

**Local Anti-Trust Policy**

**Field of Application:** Applicable to all concerned departments / sites of Fresenius Kabi Oncology Limited.

**Scope:** This policy provides an overview of how anti-trust risks will be managed in the entity and describes specific control measures required for certain sensitive transactions.

**Process Owner:** Legal Entity Hotelkeeper (Managing Director's Office)

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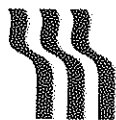
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## Local Anti-Trust Policy

**Objective:**

Worldwide compliance with the legal requirements of anti-trust and competition laws is a pre-requisite for the continued successful operation of Fresenius Kabi.

From a legal and commercial perspective, anti-trust non-compliance is a high risk area with severe penalties and consequences if the applicable legal requirements are not complied with. A breach of Anti-Trust Laws (as defined below) might for example occur by all agreements and concerted practices which cause or are likely to cause an appreciable adverse effect on competition within India. Such agreements may be critical, if entered into in writing, verbally, explicitly or implicitly, directly or indirectly. The mere fact that an agreement exists creates a presumption of an appreciable adverse effect on competition and consequential a breach of Anti-Trust Laws.

Fresenius Kabi applies a “zero tolerance” approach to Anti-Trust violations, i.e. all employees must ensure to act in compliance with Anti-Trust Laws at all times, in any location and in any transaction. Violations of Anti-Trust Laws can lead to severe fines, substantial damage claims, reputational damage and exclusion of Fresenius Kabi from tender procedures. Violations of Anti-Trust Laws are grounds for disciplinary action against the involved employee(s), up to and including termination of employment.

Fresenius Kabi has adopted a global Anti-Trust Policy in order to set clear global rules for everyday business and to provide a framework for effective anti-trust controls and preventive measures in order to ensure compliance with Anti-Trust Laws in all regions and divisions.

This global Anti-Trust Policy is hereby implemented for Fresenius Kabi Oncology Limited and Fresenius Kabi India Private Limited, by describing country and entity specific processes and requirements.

**1. Abbreviations of terms:**

<b>Term</b>	<b>Definition</b>
AAEC	Appreciable Adverse Effect on Competition
CCI	Competition Commission of India
DG	Director General (DG includes Additional, Joint, Deputy or Assistant Directors General)
KPI	Key Performance Indicator
MD	Managing Director
OEM	Original Equipment Manufacturer



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**2. Definition of terms:**

<b>Term</b>	<b>Definition</b>
Ad-hoc Task Force	Case steering committee to oversee anti-trust allegations of a severity level "High", see Sec 4.6 for composition.
Anti-Trust Laws/Competition law	All laws that regulate the conduct and organization of enterprises, generally to promote fair competition for the benefit of consumers. The laws include the Competition Act, 2002, the Competition Commission of India (General) Regulations, 2009 and various other regulations and government notifications issued from time to time. The concept is also referred to as competition law. These laws restrict the formation of cartels and prohibit other collusive practices regarded as restraints of trade. Second, they prohibit certain vertical arrangements (such as exclusive supply and distribution, tie-in, and refusal to deal) between enterprises at different stages of a production chain, where such arrangements can cause an AAEC. Third, they restrict mergers and acquisitions of enterprises that could substantially impair competition. Fourth, they prohibit the creation of monopolies and the abuse of monopoly power.
Benchmarking	Benchmarking is a structured comparison of other enterprises' data, performance, ideas, processes, practices or methods, with the intention of identifying strengths, weaknesses or best practices etc. and, where appropriate, adapting them to operate more efficiently. Benchmarking can be unilateral or can be conducted together with other enterprises active in the same or completely different industry sectors.
Contract Manufacturing	Contract Manufacturing refers to a contractual relationship between two enterprises to manufacture or supply certain components or products. In the context of this Policy it refers to the contractual relationship between two competitors.
Contract Owner	Employee who is responsible for the respective contract (contract manager or signatory of the contract).
Compliance Committee Meeting	Governance Committee for Fresenius Kabi's Compliance function
Director General (DG)	Director General is the investigative arm of the CCI. DG includes Additional, Joint, Deputy or Assistant Directors General.
Dominant Market Position	In a defined market, a business can qualify as dominant if it can implement its market behavior independently of competitors and customers or affect its competitors, consumers or the relevant market in its favour. A dominant position in the market can be present when an entity has a high market share, depending on other market conditions, such as comparative size and resources, barriers to entry, market structure/size of market, dependence of consumers and vertical integration.
E-Learning Coordinator	Role assigned in each Legal Entity which is responsible to schedule e-learning's for the Legal Entity's employees.
Hotelkeeper	A governance role in each Legal Entity, regularly the Local Compliance Officer of the Legal Entity unless otherwise assigned (see further <b>K 1 Policy on Hotelkeeper Responsibilities</b> and the respective <b>Hotelkeeper List</b> )
Horizontal Agreements	Horizontal Agreements are agreements or concerted practices, in respect of production, supply, distribution, storage, acquisition or control of goods or provision of services, between two or more enterprises, being active at the same level of production or distribution, i.e. agreements between competitors.
In-Licensing	In-Licensing means production, distribution and/or sales of products under the license of another enterprise (in the context of this Policy, a competitor); often with the sale of such products with Fresenius Kabi's company logo.



