WIRC Seminar on Pharma Industry

Direct Tax & Transfer Pricing

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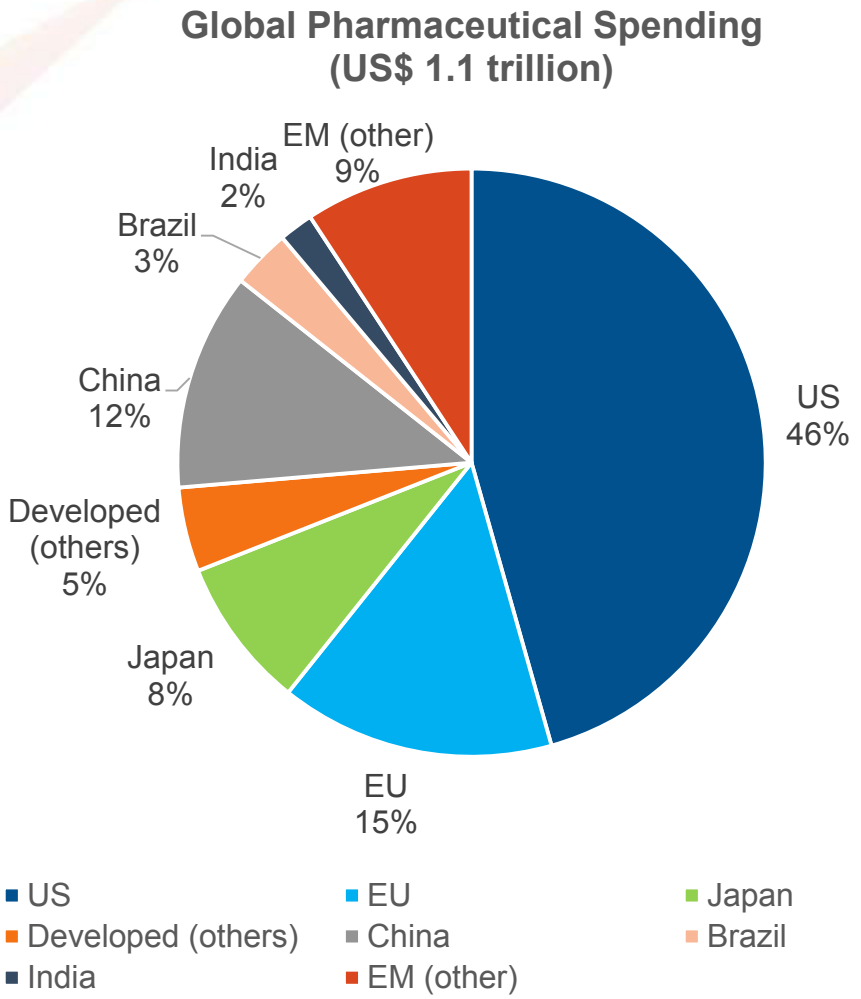
Pharma Industry: An Overview

