Accounting issues in Pharmaceutical Industry

December, 2015

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- Overview of Indian Pharmaceutical Industry
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  - Contract manufacturing
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  - Taxes on Income
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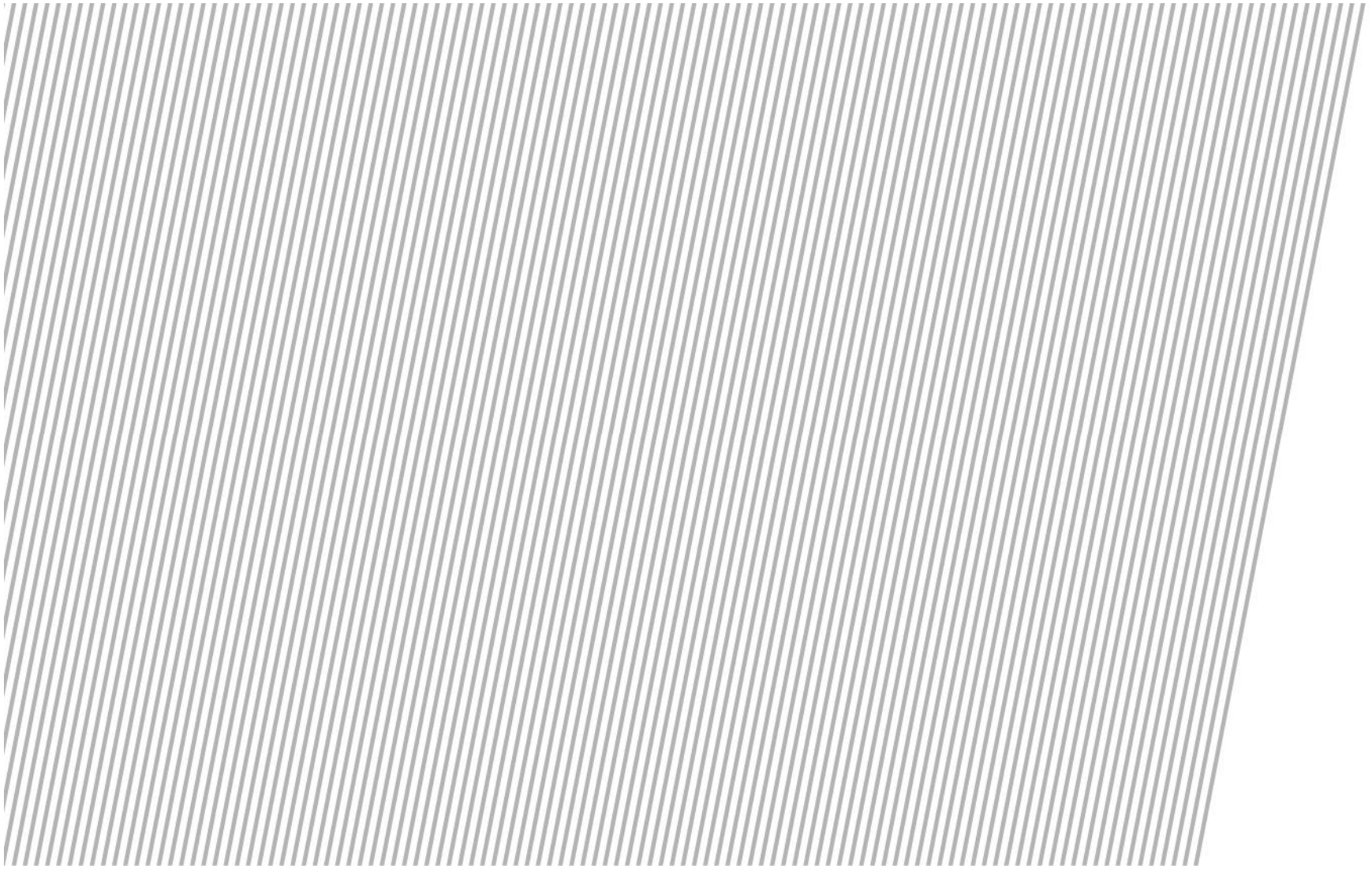
Overview of Global Pharmaceutical Industry



Overview of Global Pharmaceutical Industry

- The Global pharmaceuticals industry can be broadly classified into the following three categories: (i) Regulated and Semi-Regulated Markets; (ii) Patented and Generic Products and (iii) Geography.

- **Regulated and Semi-Regulated Markets:** Regulated markets are primarily governed by stringent government regulations such as intellectual property protection and product patent recognition. On the other hand, unregulated/semi-regulated markets have lower entry barriers in terms of regulatory requirements, but are highly competitive with industry players primarily competing on the basis of price.

- **Patented Products vs. Generic Products:** Pharmaceutical companies which hold patents for their products are given the right to exclude others from using their invented products for any commercial purpose. These Companies are allowed an exclusive marketing period, mainly to earn the revenue on a product to recover the resources spent in inventing that product. Generic pharmaceutical products are pharmaceutical products that are not protected by patents. These are drugs marketed by different companies but which contain the same active ingredients.