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<b>Term</b>	<b>Definition</b>
Legal Entity	Every entity in which Fresenius Kabi AG holds a share of at least 50% whether held directly or indirectly or otherwise has management control.
OEM (Original Equipment Manufacturer)	An enterprise that makes a part or sub-system that is used in another enterprise's end products.
Panel Law Firm	Fresenius Kabi has retained an external law firm that supports the Hotelkeeper in ensuring local anti-trust compliance. Contact details are enclosed in Annex 7.
Policy	Means this local Anti-Trust Policy.
Process Owner	Means for the purposes of this Policy (Managing Directors Office).
R&D Agreements	Agreements between Fresenius Kabi and any other enterprise where either Fresenius Kabi or the counter party, or both parties in co-operation, perform research and development tasks.
Relevant Market	The relevant market combines the product market and the geographic market, with the relevant product market generally comprising all products and/or services which are regarded as interchangeable or substitutable by the customer, e.g. by reason of the products' characteristics, their prices and their intended use. The relevant geographic market generally comprises the area in which the conditions of competition for supply of products or services are homogenous and can be distinguished from conditions prevailing in neighboring areas.
Spot Sales	Spot Sales mean any sales on a one-time or occasional basis, and not regularly.
Vertical Agreements	An agreement or concerted practices between two or more enterprises each of which operating at a different level of the production or distribution chain, such as distributors and sellers.

**3. Elements of the integrated anti-trust concept at Fresenius Kabi:**

Fresenius Kabi has adopted a comprehensive global policy to ensure anti-trust compliance in all its business operations and Legal Entities. The global Anti-Trust Policy sets forth certain key elements which are implemented in Fresenius Kabi Oncology Limited as detailed in Section 4 below:

- risk assessment
- specific control measures for sensitive transactions, training and communication
- reporting of anti-trust cases and remediation
- dawn raid guidelines / search by authorities
- trainings/communication
- monitoring in each legal entity
- reporting
- remedies

**4. Implementation in the Legal Entities:**

Fresenius Kabi Oncology Limited has implemented the Global Antitrust Policy by adopting this local Anti-Trust Policy which reflects country and entity-specific requirements. The Hotelkeeper has been assigned to oversee the local adoption and implementation of this Policy. The regional and divisional compliance coordinators shall support the adaptation and implementation.



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### **5. Key Elements of the local anti-trust policy:**

#### **5.1 Risk assessment:**

As part of its regular compliance risk assessment process under **gSOP LE 004, "Compliance Risk Management Process"**, Fresenius Kabi Oncology Limited by its Hotelkeeper shall regularly review the anti-trust risk profile of Fresenius Kabi Oncology Limited.

This risk assessment shall in particular take into account:

- the applicable Anti-Trust Law and the enforcement activities in the related industries
- the effectiveness of anti-trust checks for sensitive transactions
- changes resulting from acquisitions, divestitures or changes in business models

The regular review of the relevant anti-trust risk profile shall be based on an assessment by the Panel law firm.

Pre-defined KPIs shall serve as an indicator for increased or decreased risks.

Such KPIs shall include a regular, at least annual review of the Fresenius Kabi Oncology Limited's market share in relation to the individual product(s) sold and/or distributed in relevant markets. For sensitive transactions as listed under 4.2 below, specific KPIs shall be set and monitored.

#### **5.2 Specific control measures for sensitive transactions:**

This section sets forth specific control for transaction types that by their nature require a particular anti-trust monitoring and control.

As a general rule, any, even seemingly legitimate, commercial agreements, may violate Anti-Trust Laws if the activities under or in connection with the agreement are intended or used as a vehicle to restrain competition or cause an AAEC within India (e.g. to fix prices, divide markets, restrict output or otherwise impair competition).

The control measures mentioned in this Section shall be integrated into Fresenius Kabi Oncology Limited's internal control system and shall be regularly reviewed and tested as part of the internal control reviews.

##### **1) R & D:**

###### **a) Restrictions in R&D agreements:**

**Description:** R&D Agreements are agreements between Fresenius Kabi and any other enterprise where at least one of the parties performs research and development tasks.

**Anti-trust relevance:** R&D Agreements and the corresponding IP rights may not be used to improperly restrict market access or manufacturing activities (for e.g., through exclusive licensing, which is not reasonable. Exclusive dealing occurs when a license prevents the licensee from licensing, selling, distributing, or using competing technologies). However, R&D agreements may be lawful, for instance, if both parties to the agreement are allowed to afterwards use intellectual property and know-how resulting out of the research activities.