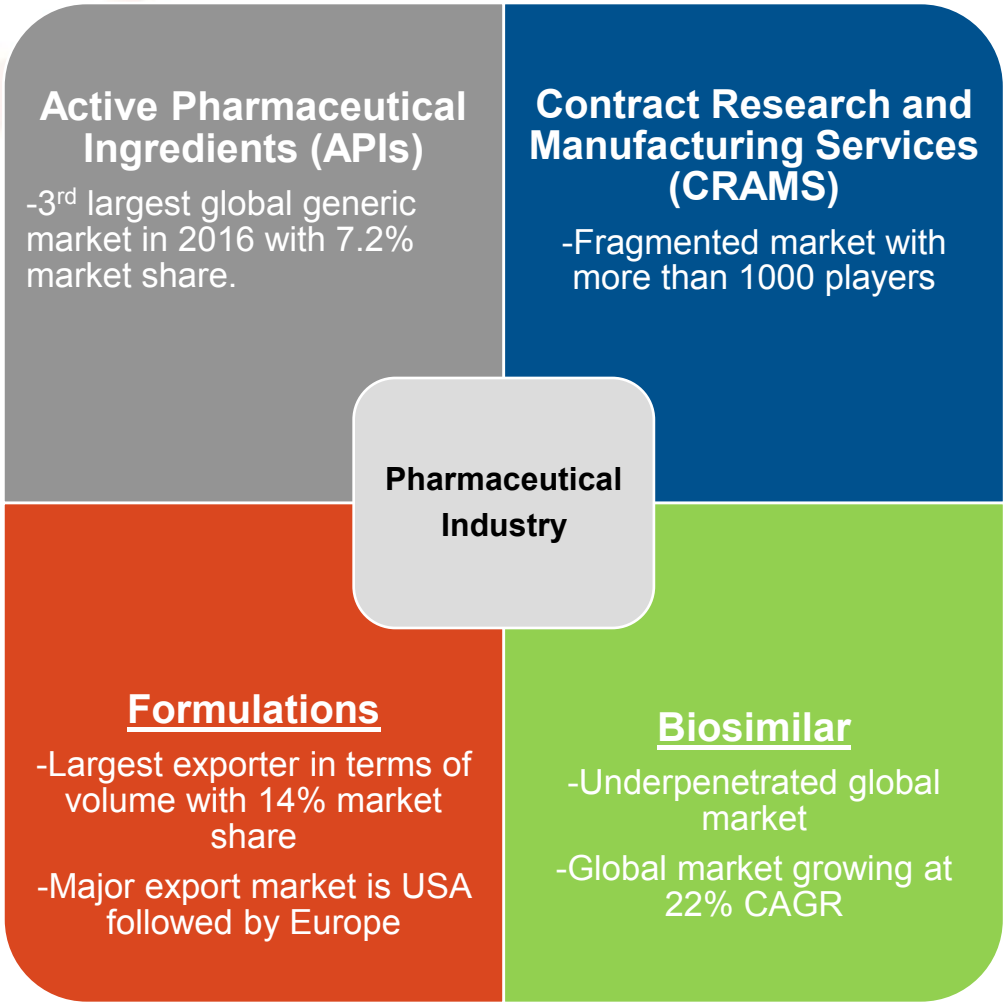
Global Pharma Market - Overview

- Developed markets expected to grow at 2-5 % CAGR.
- EM expected to register 6-9 % CAGR over next 5 years
- Indian Companies slowly shifting focus towards specialty pharmaceuticals / branded generics.
- India ranks 2nd in ANDA filings and ranks 1st in Drug Master File applications
- Ageing population, lifestyle, enhanced medical infrastructure, insurance penetration, chronic diseases to drive growth



Pharma Industry – India outlook

- Global Position:
  - 10th in value
  - 3rd by volume
- Pharma export stands at about US$18 bn. (6 % of India's total export)
- Large companies – Pursuing inorganic growth to diversify across markets and products
- 5 Indian companies amongst top 15 global generic pharma companies (by sales)



Pharma Industry – Direct tax issues

Scientific research expenditure

Scientific Research Expenditure

Sec.	Nature	Extent	Sunset	Conditions
35(1)(i)	Revenue Expenditure on R & D	100%	No sunset	No approval required
35(1)(iv)	Capital Expenditure (including Building) on R & D	100%	No sunset	No approval required
35(2AB)	Inhouse R & D – Capital & Revenue (other than land and building)	150%	31.3.2020	DSIR Approval + Others (see below)

Background – 35(1)(i) & (iv):

- 100% deduction allowed of expenditure on R&D
- Section 43(4) – Scientific Research *inter alia* means:
  - Any activity of research leading to / facilitating in extension of the business
  - Any activities for the extension of knowledge in natural / applied science
- Section 35(1)(i) – R&D expenditure need not be charged to profit and loss account

Issues:

- Deduction of capital expenditure where the asset is not complete in all respect?
  - Rane Brake Linings Ltd. [2002] 255 ITR 395 (Madras)
- Admissibility of deduction u/s. 35(1)(iv) for outsourced R&D activity – Debatable – will depend on nature of outsourcing

In-house R&D - Overview

Section 35(2AB) read with Rule 6

- Deduction allowed only of R&D expenditure incurred by in-house R&D Center approved by the Department of Scientific and Industrial Research (DSIR)
- Explanation – includes clinical trial, product approval and patent filing expenses
- Framework and conditionalities :
  - Application to DSIR in **Form 3-CK**
  - DSIR approval in **Form 3-CM**
  - Accounts of R&D center to be audited; Report in **Form 3-CLA** to be submitted to the DSIR
  - DSIR to submit its report to the Income-tax department in **Form 3-CL**
- **Following expenditure not eligible for weighted deduction u/s. 35(2AB) as per DSIR guidelines updated as on July 2017**:
  - Capitalized expenditure of intangible nature
  - Expenditure reported as Capital Work In Progress (CWIP)
  - Remuneration paid to the members of the board of Directors
  - Expenditure on non scientific manpower - retainership/trainees/consultants/contractual
  - Proceeds of assets to be adjusted against R&D expenditure of approved R&D Centre

In-house R&D - Issues

- **Whether DSIR approval of expenditure necessary**
  - Amendment to Rule 6(7A) requiring DSIR to quantify expenditure eligible for weighted deduction – applicable w.e.f. 1.7.2016
  - No power / provision under Act requiring or empowering DSIR to approve expenditure
  - Provisions of Rules cannot widen the provisions of Act
  - Judicial precedents rendered for years before the amendment to Rule 6(7A) made:
    - Claris Lifesciences Ltd. [2010] 326 ITR 251 (Gujarat HC) and others
- **Weighted deduction on expenditure incurred outside in-house R&D Centre – say expenses on overseas clinical trials, patent registration, etc.**
  - Cadila Healthcare Ltd. [2013] 263 CTR 686 (Gujarat HC)
- **Admissibility of weighted deduction where Form 3CL not submitted by DSIR**
  - Sun Pharmaceutical Industries Ltd. [2017] 85 taxmann.com 80 (Gujarat HC)
- **Expenditure incurred prior to the date of approval of the R&D Centre by DSIR**
  - Banco Products (India) Ltd [2018] 405 ITR 0318 (Gujarat HC)
  - Maruti Suzuki India Ltd. [2017] 397 ITR 0728 (Delhi HC)
- **Reduction of R&D expenditure by proceeds from sale of IPs**
  - Microlabs Ltd. [2016] 383 ITR 490 (Karnataka HC)

Section 37(1) – Key issues

Doctors Freebies

- Pharmaceutical companies engage medical practitioners for receiving feedbacks on medicines, developments in the medical fields, educating them, etc.
- Promotion expenses including sponsoring CME conferences, gifts, free sample medicines, other personal expenses of doctors
- Medical Council of India ('MCI') prohibits medical practitioners to accept specified benefits from pharmaceutical and allied health sector industry
- Uniform Code for Pharma Marketing Practices (UCPMP) – currently voluntary
- CBDT Circular No. 5/2012 dated 01.08.2012 provides for disallowance of such payments under Explanation 1 to section 37(1) categorizing it as expenses for prohibition of law / offence
- **MCI Regulations do not regulate and govern the pharmaceutical companies**
  - MCI admits it has no jurisdiction over pharmaceutical companies – [Max Hospital vs. MCI (WPC 1334/2013, dated 10.01.2014) (Delhi HC)]
- **Circular cannot expand the ambit of the provision of the Act**
  - CBDT circular are suggestive and in no manner are they binding on the taxpayer

Favorable	Against
Solvay Pharma India Ltd. [2018] 89 taxmann.com 249 (Mumbai Trib.)	Apex Laboratories (P.) Ltd. [2017] 80 taxmann.com 236 (Chennai - Trib.)
PHL Pharma P Ltd. [2017] 163 ITD 10 (Mumbai Trib.)	Liva Healthcare Ltd. [2016] 73 taxmann.com 171 (Mumbai - Trib.)