- **Geography:**
  - The global pharmaceuticals industry has been dominated by the US, German, French, Italian, Spanish and the UK (collectively known as the “EU5”) and Japanese markets, with these three markets having combined sales of approximately US$635.4 billion in 2014 (60% of total sales).

Overview of Global Pharmaceutical Industry

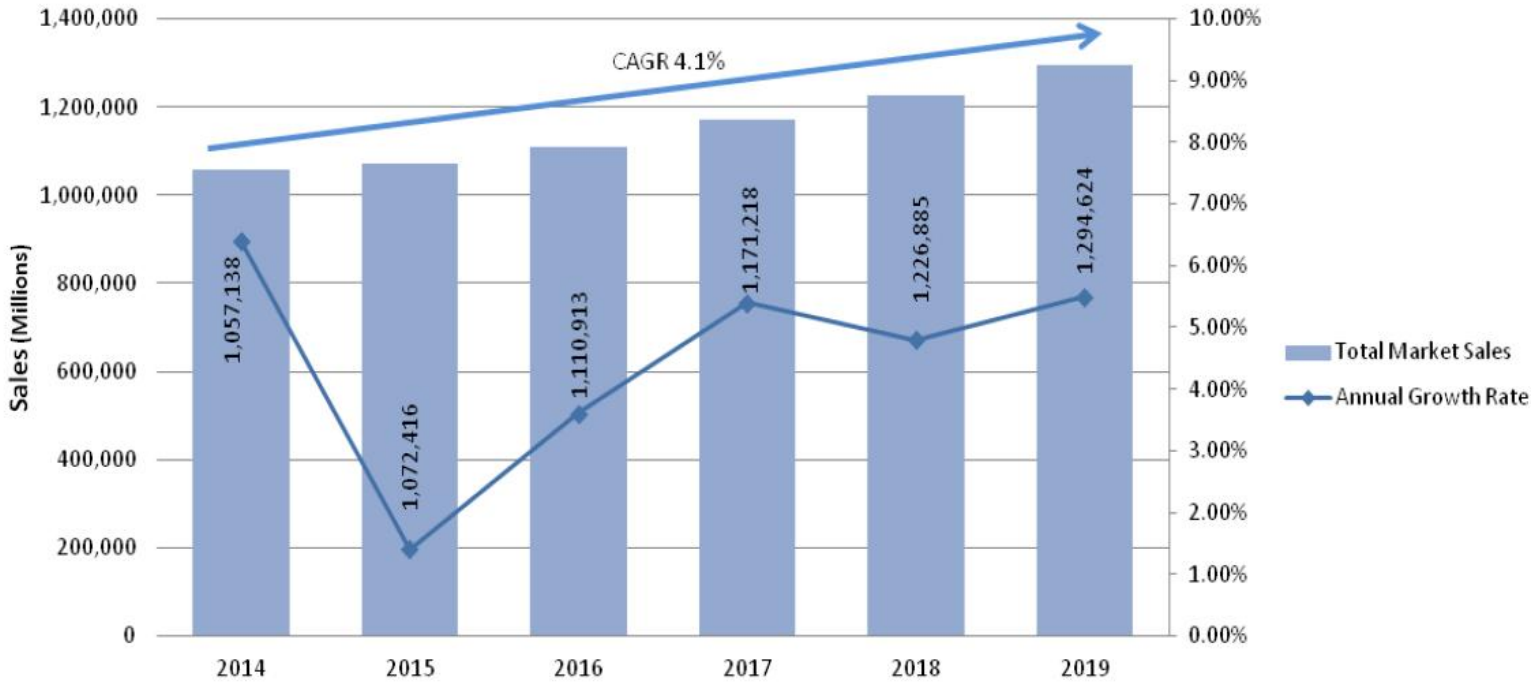
- The US is the largest pharmaceuticals market in the world, both for brand-name drugs and generic drugs. The US is a prime destination for most India-based pharmaceutical companies to expand and increase their potential. Further, continued government initiatives to cut increasing healthcare spending and a high rate of generics substitution has also made the US market increasingly attractive for key generic manufacturers.

- Emerging markets including China, Brazil, India, Russia, etc have long been considered as significant growth potential considering their large populations, increasing prosperity. The growth in these are primarily driven by government healthcare investments and increasing burden of chronic disease.

