For less innovative companies, established brands are vital since they constitute their core business
- In this context, Smart Pharma Consulting proposes to review the best practices to optimize the value of the established brands

Approach

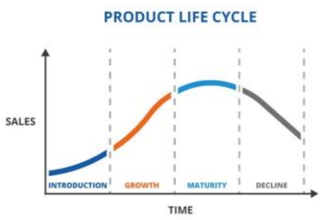
- To do so, Smart Pharma Consulting has:
  - Reviewed the literature re. established brands with a special focus on drugs[1] and…
  - … its previous publication released on Mature Brand Management (2016)
  - Capitalized on insights shared, and recommendations made during its consulting missions
  - Interviewed 16 senior executives from six pharma companies with various profiles and strategies re. the management of established brands
  - Analyzed the collected information
  - Formulated recommendations

Sources: Smart Pharma Consulting

[1] The book written by Tony Ellerly & Nel Hansen "Pharmaceutical Lifecycle Management" has been particularly inspiring

Established brands are more often mature, having lost their marketing exclusivity, requiring or not investment, and contributing significantly to the profits of pharma companies

Definition



- Different names and definitions are used by different pharma companies to describe late-stage brands
- Whatever the name used (e.g., established, legacy, mature brands), it is important to agree on a common and clear definition throughout the company to avoid misunderstanding

Zero-growth brands

Patent-expired brands

Non-priority brands

and / or

2-year pre-patent expiry brands

Local brands

Non-promoted brands

Sources: Interviews and analyses by Smart Pharma Consulting

Amongst the external factors influencing the performance of established brands, pricing is the most important one to drive customers behavior and preference

Market attractiveness determinants

Health authorities

- Limited regulatory hurdles to get MA[1] for branded generics because the clinical value of the active ingredients is yet well-established (bioequivalence required)

Suppliers

- Original and generic established brands production are most often outsourced
- It is essential to ensure a good control of manufacturing costs which account for 30-50% of sales prices[2]

Established brand portfolio performance

Customers

- Payers: increasing price sensitivity
- Prescribers: prescribing by brand name or by INN[3]
- Pharmacists: switching or not
- Patients: accepting the brand or not

Competitors

- Low entry barriers (limited development costs)
- High probability to obtain a MA
- Competition mainly on price (strong competitive advantage for lean and agile organizations with high economies of scale)
- Branded generics markets (e.g., USA, Western Europe) vs. non-branded generics markets (e.g., BRIC[4] countries, CEE[5] countries
- Branded generics trying not to compete on price but on value by offering customer services and capitalizing on corporate reputation

Sources: Interviews and analyses by Smart Pharma Consulting

[1] Marketing Authorization – [2] Before discounts – [3] International non-proprietary name – [4] Brazil, Russia, India, China – [5] Central Eastern European

The performance of established brands, in terms of sales and profits, strongly depends on the dynamism of the portfolio management and on the relevance and level of allocated resources

Brand performance determinants

Portfolio management

- Promotion:
  - Internal
  - External[1]
- Out-licensing
- Milking

Original brand entry

or

Branded generic entry

- Original brands becoming established
- Branded generics[2] (e.g., basic version, improved formulation, fixed-dose combination, etc.)

Inbound

Established brand portfolio performance

Outbound

Original brand exit

or

Branded generic exit

- Market withdrawal:
  - Authoritative decision (e.g., safety issues)
  - Strategic decision (e.g., marketing cessation due to manufacturing, profitability issues, etc.)
- Selling of the brand (cash opportunity)

Operational support

- Market access (national, regional, local levels)
- Medical affairs (medical meeting, data generation, etc.)
- Marketing:
  - Positioning (brand, associated services, corporate reputation)
  - Targeting (physicians, pharmacists, patients, PAGs[3], etc.)
  - Promotion: conventional and/or digital (medical calls, medical meetings, phoning, webinars, e-mailing, etc.)