IP Settlement Compensation

Background:

- Pharmaceutical Companies with their very nature of business, have significant litigation exposure particularly in overseas jurisdictions
- To avoid litigation, often parties settle patent / IP disputes through out of court settlement
- Entities end up paying huge amount of money as compensation

Issues:

- Compensation paid whether for an offence/prohibition of law - Explanation 1 to Section 37(1)
- What if it pertains to patent laws outside of India / foreign law
- Compensation paid – capital expenditure vs. revenue expenditure
- Taxability of the amount received by the recipient on account of giving up his rights to sue
  - Bhojison Infrastructure Pvt. Ltd vs. ITO (ITAT Ahmedabad)

Profit-linked deductions

Profit-linked deductions – 80IE, 10AA

Section	Sunset date	Deduction	Conditions
80-IE	April 1, 2017	100% of the profits of the undertaking for a period of 10 years	- Undertaking shall be set up in North – Eastern States - Shall begin to (i) Manufacture eligible article/things; (ii) Undertakes substantial expansion; (iii) carry on eligible business specified in section 80-IE - Anytime from 1st April 2007 to 31st March 2017
10AA	April 1, 2021	- 100% of the profits of the units for 5 years; - 50% of the profits of the unit for further 5 years - For next 5 years – amount credited to SEZ Reinvestment Reserve Account (subject to maximum 50% of profits as per P&L Account) – amount credited to Reserve shall be utilized for specified purposes	- Unit shall be set up in SEZ - To undertake manufacturing / production of articles or things, or provide services, - Anytime from 1st April 2005 to 31st March 2020

Profit-linked deductions – 80IE, 10AA

- **Can the eligibility of a undertaking be questioned in subsequent years?**
  - Eligibility conditions to be investigated only in the initial year, Assessing Officer is precluded from examining the same in a subsequent year
    - Ganpati Herbal Care (P.) Ltd. v. PCIT [2018] 97 taxmann.com 575 (Delhi – Trib.)
  - Certain qualifications that have to continue to exist can be examined in subsequent years
    - DCIT v. ACE Multi Axes Systems Ltd. [2018] 400 ITR 141 (SC)
  - Whether conditions relating to maintenance of separate books of accounts is to be tested for entire period or in the year of formation?
- **Whether on transfer of Undertaking - deduction shall be admissible to transferee?**
  - **Deduction attaches to the Undertaking**
    - CBDT Circular F. NO. 15/5/63-IT(AI) dated 13.12.1963
    - Sonata Software Ltd. (2012) 343 ITR 397 (Bombay HC) and many other
  - Section 80-IA(12A) introduce to deny deduction to amalgamated / resulting company
    - Provision not imported in to other sections including section 80-IE
- **Whether R&D expenses to be apportioned to the eligible undertaking – simple or weighted, capital or only revenue?**
  - R & D generally undertaken for futuristic business prospects, not affecting current operation of Undertakings
    - Zandu Pharmaceutical Works Ltd v. CIT [2013] 350 ITR 366 (Bom HC)

Profit-linked deductions – 80IE, 10AA

- Eligible Unit set up in SEZ may also earn income other than income from export
  - Whether section 10AA deduction available with respect to such other income?
- Section 10AA(1) states that deduction to be claimed by eligible Unit on '<u>profits and gains derived from the export</u>'
  - In case where any income is inextricably linked to exports activity – deduction under section 10AA may be claimed
  - Further, section 10AA(7) has defined 'profits and gains derived from the export' to mean –

    *"amount which bears to the **<u>profits of the business of the undertaking, being the Unit</u>**, the same proportion as the export turnover in respect of such articles or things or services bears to the **total turnover of the business carried on by the undertaking**"*
- Thus, it has to be evaluated whether other income could form a part of **business of the undertaking** in order to claim deduction under section 10AA
- Understand Supply Chain and value creation

Profit-linked deductions – 80IE, 10AA

- Profits derived from activities directly related to either manufacturing or export of articles - includible as profits of business on which section 10AA deduction can be claimed
  - CIT vs. Amber Exports (India) [2010] 326 ITR 455 (Bom)
- Profits derived from activities not directly related to either manufacturing or export of articles, but in nature of 'profits of business of undertaking' – may be included as business income on which section 10AA deduction can be claimed
  - 'Profits **of** the business of the undertaking' is a wider term as compared to 'profits **derived** from business of undertaking' as used in section 80HHC
    - Hewlett Packard Global Soft Ltd (2018) 403 ITR 0453 (Karnataka) (FB)
  - Thus, profits of the business of the undertaking may include other income say benefits from export licenses, interest income, etc – since related to business of the undertaking
- Thus, based on above, it may be argued that 'profit derived from business of undertaking' - not restricted to profits **derived from** undertaking / export