Overview of Global Pharmaceutical Industry

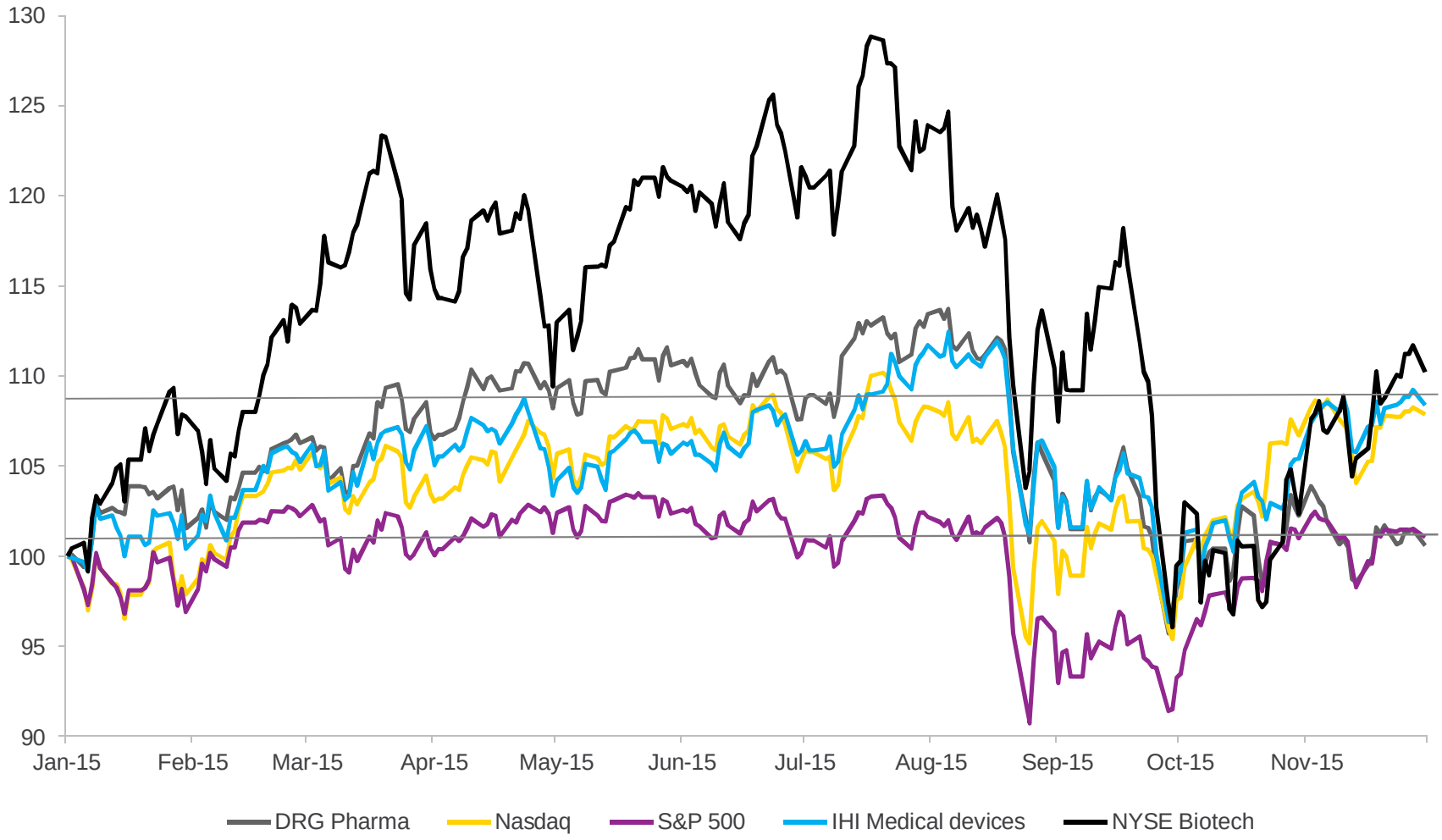
- According to IMS Health, the size of the global pharmaceuticals market is expected to grow at a CAGR of approximately 4.1% between 2014 and 2019, to reach sales of approximately US$1,294.6 billion by 2019, compared with US$1,057.1 billion in 2014.

- The chart below demonstrates the global pharmaceutical expected sales between 2014 to 2019