Sources: Interviews and analyses by Smart Pharma Consulting

[1] Through a distributor, a pharma company, a CSO, etc. – [2] Developed in-house, subcontracted or in-licensed – [3] Patient advocacy groups

Depending on each company history and vision, three primary objectives have been identified regarding the management of established brands

Objectives and Strategic options

Primary objectives / Strategic options

Generate cash to fund innovation

- Established brands being often milked or supported by limited investments, they generate high profitability levels and…
- … contribute significantly to the company profits

"At Sanofi, our established brands represent a significant part of our business operating income"

Generate cash to survive

- For certain companies (e.g., Recordati, Menarini, Organon), established brands are their core business
- In this case, the sustainability of their business depends on their established brand portfolio

"Organon primary objective is to create as much value as possible from its established brands"

Contribute to sales

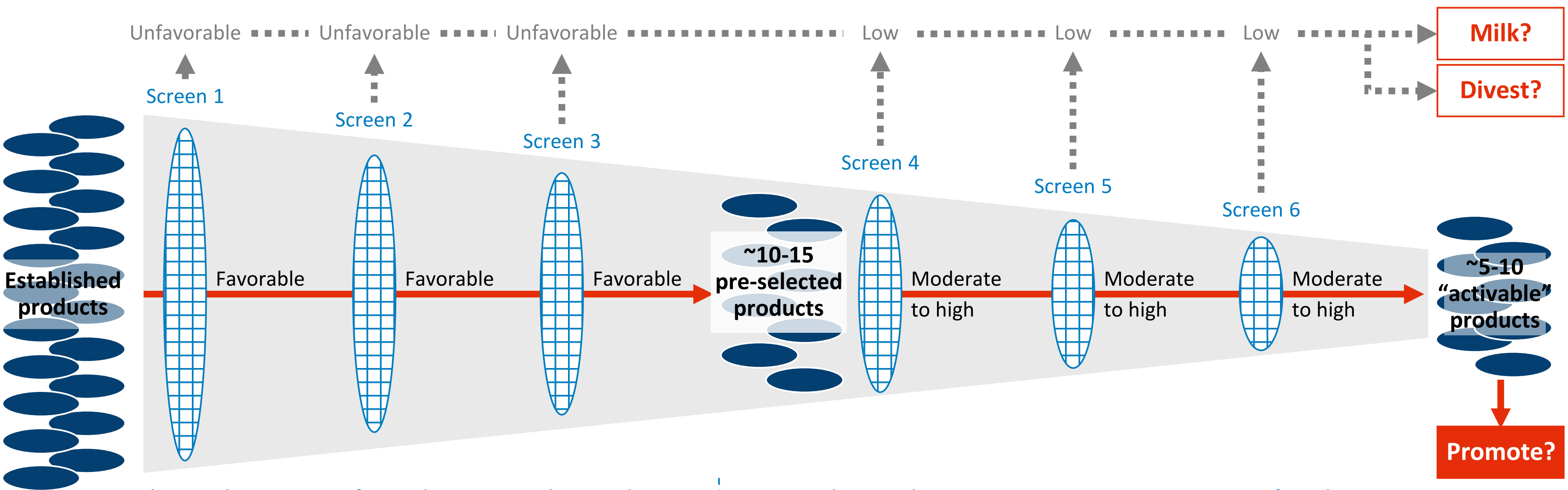
- Some other companies do not actively manage their established brands…
- … which are mainly kept in the market for their contribution to their sales

"Companies like AstraZeneca, GSK or Roche allocate a minimum level of resources – if any – once generics / biosimilars enter the market"

Sources: Interviews and analyses by Smart Pharma Consulting

The selection of "activable" established brands should be based on tangible regulatory and business criteria

Selection of established brands to promote (1/2)



Parameter examples ▶

Step 1: Quantitative screening

Sales trends
- Level
- Growth

Contribution to portfolio trends

Profit trends
- Level
- Growth

Contribution to portfolio trends
- Price variations

Market trends
- Size
- Growth
- % generics

Step 2: Qualitative screening

Regulatory risk
- Patent
- SmPC
- Guidelines
- Reimbursement

Competitive risk
- Market position
- Differentiation
- Newcomers
- Entry ticket

Strategic fit with core products
- Door opening
- Scientific legitimacy
- Prescribers overlap
- Company image and responsibility