Income Computation and Disclosure Standards (ICDS)

ICDS VI: Treatment of transactions in foreign currencies

Particulars	Pre ICDS	Post ICDS
Monetary items:		
• For revenue purpose	Loss allowed, gains taxable	Loss allowed, gains taxable
For capital purpose:		
• imported assets	Section 43A - adjusted to the cost of asset	Section 43A - adjusted to the cost of asset
• Other assets	loss - not deductible; gain - not taxable (Sutlej Cotton Mills Ltd 116 ITR 1 [Supreme Court]) (However, held allowable - Cooper Corporation - 69 taxmann.com 244 (Pune)	Loss allowed, gains taxable - discuss
Non Monetary items:	As per the accounting method followed by the Assessee (Woodward Governor India (P.) Ltd [2009] 312 ITR 254)	loss allowable / gain taxable on settlement

- Managing transition
- **FA 2018**:
  - S. 43AA – any gain or loss on forex. contracts is income or loss, to be computed as per ICDS u/s 145(2) – whether rulings overruled??
  - S. 36(1)(xviii) – Marked to market loss or other expected loss deductible as computed in accordance with ICDS

ICDS X : Provisions, contingent liabilities and contingent assets

- Pharma companies generally accept the unsold products on its expiry
- Year on year companies make provision for the product return liability
- Allowable if the provision is based on a reasonable past experience - Rotork Controls India (P.) Ltd. vs. Commissioner of Income-tax [314 ITR 62 (SC)]
- Substitution of the word “probable” used in the AS 29 with the word “reasonably certain” in ICDS
- Impact of ICDS on principles laid down by Apex Court?

ICDS IV : Revenue Recognition

- Pharma company generally enter into service contracts with gestation period (contract R&D with or without milestones, CRAMs, etc)
- As per ICDS IV - revenue from service transactions shall be recognized by the percentage completion method
- However, service contracts with duration of less than 90 days – recognized when the contract is completed or substantially completed

Key TDS issues

Agreement with distributors

- Pharma companies – Agreements with distributors for sale of drugs / medicines
- Agreements may provide for:
  - Sale of medicines at discount
  - Other incentive payments
  - Return of expired medicines, monitoring / specific instructions

Issues:

- Whether discounts / incentive payments are "Commission" u/s. 194H?
- No TDS implication – Relationship between parties is on a "principal to principal" basis
  - Relationship to be determined on basis of agreement
  - Following factors will not be relevant for determining nature of relationship between parties
    - Restricted area of operation;
    - Return of goods after expiry date;
    - Restrictions placed on sub-distributor;
    - Supervision of transactions undertaken by distributor and sub-distributor;
  - Hindustan Coca Cola Beverages Pvt. Ltd [2018] 402 ITR 539 (Rajasthan); SLP dismissed by Supreme Court

Bioequivalence studies / Clinical trials, Patent lawyer fees

- Pharma companies – Payment to overseas service providers for
  - Bioequivalence studies
  - Clinical trials
  - Patent lawyer fees

TDS implications:

- Fees for Bioequivalence studies / clinical trials
  - Check DTAA – "make available" test, MFN clause
  - Test of "make available" not satisfied
    - Recipient receives only final results / reports, not enabled to self use;
    - No technical knowledge, experience, skill, plan provided
  - Thus, taxable in hands of service provider only if it has PE in India
  - In absence of PE, not taxable – No TDS obligation
    - Dr. Reddy's Laboratories Ltd – [2013] 144 ITD 302 (Hyderabad – Tribunal)
- Patent lawyer fees – rendered from outside, IPS – No travel to India; Not taxable – No TDS

Patent Box Regime

Overview

- With a view to incentivize indigenous R&D, the Finance Act, 2016 introduced Patent Box regime in India u/s 115BBF
- Gross amount of royalty earned from patents developed and registered in India will be taxed at a concessional rate of 10%
- Such royalty income to be excluded from tax under MAT provisions
- Patent Box is a optional regime and can be opted by furnishing Form No. 3CFA
- Once opted, regime to apply for 5 consecutive years, failing which, the scheme would not be available for next 5 years
- Indian Patent Box is in line with Action Plan 5 (Harmful Tax Practices) of the BEPS Project

Conditions and Issues

Conditions:

- Eligible Assessee - a person resident in India and who is a patentee
- Patentee - True and first inventor (Patents Act, 1970) and named in patent register
- Only royalty from Patents covered - other IP such as copyright, trademarks, designs, computer software, other knowhow are not covered
- In respect of patents that are *developed* and *registered* in India

Developed in India -

- At least 75% of the expenditure incurred in India by the eligible assessee

Key Concerns:

- Indian Patent Regime – is it attractive?
- Whether Patents in US / EU can be covered?
- Whether some activities – like clinical trials if outsourced impacts eligibility?
- Whether pending registration – eligibility commences
- Business model for exploitation of Patents - Embedded royalties

Other issues

Profit Repatriation Strategies

- Various Indian headquartered pharmaceutical MNCs have overseas subsidiaries
- Cash extraction from Subsidiaries by way of:
  - Management Fees
  - Royalties, Interest
  - Dividends
  - Buy backs / Reduction of Capital / Redemption of Preference Shares
- Dividend distribution is one of the popular ways for profit repatriation since it is-
  - taxable in India at concessional rate of 15% plus SC & Cess u/s 115BBD
  - eligible for rollover credit u/s 115-O on onward distribution
- Key Aspects:
  - Transfer Pricing justification – in both jurisdictions
  - Withholding taxes and availability of tax credit including UTC, tax sparing
  - Inter play between section 115JB vs. section 115BBD