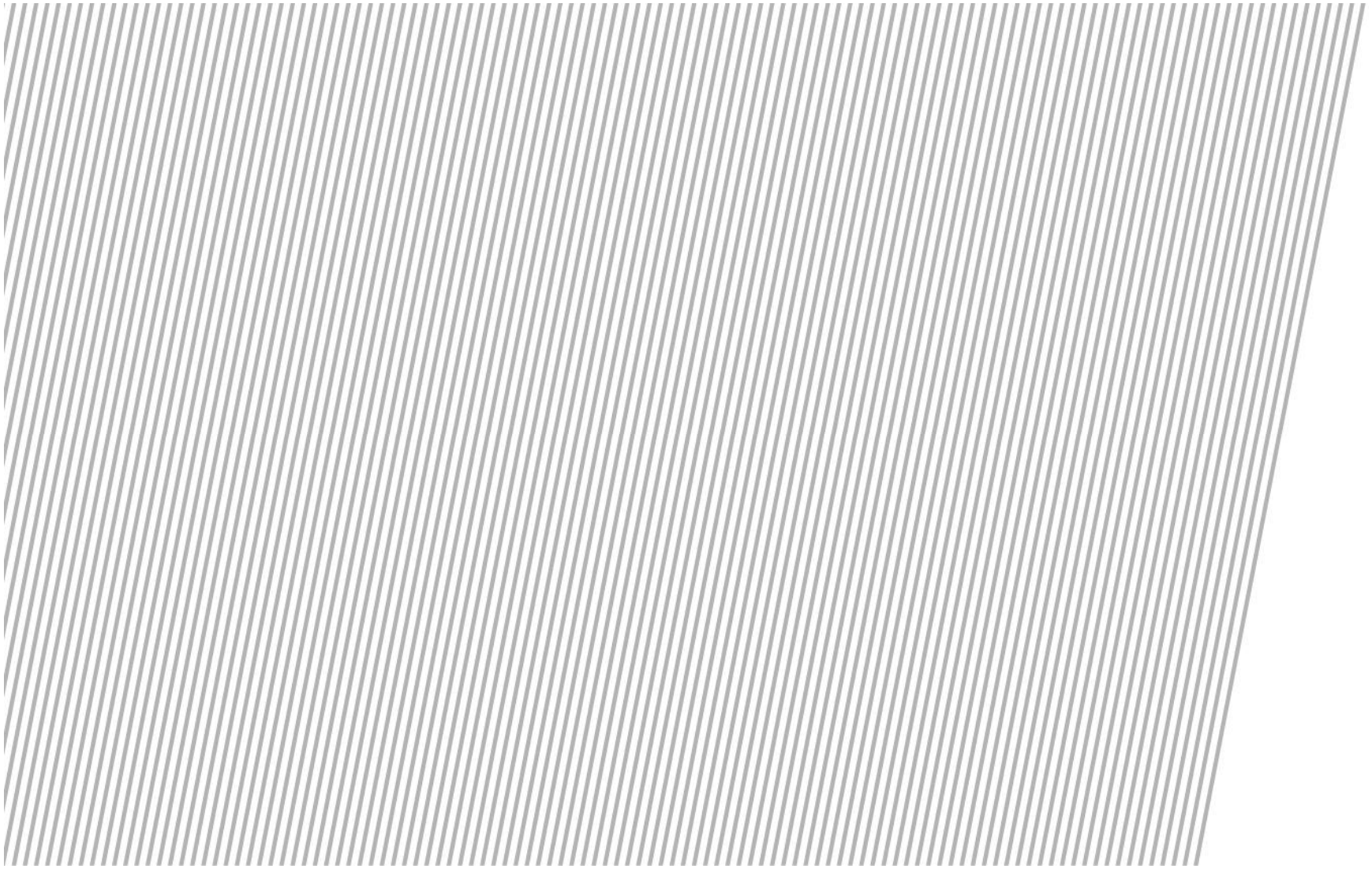
Source: IMS Health

Different Market Indices for 2015



Source: ThomsonOne

Overview of Indian Pharmaceutical Industry



Overview of Pharmaceutical Industry in India

- According to CRISIL Research, the Indian pharmaceuticals market is estimated to be worth US$36.8 billion in revenues for the fiscal year 2015.

- The chart below illustrates the outlook of the Indian pharmaceuticals industry by sales in the key segments:

	2009-2010	2014-2015	2019-2020 (projected)	Past 5 year CAGR up to 2014-2015	Future 5 year CAGR up to 2019-2020
Domestic formulation (₹ billion)	417.1	745.8	1,359-1,484	12.3	13-15
Formulation exports (US$ billion)	5.2	11.7	18.9-20.4	17.7	11-13
Bulk drug exports (US$ billion)	6.3	12.9	20.4-22.3	15.2	10-12
Total market (US$ billion)	20.3	36.8	61.9-67.4	12.6	11-13

(Source: CRISIL Research)

- The Indian pharmaceuticals market can be broadly classified into the domestic and export segments in terms of the target geographical sales markets.

- Domestic Market Overview: The domestic formulations industry is currently the largest component of the Indian pharmaceuticals market. The domestic formulations industry was valued at Rs. 745.8 billion in fiscal year 2015 and recorded a CAGR of 12.3% from 2009 to 2015.

Source: CRISIL research

Overview of Pharmaceutical Industry in India

- Export Market Overview: In terms of exports, Indian pharmaceuticals manufacturing can be divided into two sub-segments; formulations and bulk drugs. These segments recorded a combined near 16.3% CAGR over the past five years to reach an approximate value of US$24.6 billion.

- Indian formulations exports are expected to grow at a CAGR between 11% and 13% between financial years 2015 and 2020, to nearly US$20.0 billion in revenues. Exports to regulated markets are expected to increase at a CAGR between 12% and 14% for the same period, driven by the expanding penetration of India generic products along with the improving pace of product approvals. Exports to semi-regulated markets are expected to grow at a CAGR between 10% and 12%.

- The US is expected to remain the key export market for Indian pharmaceutical products. According to CRISIL Research, Indian pharmaceutical companies are well-positioned to expand their presence in the US generic drugs market, as reflected in the rising number of such companies seeking ANDA approvals and tentative approvals from the US FDA. As of March 2015, India ranks second, after the US, in having the most number of ANDA approvals.