SmPC = Summary of product characteristics

Sources: Smart Pharma Consulting

Decisions to support an established brand with promotional investments are often based on intuitive feeling of managers and rarely on the results of rigorous analyses

Selection of established brands to promote (2/2)

Key criteria driving promotion

Sales level → **Sensitivity to promotion** → **Expected profit impact**

Sales level

- The level of the brand sales should be high enough to expect a significant impact at local level

"If the brand sales are too low, the expected promotional impact will not be meaningful – GSK"

Sensitivity to promotion

- In-person or remote interactions with physicians should be possible to promote the brand

"At Recordati, decisions are made at local level considering the competitive environment and the brand potential"

"Due to budget constraints, we do not carry out in-depth sensitivity studies – Pfizer / Upjohn"

Expected profit impact

- The profit impact should be positive in the short term…
- … and significant enough

"With established brands, all promotional investments should deliver results within a year – Pfizer / Upjohn"

"More than for innovative brands, return on promotional investments for established brands should be objectified "

Sources: Interviews and analyses by Smart Pharma Consulting

For successful brand value optimization, developments must comply with four principles and decisions must be made long enough before patent expiry

Life-cycle management: Prerequisite

Provide clinical improvement

- LCM development should bring additional value vs. existing solutions
- The added value should be relevant and significant for stakeholders (i.e., prescribers, patients, pharmacists, payers)

Increase patient base

- Additional patients could be "captured" through:
  - New indications, formulations and/or combinations
  - Launching of own generic drug
- Probability of expansion should outweigh the risk to cannibalize existing SKUs

Generate significant ROI

- Four factors to consider:
  1. When to invest?
  2. How much to invest?
  3. When to stop investing?
  4. What alternatives might generate a better ROI?
- Market attractiveness should be evaluated and…
- … shaped to optimize ROI

Extent market exclusivity

- Market exclusivity can be extended through:
  - Patent protection
  - Prolonged exclusivity
- Timing is key to benefit from exclusivities for new indications (e.g., pediatric), formulations, combinations

"LCM initiatives such as new dosages, formulations, FDCs, etc. should be implemented 24 months prior to LOE"

- Successful launch by Merck & Co of Fosamax 70, once-weekly to replace Fosamax 10, once-daily, increasing the franchise sales by 80% within 2 years in the USA and Europe as a result of a significantly improved convenience for patients[1]
- Lilly launched a once-weekly version of Prozac – completing its once-daily formulation – which failed because it was not fulfilling a real need and it was significantly more expansive than the once-daily generics, launched one year later

Sources: Adapted from T. Ellerly et al. – Interviews and analyses by Smart Pharma Consulting

[1] Fosamax must be taken in the morning, standing up for between 30 minutes and 1 hour before food. Switching from once-daily to once-weekly was perceived by patients as a very important improvement in terms of convenience, which resulted in a strong acceleration of the product sales. At that time, Fosamax 10 was not yet genericized but considered as obsolete vs. once-a-week formulations proposed by competitors

Launching new indications can be an effective life cycle management initiative, provided they are medical relevant, offer a significant business potential and appropriate resources will be available

New indications: Decision-making factors

What is the medical benefit?

- Strength of rationale and/or track record of the mechanism of action
- Existing proof-of-concept (POC)
- Robustness of dose selection
- Safety signals in pre-clinical studies
- Position in the treatment strategy
- Etc.

What is the commercial potential?

- Importance of unmet needs
- Patent expiry date of the original brand, or of the combined product, in case of FDC
- Potential exclusivity related to the new indication
- Competitive intensity
- Likely acceptability of target pricing
- Likely reimbursement
- Depth of knowledge re. the targeted market
- Etc.

What are the available resources?

- Internal competition for resources vs. other products in development
- Company priority for the targeted indication
- Willingness and ability to co-develop a new indication with partners
- Etc.