MAT Credit Utilization

- Various tax incentives (such as weighted R&D deduction, 10AA exemption, 80-IC / 80-IE deduction) claimed by pharma cos. have resulted into accumulation of huge MAT credit

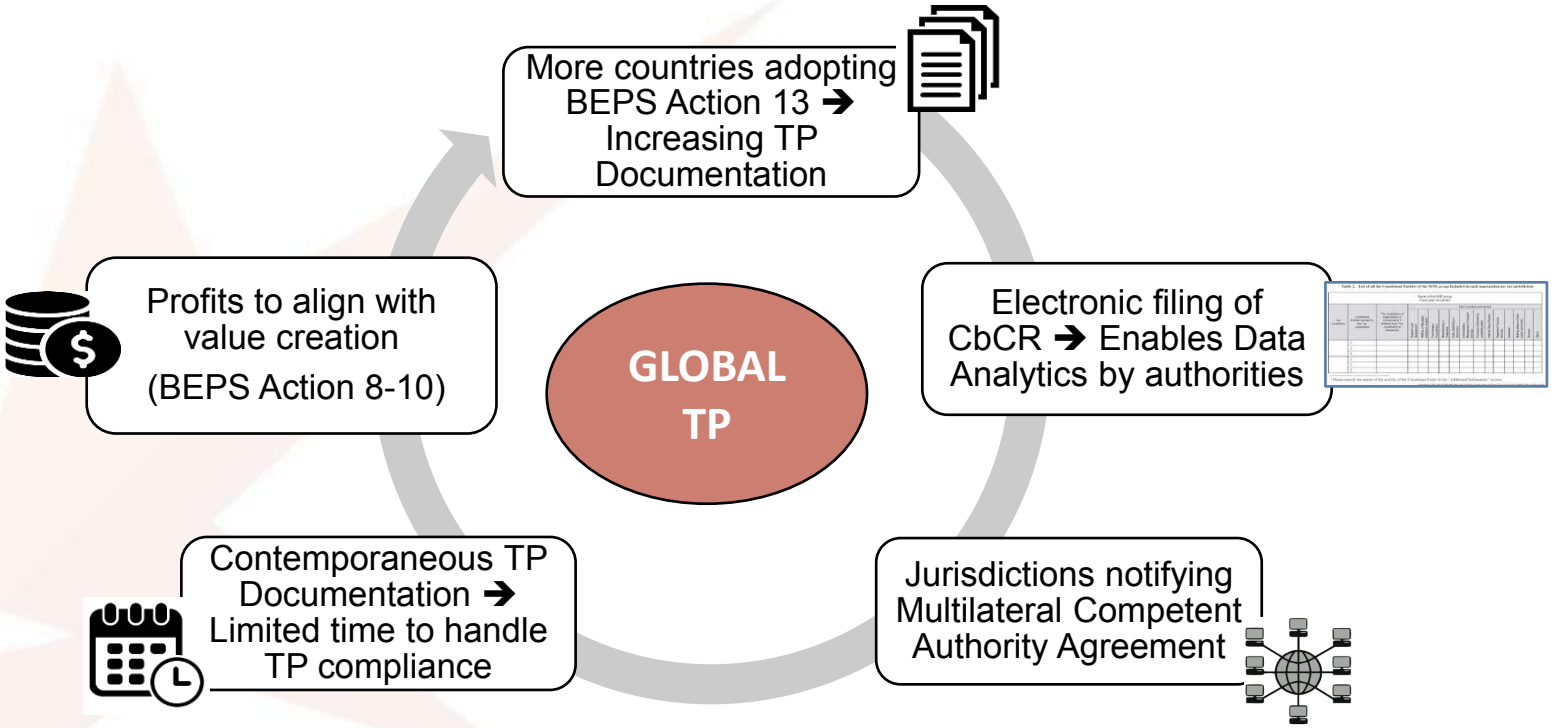
- Due to sunset provisions for exemptions, effective tax rates going up, credit utilization may get speeded up

- Faster MAT credit utilization – time value of money

- **Approaches**:
  - MAT neutral transactions
  - Internal restructuring subject to GAAR
  - Ind AS implications
  - Future Projections, Supply Chain and Value creation analysis