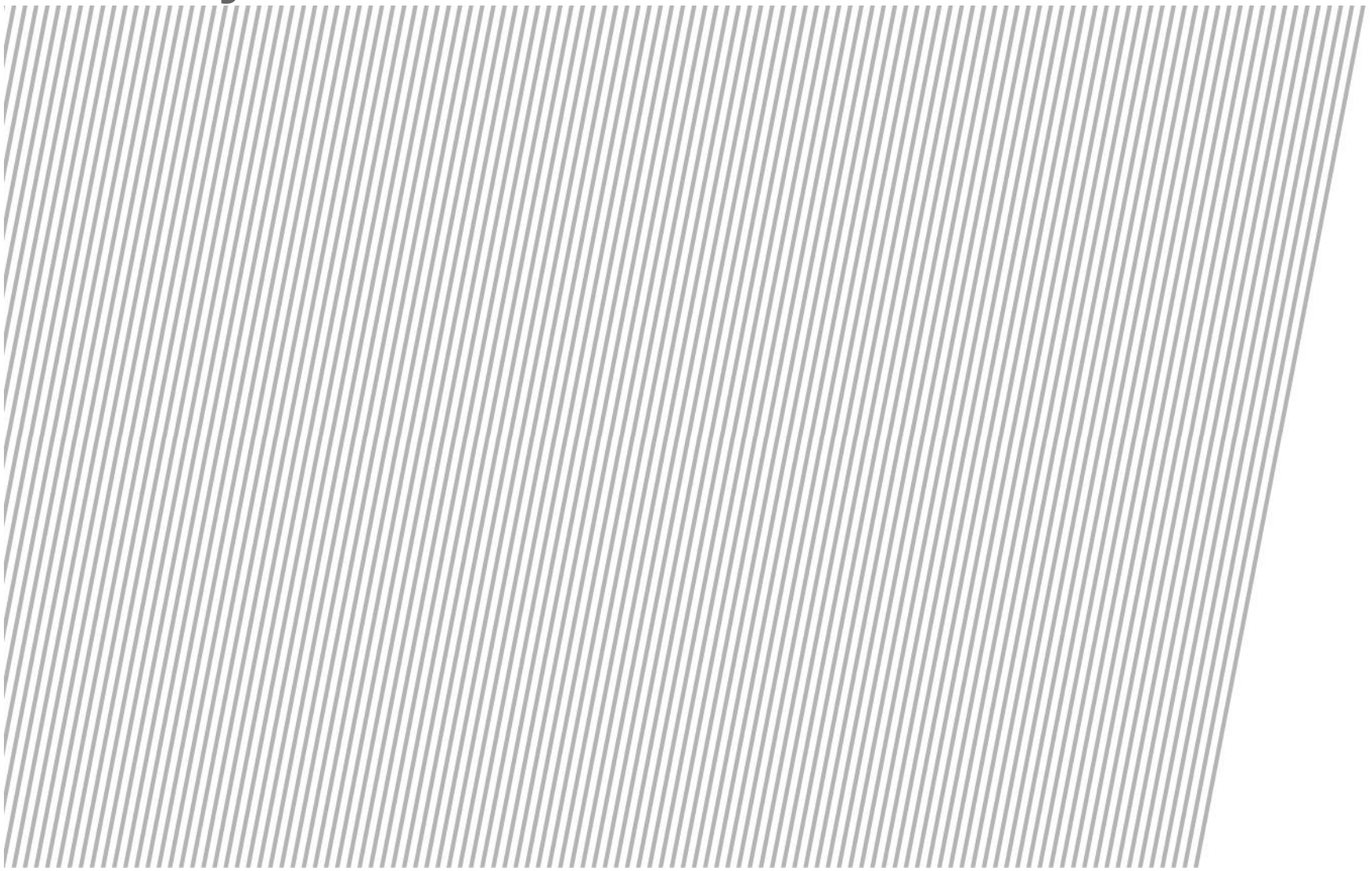
- India's key strengths of low cost manufacturing, high process chemistry skills, approved manufacturing facilities and increasing numbers of drug master filings, are seen as core drivers of future growth.

Source: CRISIL research

Overview of Pharmaceutical Industry in India

- Some of the key risks involved for Pharmaceutical companies in India
  - Compliance with Government regulations and requirements for continuous regulatory oversight.
  - Ability to successfully develop and commercialize new pharmaceutical products.
  - Quality in products, manufacturing processes and services.

Key accounting issues in Pharmaceutical industry



Research and Development (R&D) costs

A) Guidance in accounting for R&D expenditure as per AS-26

- Research is an original and planned investigation undertaken with the intention of gaining new scientific or technical knowledge and understanding. – Capitalisation is prohibited.

- Development is the application of research findings or other knowledge to a plan or design for the production of new or substantially improved materials, fixtures, products, processes, systems, or services before the start of commercial production or use. – Capitalisation required, if criteria are met.

B) Key stages involved in R&D in a pharmaceutical company are as under;

Research and development in pharmaceutical industry primarily includes in house research and development.

Research and Development (R&D) costs

- The costs of in-house development activities are recognised as an internally generated intangible asset from the date on which all the criteria for the asset's recognition are met. The capitalisation of the costs of in-house development activities is a three-step process.

I. Do the activities qualify as Development activities

- Development activities are when products, fixtures, materials, processes, systems, or services are newly developed or substantially improved.

- Examples of Development activities as per AS-26:
  - the design, construction and testing of pre-production or pre-use prototypes and models
  - the design of tools, jigs, moulds and dies involving new technology
  - the design, construction and operation of a pilot plant that is not of a scale economically feasible for commercial production
  - the design, construction and testing of a chosen alternative for new or improved materials, devices, products, processes, systems or services.