A new indication is not very effective to defend a brand franchise after patent expiry because one cannot prevent physicians prescribing and pharmacists dispensing generic versions, even if the indication is protected

Sources: Adapted from T. Ellerly et al. – Interviews and analyses by Smart Pharma Consulting

Combining a new dosage strength or a new dosage regimen with a new indication can be an effective life-cycle management strategy

New dosage strengths and regimens

New dosage strengths

- Adding dosage strengths can be a useful strategy at different phases of the brand life cycle
- This can enable physicians to customize dosage according to the needs of individual patients and…
- … may help to gain market share from alternative original brands or generics that do not offer the same flexibility
- The benefit of providing a wide range of dosage strengths must be weighed against the extra cost of multiple SKUs, by quantifying the upside provided by each dosage strength
- Example: Lovenox (enoxaparin) is marketed in 8 different SKUs in the USA and 11 in France

New dosage regimens

- New dosage regimens are usually the result of reformulations, as when a twice-daily form is replaced by a once-daily form, in a controlled release formulation
- The objective of a new dosage regimen can be to:
  - Differentiate from competition:
    Schering-Plough launched Intron-A[1] (interferon alfa-2b) for hepatitis B followed by PEGIntron[2] (peginterferon alfa-2b)
  - Close a gap:
    Actonel 75 mg, taken once-monthly, was developed to replace Actonel 35 mg once-weekly to compete with Bonviva 150 mg from Roche/GSK which was used on a monthly basis
  - Increase cost-effectiveness:
    By spacing drugs injections from weekly to bi-monthly, one can reduce the cost of treatment, especially if done by a nurse
  - Get a patented SKU:
    Genentech obtained a patent in Europe on a new dosage regimen for an IGF-1[3] injected discontinuously in a cyclic "on/off" fashion

Sources: Adapted from T. Ellerly et al. – Interviews and analyses by Smart Pharma Consulting

[1] Also named Rebif and injected 3 times a week – [2] Also named Viraferonpeg, a pegylated formulation, injected once-weekly – [3] Insulin-like-Growth Factor-1

Drug reformulations, which mostly aim at reducing the dosage frequency or changing the route of administration, have become rarely recognized as a valuable differentiating factor

New formulations

- Improving efficacy, safety and/or convenience through reformulation can lead to a significant uptake amongst stakeholders[1]

Key Success Factors	Key Barriers
▪ Launch early, prior to patent expiry to switch patients before generic entry ▪ Lower investment required compared to new product development and launch ▪ Maintain sales of brand franchise when patients switched to the reformulated version, ahead of patent expiry ▪ Capitalize on the brand equity established for the original product	▪ Increasing use of tiered and/or restrictive drug plan formularies may limit uptake ▪ Withdraw and switch strategies blocked by EU regulations ▪ Reformulated products risk of being included in jumbo reference pricing system like in Germany ▪ Increasing bad perception of physicians and payers viewing reformulations as a generic defense strategy ▪ No additional data exclusivity periods under EU regulations, even for patented reformulations

Drug delivery devices

- In certain TAs like respiratory diseases[2], inhalers (i.e., vaporizer, dry powder, nebulizer) or in diabetes (insulin syringe and vial, prefilled syringe, pen, connected pen, "artificial pancreas"[3]) have participated to drive competitive differentiation and to raise a certain level of protection against generic and biosimilar competition

Sources: Adapted from T. Ellerly et al. – Interviews and analyses by Smart Pharma Consulting

[1] Physicians, patients, pharmacists and payers – [2] Asthma and chronic obstructive pulmonary disease (COPD) – [3] Combination of a blood glucose meter and a drug delivery system that are interconnected

Before developing and launching FDCs, clinical relevance and business opportunities should be carefully assessed because the cases of success have significantly decreased over the recent years

Fixed-Dose Combinations: Single & multiple indications

Example
Arterial hypertension

Calcium channel blocker | Angiotensin II receptor blockers

Example
Arterial hypertension + Hypercholesterolemia

Calcium channel blocker | Statin

Exforge (amlodipine + valsartan)

Caduet (amlodipine + atorvastatin)

Key points to be assessed

- **Medical value of the combination:**
  – What is the clinical outcome (efficacy and safety)?
  – What is the convenience level of the FDC from physicians' (position in the therapeutic armamentarium, titration) and patients' perspectives (drug intake and regimen)?
  – Does it require a change in treatment practice, and what are, in this case, the requirements to do so?