Transfer Pricing

Changing landscape of TP compliance globally

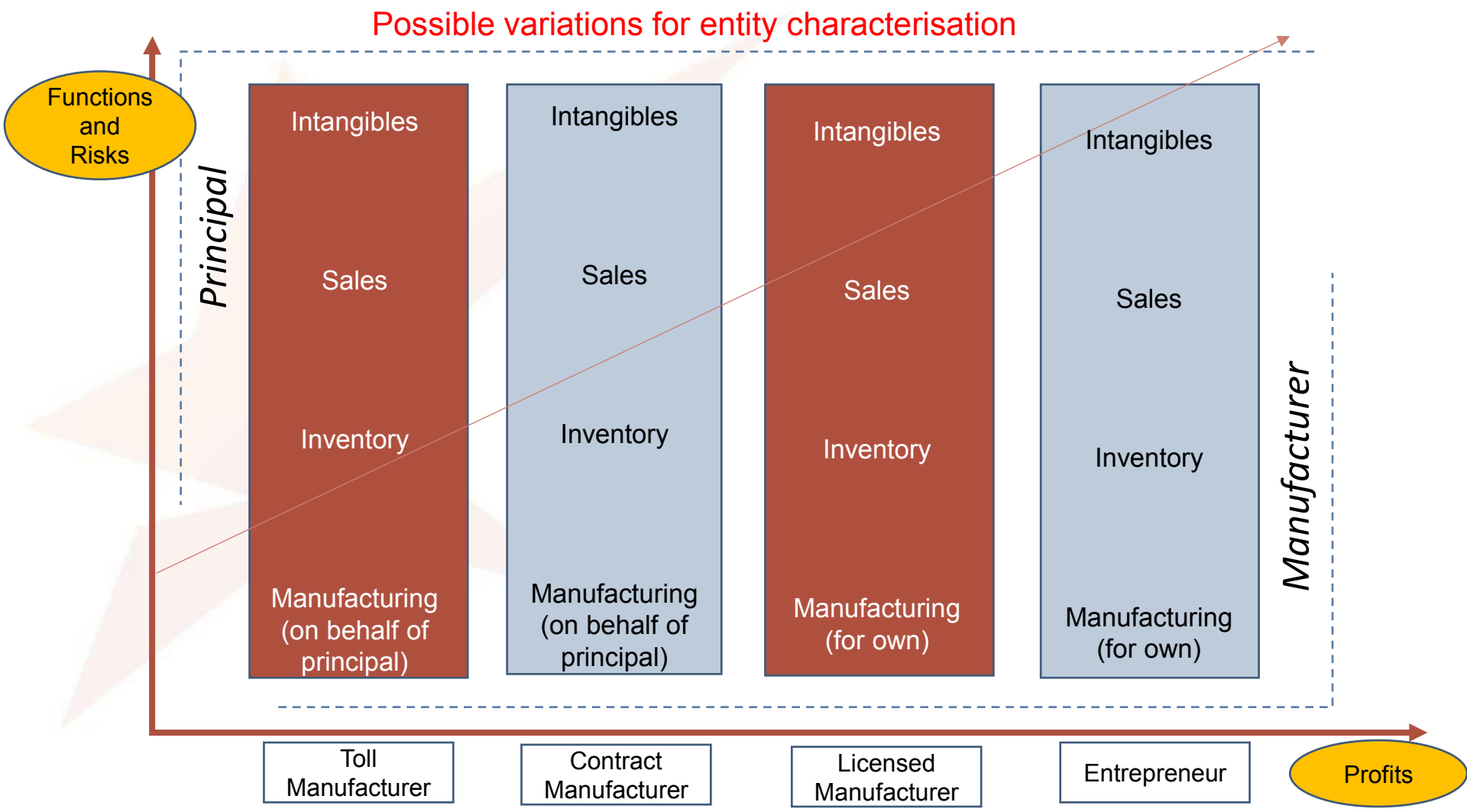


Need For

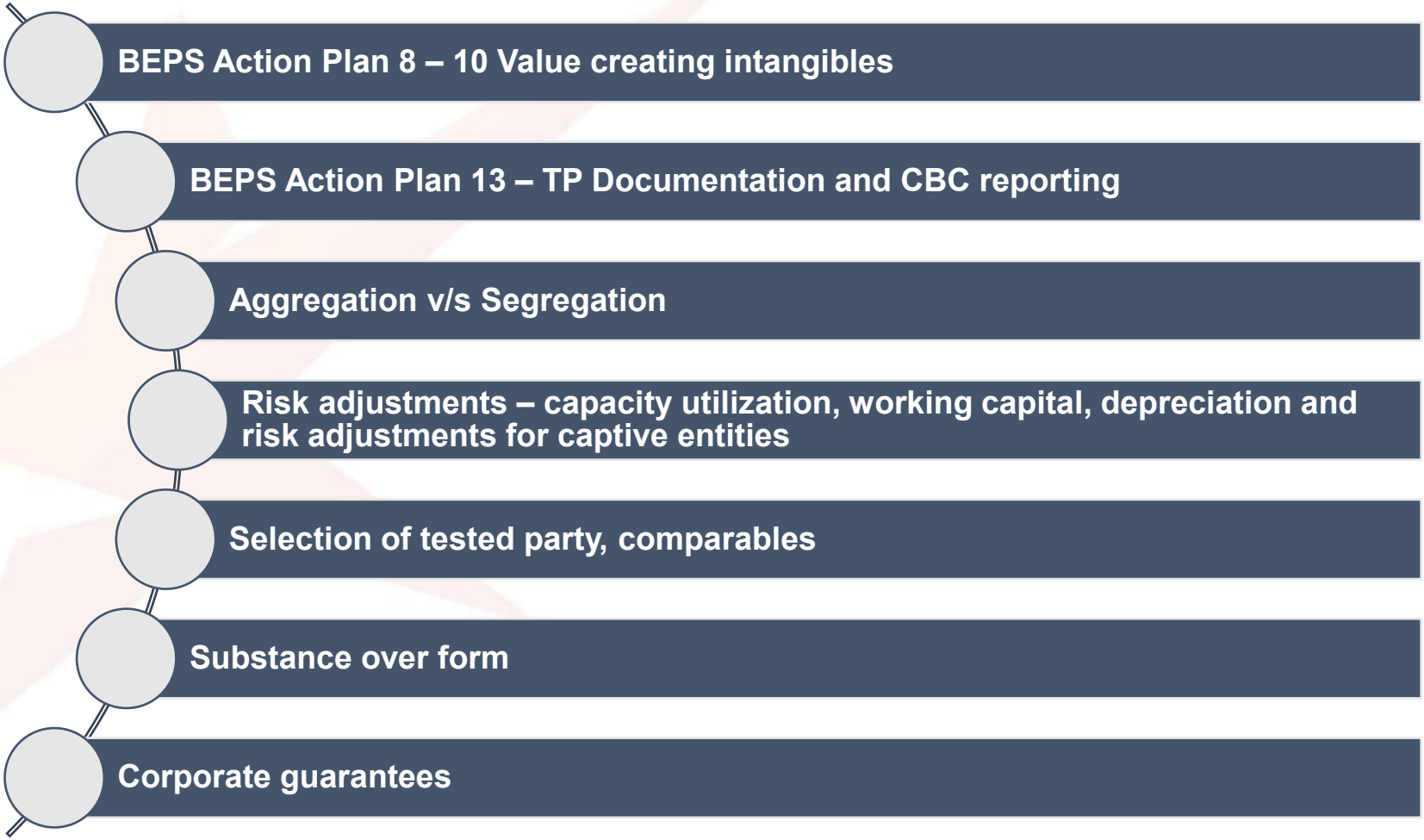
- **Worldwide consistent TP reports**
- **Local jurisdiction complaint**
- **Efficient & Effective preparation**
- **Error-Free & Quality Reports**
- **Transfer prices to ensure profits align with value creation**