II. Have the general criteria for an intangible asset been met?

- An intangible asset generally exists if the following general criteria are met;
  - the asset is a non-monetary asset without physical substance
  - the asset is identifiable.
  - future economic benefits can be attributed to the asset.
  - the asset is controlled by the reporting entity

Research and Development (R&D) costs

III. Have the recognition criteria for an intangible asset been met? Have the recognition criteria been substantiated by specific indications of an internally generated intangible asset? Do the activities qualify as Development activities

- An intangible asset shall be recognised if it is probable that the expected future economic benefits that are attributable to the asset will flow to the entity and the cost of the asset can be measured reliably.

- Indian GAAP and IFRS specify six indications that are designed to substantiate the probability of the expected future economic benefits and the reliable measurement (measurability)
  - the entity is technically able to complete the development project so that the results can be used or sold.
  - the entity has the intention to complete the development project in order to use or sell the results.
  - the entity has the ability to use or sell the results of the development project.
  - a future economic benefit will probably flow to the entity
  - the entity has adequate technical, financial and other
  - resources to complete the development project and use or sell the results.
  - the entity can reliably measure the expenditure related to the development and attribute it to the development project.

- Generally, final regulatory approval provides substantial evidence at which point all the criteria for capitalisation of in-house R&D costs as intangible assets have been met.

Income from Development revenue

- There are cases where pharmaceutical companies enters into development agreements with Multinational Companies for development of a generic formulations whose patent is expected to expire shortly. The development activity requires the Company to perform various activities such as;
  - Identification of generic product in US market for which innovators patent will be expiring
  - Performing background check of the product in terms of any legal actions that can be faced by the Company in undertaking and completing Development activities
  - Transfer of future marketing rights of the product to customer
  - Initiation and completion of formulation development
  - Production of exhibit batches of the product and performing clinical trials
  - Submitting the results of clinical trials to the US FDA authorities along with other documents for obtaining US FDA approvals.

- As consideration for the development activities, the Company sometimes agrees a lumpsum amount to be received in various milestone basis. The milestones are linked to various services to be provided by the Company. Sample milestone basis is as below:
  - 20% of the consideration is received upfront on transfer of future marketing rights to the customer
  - 25% of the consideration is received on completing formulation development
  - 25% of the consideration is received on completing production of exhibit batches
  - 20% of the consideration is received on filling abbreviated new drug application with US FDA
  - 10% of the consideration is received on receiving US FDA approval

Income from Development revenue

A. Accounting treatment in respect of completion of fist milestone

- The Company receives proportion of total consideration as upfront consideration for transfer of marketing rights to the customer.

- As per Para 7.1 of AS-9, Proportionate completion method - Performance consists of the execution of more than one act. Revenue is recognised proportionately by reference to the performance of each act. The revenue recognised under this method would be determined on the basis of contract value, associated costs, number of acts or other suitable basis.

- Upfront payments that have been received without the provision of any goods or services should be deferred and recognised over the contract period. Nothing has been provided in return for the payment; the payment is for the entire contract period. Where the milestone payment method is being applied, then the upfront milestone payment should be recognised on the basis that is consistent with the service delivered over the contract period. In such a case the upfront payment should be spread on a straight line basis. If the services are not delivered evenly the upfront payment should be recognised in line with delivery.

- Agreements may also contain reference to payments for past research and development services. Immediate recognition of an upfront payment is only appropriate if there is an outright disposal and the criteria for sale of goods under AS-9 are met.

Income from Development revenue

B. Accounting treatment in respect of milestone revenue in case where the milestone amount received is contingent to obtaining US FDA approval or any other regulatory approval

- As per Accounting Standard 29 (AS-29), “A contingent asset is a possible asset that arises from past events the existence of which will be confirmed only by the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the enterprise. An enterprise should not recognise a contingent asset”

- Accordingly, Companies will need to evaluate the terms and conditions in the agreement for accounting for development revenue.

Income from Profit share revenues

- Pharmaceutical companies from time to time enters into marketing arrangements with certain business partners for the sale of its products in certain markets. Under such arrangements, the Company sells its products to the business partners at a non-refundable base purchase price agreed upon in the arrangement and is also entitled to a profit share which is over and above the base purchase price. The profit share is typically dependent on the business partner's ultimate net sale proceeds or net profits, subject to any reductions or adjustments that are required by the terms of the arrangement.

Guidance under AS-9:

- Revenue from sales of service transactions should be recognised when the requirements as to performance set out in paragraphs 11 and 12 are satisfied, provided that at the time of performance it is not unreasonable to except ultimate collection. If at the time of raising of any claim it is unreasonable to except ultimate collection, revenue recognition should be postponed.

- In a transaction involving the sale of goods, performance should be regarded as being achieved when the following conditions have been fulfilled:
  - the seller of goods has transferred to the buyer the property in the goods for a price or all significant risks and rewards of ownership have been transferred to the buyer and the seller retains no effective control of the goods transferred to a degree usually associated with ownership; and
  - no significant uncertainty exists regarding the amount of the consideration that will be derived from the sale of the goods.