- **Commercial value of the combination:**
  – What is the importance of the comorbidity in terms of treated patients (if multiple indications like for Caduet)?
  – What is the reservoir of growth for the FDC (i.e., main competitors, either original brands or generics)?
  – Is there a risk of cannibalization and how important is it?
  – What is the price level that can be expected from the FDC?

"In the USA and Europe, the benefits of FDCs in terms of adherence to treatment is under-valued by payers"

Sources: Adapted from T. Ellerly et al. – Interviews and analyses by Smart Pharma Consulting

The marketing of own generics or of competitors' ones may contribute to extent the established brand portfolio offering and to improve the generated profits

Generic strategy

Own generics strategy

- Developing and marketing its own generics makes sense in price-sensitive markets like the USA, Germany, the UK, France, etc., in which established brands cannot compete head-to-head and remain profitable[1]
- This strategy has not shown to be very effective when calls for tenders are the dominant process of purchase
- The risk of cannibalization should be evaluated
- Once the decision has been made, the pharma company can market its own generics:
  - In-house, in a dedicated business unit (e.g., Pfizer with Greenstone[2] in the USA, Sanofi with Zentiva[3] in France)
  - Through a third-party, specialized in the generic business (e.g., Pfizer has signed a deal with the generic company Zentiva to market its own generic of Lipitor in France)
- This strategy requires to contain manufacturing costs at a level comparable to generic companies to offer competitive prices to be listed by retail pharmacists

Competitors generics strategy

- Pharma companies can develop or in-license and market generics from other pharma companies as:
  - Non-branded generics (e.g., Novartis markets the established brand Diovan (valsartan), its own generic through its subsidiary Sandoz, which markets also a generic of Cozaar (losartan) of Merck & Co)
  - Branded generics (e.g., Liporosa, FDC of rosuvastatin and ezetimibe, marketed by Servier)
- The choice between non-branded and branded generics will depend on the market considered
- Non-branded generics should preferably be included in a dedicated generic business unit with the right expertise
- Branded generics, promoted in priority to physicians can advantageously help to manage dynamically and in a more profitable way a portfolio of established brands

Sources: Adapted from T. Ellerly et al. – Interviews and analyses by Smart Pharma Consulting

[1] In these markets, generics can take 80% to 90% of the original brand in few weeks with price cuts by 50% to 80% – [2] Before the spin-off of Greenstone, part of Upjohn, in 2021, which is now part of Viatris – [3] Before it was sold to the private equity firm Advent in 2018

The optimization of manufacturing processes and costs are particularly important for established products which must compete on price

Manufacturing strategies

Enhanced protection

- Development of new, patent-protected manufacturing processes eliminating impurities, using different excipients and adjuvants…
- … can provide secondary protection and…
- … raise the technical hurdles to competition, and especially generics manufacturers

Improved differentiation

- It is possible, in certain cases, to delay generic entry by tightening the specifications on the original brands, late in their life cycle
- The objective is to prevent generics companies to meet the more stringent quality or the bioequivalence standards…
- … or at least, to delay their entry if they were developing their generics in comparison with earlier and looser specifications

Enhanced profitability

- Established brands are particularly subject to price competition from competitors and price pressure from payers
- Minimization of manufacturing costs by improving processes is a priority to maximize the profitability of established brands
- To do so, relocation of production to lower cost countries or outsourcing can be considered

Optimizing the cost of goods sold is a key driver of successful management of established brands

Sources: Adapted from T. Ellerly et al. – Interviews and analyses by Smart Pharma Consulting

In general, pharma companies expect from commercial activities dedicated to established brands quick, cheap and high return on medical-marketing and sales investment

Commercial strategies

Drive global access to patients

- The larger the number of countries where the brand is available, the higher the probability of sales
- Thus, it is important to get and/or maintain the drug approved by national health authorities for its different indications
- The pricing policy should be adapted to the competitive environment to be:
  - Reimbursed by public / private payers
  - Listed on formularies
  - Prescribed by physicians
  - Dispensed by pharmacists
  - Bought by patients (if out-of-pocket)