TP - Pharma Industry

FAR – Assists in characterization



Key TP issues - Indian Pharma Co



BEPS Action Plan 13

- The Organisation for Economic Co-operation and Development ('OECD') had launched an initiative in July 2013 to address Base Erosion and Profit Shifting ('BEPS'), which was endorsed by G20 countries.
- BEPS Action 13 sets out a three-tiered standardised approach to TP documentation which consists of the following:-
  - Country-by-County Reporting ("CbCR");
  - Master File ("MF"); and
  - Local File
- In India, the Finance Act 2016 introduced provisions with respect to CbCR and MF
- The Central Board of Direct Taxes (CBDT) released draft rules providing guidelines regarding CbCR and MF and timeline for furnishing the relevant information
- On 31 October 2017, the CBDT introduced much awaited **final rules governing furnishing of CbCR, MF** and timelines
- The Indian CbCR rules are largely in line with OECD's Action 13 whereas customised rules placed for MF
- Rule 10DA for MF: Laid down the thresholds for applicability, timelines, requirements and procedures of MF
- Rule 10DB for CbCR:

CbCR & Master File

The threshold limit for CbCR & MF:-

Country by Country Report	Master File
Consolidated group revenue exceeds INR 5,500 crores in the immediately preceding previous year	The consolidated group revenue of the international group for the immediately preceding previous year exceeds INR 500 crores; and • The aggregate value of the international transactions exceeds INR 50 crores; or • The aggregate value of international transactions involving intangible goods exceeds INR 10 crores

The rate of exchange for conversion shall be the telegraphic transfer buying rate of such currency which is rate adopted by State Bank of India (SBI) for buying currency

Contents of CbCR

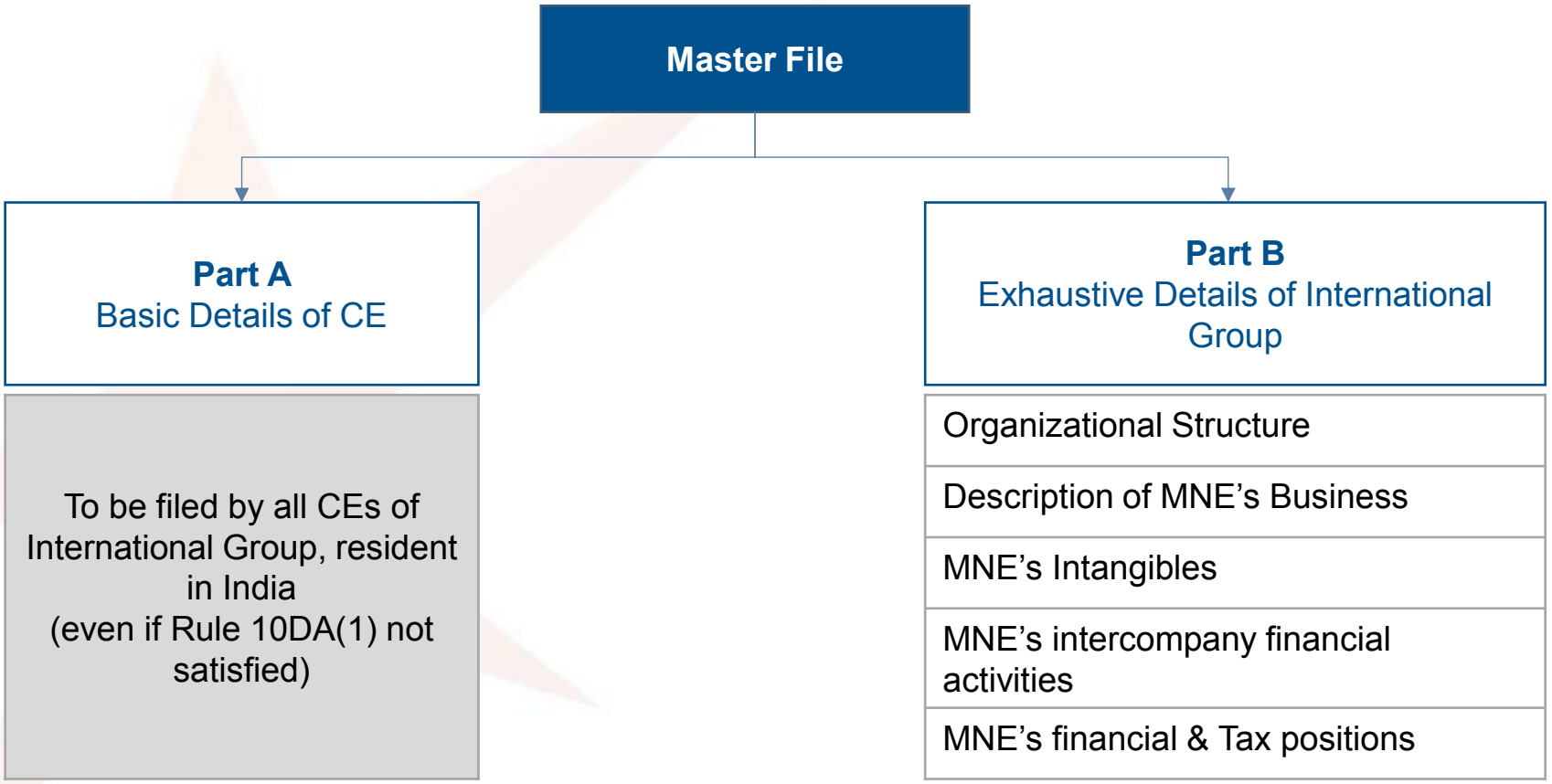
Part A: Overview of allocation of income, taxes and business activities by tax jurisdiction