Income from Profit share revenues

- There is no specific guidance under IGAAP for accounting profit share revenues.
- Ind-AS 115 includes specific guidance on the same.
- IND-AS 115 requires an entity to consider the terms of the contract and its customary business practices to determine the transaction price. The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Upon transition to IND- AS, the Company will have to estimate the sales by business partner and accrue for share of profit at the time of sale itself.

Product returns/recalls

- Product recalls are actions taken by a firm to remove a product from the market either voluntarily or at a regulator's request. There may be different type of product recalls as defined by the relevant regulatory authority of that market. For example – U.S. Food and Drug Administration (USFDA) has classified various type of recalls as below:
  - Class I recall : a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
  - Class II recall : a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
  - Class III recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
  - Market withdrawal: occurs when a product has a minor violation that would not be subject to FDA legal action. The company removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems would be an example of a market withdrawal.
  - Medical device safety alert: issued in situations where a medical device may present an unreasonable risk of substantial harm. In some case, these situations are also considered as recalls.

Product returns/recalls

A. Sales returns

- The company is required to recognise an allowance for the related cost at the time of announcement of product recall and estimation thereof may warrant a detailed analysis of particular facts and circumstances.
- The estimation process may become more challenging due to the fact that precise data relating to channel inventory (inventory lying in supply chain beyond direct customers of the company) may not be readily available and therefore, a thorough analysis of facts and circumstances plays a critical role in developing such estimates.
- As per an Expert Advisory Committee (EAC) opinion issued in March 2012, the provision against expected sales returns is recorded only to the extent of the loss expected to be incurred (and not on full sale price) and thus, the cost of sale and inventories would not be adjusted.

B. Contractual claims

- Customer contracts may contain a clause for reimbursement by the vendor of any loss incurred by the customer due to any supply disruption by the vendor.
- This being a contractual claim, recognition of loss is required from accounting perspective when recall is announced and if it is expected that there would be a situation of supply disruption.
- The estimation of such claims is dependent upon what is the ‘expected loss’ of the customer due to supply interruption and may pose a challenge in estimating the loss in the financial statements.

Product returns/recalls

C. Customer claims

- Recall of a product where there is a reasonable probability that the use of or exposure to a violative product will cause adverse health consequences or death, may trigger end user claims in the form of class action suits or otherwise.
- Depending on the probability of the outcome of the legal matter, a provision may be required and thus, again posing a challenge to estimate a particular claim.

D. Consequential impacts

- If the product recall is caused by a serious product defect and expected to have severe impact on the company's performance, it may have consequential impact on areas where evaluation is performed on the basis of current and future business performance of the company such as impairment assessment, going concern evaluation, laws and regulations compliance, recoverability of deferred tax assets and Minimum Alternate Tax, etc. Therefore, reassessment of these aspects should be performed before the finalisation of the financial statements for that period.
- As evident, product recalls may cause significant challenges from accounting perspective in the form of significant estimations, impact beyond sales return and inventory, however, these can be addressed by performing a thorough impact assessment of the event. Further, depending on the type of recall and its impact on the company's business as well as financial statements, product recalls would require due considerations for appropriate disclosures.

Export incentives

- The government over a period of time has introduced various export benefits to incentivise exporters of pharmaceutical products, which has helped in reducing costs on account of the indirect taxes involved. These export benefits are provided through the Foreign Trade Policy (the FTP) issued by the Ministry of Commerce and Industry or through various notifications issued by the Ministry of Finance.
- These export incentives are offered in terms of a duty credit scrip which can be used by the exporter) for payment of duties on procurements.
- Key considerations in the accounting of export incentives are:
  - What should be the timing of recognition
  - How should unutilised/unrealised credits be treated
  - What should be the treatment of these credits at the time of utilisation against purchase of capital goods and materials, etc.
- The Expert Advisory Committee (EAC) of the Institute of Chartered Accountants of India (ICAI) has noted that though the entitlement received under many of the schemes do not strictly fall within the definition of the term ‘revenue’, as defined under Accounting Standard (AS) 9, such duty credit entitlement is of the nature of revenue and accordingly, it should be recognised as ‘revenue’ in the books of account provided the conditions for recognition of revenue are satisfied.
- Keeping in view the above mentioned revenue recognition principle of AS 9, the credit under the scheme should be recognised only at the time when and to the extent there is no significant uncertainty as to its measurability and ultimate realisation, i.e., utilisation of the credit under the scheme.

CENVAT credit

- In order to reduce the cost of pharmaceutical products, the Government has capped the excise duty on formulations at approx 3% - 6%. However, the CENVAT on various inputs acquired by pharmaceuticals companies is approximately 12.36%, resulting in inverted duty structures.