Optimize profitability

- The lifetime profitability is a critical performance indicator throughout the brand life cycle
- The commercial tactics play a great role to optimize profitability
- The following key questions should be addressed:
  - Where and when to invest?
  - Where and when to cut investment?
  - Where and when to drop or raise prices?
  - How to invest in an efficient manner?
  - Can digital channels replace in-person interactions?
  - Etc.
- In non-branded generic markets, the most profitable strategy is, in general, to harvest the brand, by cutting medico-marketing and sales expenses

The diversity of competitive environments from one country to another requires to adopt flexible strategies to optimize the performance of established brands

Sources: Adapted from T. Ellerly et al. – Interviews and analyses by Smart Pharma Consulting

An active support of established brands in branded generic markets may pay off, depending on each specific situation

Geographical optimization

Non-branded generic markets

(USA, Germany, France, UK, northern European countries, etc.)

- The established brands, once genericized, or even once their close competitors are genericized, see their sales drop in volume and furthermore in value due to authoritative price cut and/or price discounts
- In these markets, in general, substitution right[3] is granted to retail pharmacists who have more financial interest to deliver generics than the original brands
- Few weeks or months after their market entry, generics capture up to 70% to 80% of the original brand sales

- The best strategy is, most often, not to do anything since the prescription of physicians is substituted by retail pharmacists in favor of generics, while it is rare that patients ask to be delivered the original brand

Branded generic markets

(Italy, Spain, China, India, Russia, CEE[1] countries, CIS[2], Latin America, etc.)

- In countries where the generic market is dominated by branded generics, the latter are viewed by stakeholder and promoted by pharma companies as me-too products
- Physicians, influenced by pharma companies, develop a certain degree of brand loyalty
- Substitution is either not widely applied or permitted
- It is not rare for generics to have a penetration rate limited to 40% or 50% on these markets

- Depending on branded generic market specificities, the optimization of established brand performance may require an active support in terms of market access, medical affairs, marketing and sales activities

Sources: Interviews and analyses by Smart Pharma Consulting

[1] Central and Eastern Europe – [2] Commonwealth of Independent States – [3] Not the case in the UK

Pricing strategies should be adapted to competitive position of each brand at the level of each local market, so that to optimize the brand value

Pricing strategies

Price alignment

- The decision to align the price of established brands at the level of or close to the cheapest competitors depends on:
  - Local regulations (e.g., price cuts imposed by health authorities / public health insurers in countries like France, after LOE; reference pricing system like in France, Italy, Germany, Spain)
  - Existence of national (e.g., Nordic countries) or regional (Germany) tenders
  - The opinion and behavior of:
    - Payers who set a maximum reimbursed price
    - Retail pharmacists who can substitute
    - Physicians who can "impose" a brand
    - Patients who may not accept to pay out of their pocket

Premium price

- The premium price strategy can be the preferred choice if the established brand is perceived as superior to generics and/or other me-too products in terms of:
  - **Product features** (e.g., number of dosages, device for injection, packaging, narrow therapeutic range)
  - **Services** (e.g., patient support programs, CME[1] programs, medical information)
  - **Corporate reputation** (e.g., in terms of innovation, quality of execution, Corporate Social Responsibility)
- Thus, in these conditions, a higher price can be offset by the value of the established brand for a proportion of stakeholders

Sources: Adapted from T. Ellerly et al. – Interviews and analyses by Smart Pharma Consulting

[1] Continuous medical education

Exit strategies are part of a dynamic management of an established brand portfolio and contribute to optimize its profitability

Exit strategies

Patient safety

- The exit of established brands for safety reasons is either permanent or temporary (e.g., withdrawal of Zantac from USA and Canada in 2019 contaminated by impurities, potentially carcinogens)
- Withdrawals can be either imposed by healthcare authorities or decided by the manufacturer if the cases of pharmacovigilance are judged as too frequent