Tax jurisdiction	Revenues			Profit (Loss) before Income Tax	Income Tax Paid (on cash basis	Income Tax Accrued – Current Year	Stated Capital	Accumulated Earnings	No. of employees	Tangible Assets other than Cash and Cash Equivalents
	Unrelated Party	Related Party	Total							

Part B: List of all constituent entities of MNE Group per tax jurisdiction

Tax Jurisdiction	Constituent Entities resident in the Tax Jurisdiction	Tax Jurisdiction of organisation or incorporation if different from Tax Jurisdiction of Residence	Main Business Activities
			Research and Development
			Holding or Managing intellectual property
			Purchasing or Procurement
			Manufacturing or Production
			Sales, Marketing or Distribution
			Administrative, Management or Support Services
			Provision of Services to unrelated parties
			Internal Group Finance
			Regulated Financial Services
			Insurance
			Holding shares or other equity instruments
			Dormant
			Others (Please provide description of the activity)

Contents of Master File



To be prepared by entities which meet the thresholds as per Rule 10DA(1)

Action Plan 8 to 10 - Intangibles

Action 8 proposes a taxpayer review of

- Performance/control of key functions
- Provision of assets and funding
- Bearing and Control of risks in the following key areas

Develop **E**nhance **M**aintain **P**rotect **E**xploit

- Taxpayers are directed to review the allocation of profits, for each DEMPE component, with respect to the level and nature of activity undertaken

The term intangible in the final guidelines is defined as something,

- *which is not a **physical or financial asset**,*
- *which is capable of **being owned or controlled for use in commercial activities**, and*
- *whose use or transfer would be **compensated in a transaction between third parties***

Mere legal ownership of an intangible does not confer any right to the return from its exploitation.

Economic return from intangibles will accrue to the entities that **perform the important value creating functions** of developing, enhancing, maintaining, protecting and exploiting the intangible and that assume and manage the risk associated with those functions

Entity providing the funding and exercising control over the financial risk assumed, will be **entitled to an expected rate** of return commensurate with the risk

Guidance on valuation methods

Mitigate Litigation

Safe Harbour Provisions

- Law introduced in India in Finance (No.2) Act, 2009 . On 18 September 2013, the CBDT issued the final Safe Harbour Rules
- A “safe harbor” is defined as circumstances in which the tax authorities shall accept the transfer price declared by the taxpayer
- CBDT on 7 June 2017 revised the Safe Harbour Rules by relaxing the rates and making few other prominent changes
- For the first year AY 2017-18, an eligible taxpayer has been granted an option to opt for safe harbor parameters whichever is more beneficial
- Safe Harbour – Relevant Rates for Pharma Business

Eligible International Transaction	**Revised Safe Harbour Rules From FY 2016-17 to FY 2018-19**	
	Threshold (INR)	Mark-up / Rates
Provision of contract R&D services relating to generic pharma drugs	< 200 Crores	not less than 24 % of operating expense
Providing corporate guarantee	NA	not less than 1% p.a.
Receipt of low value adding intra group services	Upto INR 10 Crore including mark-up	• 5% mark-up; and • Cost pooling method, exclusion of shareholders cost, duplicate costs and reasonableness of allocation keys is certified by an accountant.

APA in India

APA

An agreement between the tax authority and the taxpayer determining the Arm's Length Price (ALP) or specifying the manner in which the ALP is to be determined in relation to an international transaction

Effective

Legislation effective from 1st July, 2012 in India

Validity

Up to 5 years (renewal for another 5 years)

Types

Unilateral (UAPA) / Bilateral (BAPA) / Multilateral (MAPA)

APA filing fees

INR 2 million (appx US$ 30,500); additional INR 0.5 million (appx US$ 7,600) for rollback

Coverage

Existing/ ongoing transactions & new transactions

Pre-filing consultation

Optional (Anonymous filing possible) ➔ advisable to opt for official pre-filing

Rollback of APA

Covers immediately preceding 4 years ➔ withdrawal of rollback application possible

TP audits

No regular TP audits, relatively simple annual compliance audit

Binding

Taxpayer can withdraw/ renew the APA application

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Way Forward

- Be Proactive – not reactive - consider APA?
- Adopt Coordinated and centralized approach.
- Opt for Safe Harbour
- Involve operational teams in tax and TP planning and documentation process
- Holistic solutions – not fragmented responses
- Global awareness and vision
- Harmonize TP documentation with other regulatory requirements

Thank you!