- As per Guidance Note on Accounting Treatment for MODVAT, issued by the Institute of Chartered Accountants of India, “Balance in MODVAT Credit Receivable Account should be reviewed at the end of the year and if it is found that the balance of the MODVAT credit is not likely to be used in the normal course of business within a reasonable time, then, notwithstanding the right to carry forward such excess credit in the Excise Rules, the non-useable excess credit should be adjusted in the accounts. The consequence would be that the balance of the MODVAT Credit Receivable Account in the financial accounts may be lower than the credit available as per the RG-23A register. A reconciliation statement would have to be prepared indicating the amounts adjusted so that a track is kept for the difference between the two balances and the difference between the financial accounts and the credit as per the excise registers can be explained in subsequent years also.”

- The above adjustment of excess credit should preferably be made to the raw material or input purchase account. The effect would be to increase the cost of purchase and thereby to increase the cost of inputs for the purpose of accounting for consumption and valuation of closing stocks.

Contract Manufacturing

- Pharmaceutical Companies often enter into exclusive 'contract manufacturing' arrangements, whereby the contract manufacturer produces specified products for the Pharmaceutical companies with use of specified machinery / assets.

- Guidance to Appendix C to Ind AS 17 Leases - Determining whether an arrangement contains a lease, requires a careful analysis, to identify any embedded lease component, included as part of the underlying product supply transaction where there are specific identified assets and conditions as to 'right to use' of the identified asset/group of assets are satisfied.

- An arrangement is or contains a lease if the following conditions are met:
  - Fulfilment of the arrangement is dependent on the use of a specific asset or assets;
  - An arrangement conveys the right to use the asset if the arrangement conveys to the purchaser (lessee) the right to control the use of the underlying asset :
  - The purchaser has the ability or right to operate the asset or direct others to operate the asset in a manner it determines while obtaining or controlling more than an insignificant amount of the output or other utility of the asset;
  - The purchaser has the ability or right to control physical access to the underlying asset while obtaining or controlling more than an insignificant amount of the output or other utility of the asset
- Entities while obtaining more than an insignificant amount of output, either controls the use of the asset or has the ability to restrict physical access to the asset. Accordingly, the same will need to be evaluated to identify a lease component. Further evaluation will also need to be made if the same constitutes an operating or finance lease. In case of finance lease, the assets used for production, would need to be recognised as part of lessee's balance sheet.

Free samples

- Pharmaceutical programmes are run by pharmaceutical companies which are high priced and consumed over a period of time. The programmes comprises providing free drugs to doctors and patients on purchase of certain quantity of these drugs.

- Technical guide on Accounting issues in Retail sector relating to customer loyalty programmes provides for a provision model or deferment model.

- Ind AS 18 has specific guidance on customer loyalty programmes. Though the patient programmes may not entirely be comparable to these loyalty programs, inference can be drawn from the same.

- In accordance with such guidance, the entity shall allocate the fair value of consideration received or receivable in respect of the initial sale between the free samples and other components of sale.

- The consideration allocated to the free samples should be measured with reference to their fair value, i.e. the amount for which these samples could be sold separately.

- Under Ind AS 115, on similar lines as Ind AS 18, the transaction price is to be allocated to the free samples and deferred to the period in which such goods are promised to be provided.

Taxes on Income

- Pharmaceuticals Company involved in R&D activities and registered with DSIR will enjoy benefits of Income Tax deduction under section 35 of the Income tax Act, 1961. The Companies will get 200% weighted deduction for certain revenue expenses and 100% weighted deduction for certain Capital expenditure.
- This would have an impact in the Tax on total income being lower than the Tax computed under Minimum Alternate Tax (MAT). This could result to Companies accumulating MAT credit.
- Per the guidance note on MAT, It becomes important for the management / auditors to check the recoverability of MAT Credit balance.

Ind AS – 12 : Para 49

When different tax rates apply to different levels of taxable income, deferred tax assets and liabilities are measured using the average rates that are expected to apply to the taxable profit (tax loss) of the periods in which the temporary differences are expected to reverse.

Inadmissibility of expenses - Doctor payments

- Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (the regulations) ["Act'] on 10-12-2009 imposed a prohibition on the medical practitioner and their professional associations from taking any Gift, Travel facility, Hospitality, Cash or monetary grant from the pharmaceutical and allied health sector Industries.
- Section 37(1) of Income Tax Act provides for deduction of any revenue expenditure (other than those failing under sections 30 to 36) from the business Income if such expense is laid out/expended wholly or exclusively for the purpose of business or profession. However, the explanation appended to this subsection denies claim of any such expense, if the same has been incurred for a purpose which is either an offence or prohibited by law.
- CBDT has issued circular no. 5/2012 dated August 5, 2012 stating that any expenses incurred in providing freebies to a medical practitioner which are in violation of the Regulations shall not be admissible as 'business expenses deduction'.
- It is also clarified that the sum equivalent to value of freebees enjoyed by the aforesaid medical practitioner or professional associations is also taxable as business income or income from other sources as the case may be depending on the facts of each case. The Assessing Officers of such medical practitioner or professional associations should examine the same and take an appropriate action

List of few inadmissible/ prohibited expenses:

- Gifts like computers / laptops / I-pads / mobile, etc.,
- Travelling / hospitality (Foreign / domestic leisure trip; Travelling for attending conferences;
- Hospitality
- Cash or monetary grants
- Promotional expenses, in some cases

Thank You