Change in strategy

- Pharma companies can decide that a brand or a complete TA is not anymore strategic and decide to exit the market to refocus its efforts (e.g., Novo Nordisk withdrawn its older porcine insulin range from the UK market, to bolster the transition onto its recombinant insulins – decision of Sanofi to sell its USA dermatology business in 2011, considered as too small)

Failing profitability

- The less profitable formulations and dosage forms can be removed from all or certain markets, according to local competitive situations
- The decrease of profitability can result from price cuts, volume drops, increase of manufacturing costs, investments required to maintain registration dossiers up-to-date, or higher medico-marketing expenses

Opportunity cash

- The selling of an established brand will generate one-off cash injection vs. long-term declining revenues
- The selling of established brands is mainly driven by the wish to streamline a portfolio of too many SKUs (e.g., in 2020, AstraZeneca sold the commercial rights of established hypertension drugs[1] for an upfront payment of $350M to Atnahs Pharma to reinvest in main therapeutic areas)

Sources: Adapted from T. Ellerly et al. – Interviews and analyses by Smart Pharma Consulting

[1] Inderal (propranolol), Tenormin (atenolol), Tenoretic (atenolol, chlorthalidone fixed-dose combination), Zestril (lisinopril) and Zestoretic (lisinopril, hydrochlorothiazide fixed-dose combination)

Pharma companies for which established brands are their core business tend to adopt a locally-driven organization which provides more flexibility and better adaptation to the environment

Organization

Global vs. Local management

Model A: Globally-driven management	Model B: Locally-driven management
▪ Regulatory, Life-cycle management, and medico-marketing support concentrated at global level	▪ Broad autonomy given to affiliates which decide to support or not established brands with promotion…
▪ Acquisitions and divestments decisions driven by global department in charge of established brands	▪ … and to carry out BD&L initiatives to develop the local business
▪ Regular interactions between global and national teams, fostering best practice sharing	▪ Investment decisions are submitted to the company HQ
(e.g., Sanofi for global brands with potential)	(e.g., Recordati, Sanofi non-core assets with various potential at local levels)

"General Medicines division includes core assets brands(e.g., Toujeo, Lovenox, Plavix) and non-core assets brands (e.g., Lantus, Aprovel), on which investments are more limited but adapted to local market attractiveness – Sanofi"

"The management of established brands requires a lean and agile structure with highly skilled collaborators"

Sources: Interviews and analyses by Smart Pharma Consulting

Established brands are mainly promoted in branded generic markets where exist opportunities to grow, maintain or slow down the decrease of revenues and attached profits

Established brand value optimization: Recommendations (1/3)

Market / Established Brand Matrix

	Non promoted brands	Promoted brands
Branded generic markets (e.g., Italy, Spain, China, Russia, CEE, CIS, Latin America, etc.)	When the sales and profit contributions of established brands are too low, they are milked	Brand heritage being highly valued, established brands are often promoted after LOE
Non-branded generic markets (e.g., USA, Germany, France, UK, northern European countries)	The great majority of established brands are not promoted	Certain therapeutic areas (e.g., dermatology, ophthalmology, women's health) are less sensitive to non-branded generics

- Depending on companies' profile, the priority of established brands can be to:
  - Generate cash to fund innovation
  - Generate cash to survive
  - Contribute to sales
- Pricing is the most important factor driving customers behavior and preference
- The performance of established brands requires:
  - A dynamic management of the portfolio[1]
  - An efficient level of allocated resources (market access, medico-marketing)
  - A good control of manufacturing costs
- Decision to maintain and promote established brands will strongly depends on:
  - Market attractiveness[2]
  - Intrinsic value of brand attributes[3]

Sources: Smart Pharma Consulting

[1] New indications, new dosage strengths and regimens, new formulations, fixed-dose combinations, generic strategy, exit strategies – [2] Level of price capping, reference price, substitution right, level of substitution by pharmacists, competitive intensity, sensitivity of physicians to promotion, price sensitivity of patients if co-payment – [3] Efficacy, safety, convenience vs. competition, value of the brand heritage

The optimal management of established brands requires highly experienced collaborators focusing on short-term efficiency and supported by a lean and agile organization

Established brand value optimization: Recommendations (2/3)

- Collaborators managing established brands should:
  - Be experienced
  - Have an entrepreneurial mindset
- Decision-making processes should be:
  - Fact-based with a permanent double valuation at global and local levels
  - Supported by cost-efficient market studies and analyses…
  - … rather than intuitive considerations, as it is often the case by lack of resources
- When established brands have shown to be sensitive to promotion, the level of effort should demonstrate a quick impact on performance, at national level
- Mature products franchises or BUs should:
  - Be set-up at national level to better address local specificities…
  - … while remaining lean and agile…
  - … capitalizing as much as possible on shared support functions (i.e., finance, manufacturing, supply, regulatory, legal, BD, medical, commercial, etc.)

Sources: Smart Pharma Consulting

To get the best of their established brands, pharma companies should determine why and where to play, and how to win, considering their corporate vision and their own capabilities and assets

Established brand value optimization: Recommendations (3/3)

Why to Play?

1. Craft clear objectives:
   - Priority given to revenue vs. profit optimization
   - Priority given to short vs. mid vs. long term performance

Where to Play?

2. Define the scope of the established brand portfolio:
   - In-house original brands only with or without FDCs[1]
   - Branded and/or non-branded generics of own original brands and/or of competitors brands
   - Established brands of competitors (in-licensing and/or acquisition)
3. Select the most attractive markets (i.e., offering the best match with the brand values)

How to win?

1. Set rules and methods to select "activable" established brands by markets
2. Implement a dynamic brand and portfolio management:
   - Regular entries of new established brands (e.g., own or competitors', incl. generic versions) or extensions (e.g., FDCs, new dosages or formulations) of existing brands to boost the portfolio value
   - Exit of less profitable or at-risk[2] brands
3. Define a clear governance (global – local – glocal) re. BD&L initiatives (in-licensing, acquisition, out-licensing)
4. Allocate carefully operational resources – looking for short term efficiency – and with a special attention to manufacturing costs and the quality of the supply chain
5. Evaluate the quality of execution and impact of decisions made with relevant Key Execution Indicators (KEIs)

Sources: Smart Pharma Consulting

[1] Fixed-dose combinations – [2] In terms of safety

Smart Pharma
CONSULTING

Consulting firm dedicated to the pharmaceutical sector operating
in the complementary domains of strategy, management and organization

The best-in-class Series

- This series intends to share concepts, methods and tools to boost the efficiency and efficacy of executives having operational responsibilities in the pharma business
- We have yet published several issues including:
  - Operational functions (e.g., marketer, med rep, MSL, KAM)
  - Operational activities (e.g., Market research, BD&L, strategy crafting, reputation enhancement, field force organization)

Value of Established Pharma Brands

How to get the best of it?

- The challenge in the management of established brands is to maintain or even to increase the cash they generate to fund innovation or…
- … to survive for the less innovate companies
- This position paper is based on literature review, Smart Pharma Consulting experience and interviews of 16 senior executives from various profiles of pharma companies
- The strategic and operational best practices identified are illustrated with numerous practical examples

Smart Pharma Consulting Editions

- Besides our consulting activities which take 85% of our time, we are strongly engaged in sharing our knowledge and thoughts through:
  - Our teaching activities in advanced masters (ESSEC B-school, Paris Faculty of Pharmacy)
  - Training activities for pharma executives
  - The publication of articles, booklets, books and expert reports
- Our publications can be downloaded from our website:
  - 41 articles
  - 63 position papers covering the following topics:
    1. Market Insights
    2. Strategy
    3. Market Access
    4. Medical Affairs
    5. Marketing
    6. Sales Force Effectiveness
    7. Management & Trainings
- Our research activities in pharma business management and our consulting activities have shown to be highly synergistic
- We remain at your disposal to carry out consulting projects or training seminars to help you improve your operations

Best regards

Jean-Michel Peny

1, rue Houdart de Lamotte – 75015 Paris – France • Tel.: +33 6 11 96 33 78 • E-mail: jmpeny@smart-pharma.com • Website: www.smart-pharma.com