**Control measure description:** The Contract Owner of the relevant agreement must ensure that such agreement is legally checked. For details for legal check please refer to Chapter 4.7.

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**b) Patent settlement agreements with originators:**

**Description:** Patent settlement agreements are commercial agreements to settle patent-related disputes between originator and generic enterprises.

**Anti-trust relevance:** Such patent settlements may be regarded as problematic if they restrict generic market entry in exchange for benefits transferred from the originator to the generic enterprise (sometimes referred to as "pay-for-delay" deals). Such agreements result in limiting or controlling production, supply and delayed market entry of cheaper generic drugs to the detriment of patients and taxpayers financing the health system.

**Control measure description:** Mandatory review of all patent settlement agreements by the legal department and IP department of Fresenius Kabi Oncology Limited.

**2) Sales:**

**a) Tender business:**

**Description:** Suppliers such as Fresenius Kabi will regularly be invited to submit a bid to supply products or services to a customer.

**Anti-trust relevance:** Written or oral exchange of price and other market relevant information and/or collusion with other potential bidders in the tender process is prohibited.

In particular, it is forbidden to, e.g.:

- Influence the tendering behavior of competitors or their suppliers by offering any benefits, or
- Enter into agreements or understandings with other tender participants to coordinate price offers, allocate customers, divide markets, restrict output, etc.
- Allow competing enterprises insight into relevant company data (by way of i.e. contract manufacturing, in-licensed product contracts or in-licensed ingredient contracts).

**Control measure description:**

- A local tender management guidance document, i.e. **INGD-002, "Tender Management"** has been issued for Fresenius Kabi India Private Limited, a dedicated tender contract management or tender office has been set up.
- Maintain written tender documentation, including: tender requests, Fresenius specifications including back-up documentation (including methodology and costs considered) for submitted prices and approval thereof.
- Monitor tender win rates by product group, sales region or tender segments and follow up unusual tender win rates.
- Hold regular trainings on local tender requirements.
- Implement processes to avoid information exchange through distributors or subcontractors that are co-operating with other bidders.

The Contract Owner of the relevant bid process must ensure that any local tender requirements are complied with.



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**b) Product bundling:**

**Description:** By way of definition, product bundling means for purposes of this policy, the offer of a combination of products to customers (e.g. equipment and disposables or generic drugs). Offering products together as part of a package can benefit customers who like the convenience or economics of a bundle of products at the same time.

**Anti-trust relevance:** Anti-trust concerns arise when an enterprise with Dominant Market Position uses forced buying, or "tie-in" sales, to gain or protect sales in other product groups where it is not dominant and, thus, to make it more difficult for rivals in those markets to obtain sales. If the seller offering the tied products has sufficient market power in the "tied" product, these arrangements can violate Anti-Trust Laws.

Contracts with hospitals for product bundles need to be aligned with local Anti-trust Law and transparency rules must be followed. For example in some jurisdictions bundled product offers, where permitted, must only be offered for tenders that request such offers or where alternative offers have been permitted in accordance with the tender rules.

**Control measure description:**

- Mandatory local legal review of the product placement models: for general restrictions and for which products to be offered in combination.
- Issue a local product placement process addressing restrictions with combination offers, if any.
- Where product bundling restrictions are dependent on the market share, monitor relevant market share closely.
- Monitor product sales per bundling transactions and follow up unusual developments.
- Implement process to track device returns and installed equipment basis.

The Contract Owner of the relevant bid process must ensure that any local requirements are complied with.

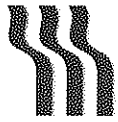
**c) Sales to competitors:**

**Description:** Other product manufacturers or distributors may procure raw materials and products (i.e. APIs) from Fresenius Kabi to serve their customers, while also competing with Fresenius Kabi for the same or other products.

**Anti-trust relevance:** The mere fact that Fresenius Kabi sells one or more products to another enterprise does not necessarily infringe Anti-Trust Laws, however, such co-operations must not be used to improperly exchange price or other market-sensitive information, or result in agreements on sales prices to endcustomers, restriction of markets or allocation of customers, etc.

**Control measure description:** The following requirements must be followed by the Hotelkeeper:

- Implement organizational separations for sales to other manufacturers/distributors and sales to endcustomers to prevent information exchange and any appearance of impropriety.
- Implement particular checks as needed for Spot Sales to competitors, product partnering or OEM supplies to competitors to ensure compliance with Anti-Trust Laws



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- Maintain written documentation, including: order request, and back-up documentation for submitted prices and approval thereof.
- To the extent possible and based on information which is publicly available, monitor price development compared to third parties by product group and sales region and follow up unusual price developments.

The Contract Owner of the relevant agreement must ensure that such agreement is legally checked. For details for legal check please refer to Chapter 4.7.

### **d) In-licensing / Contract manufacturing:**

**Description:** Contract manufacturing refers to a contractual relationship between two enterprises to manufacture or supply certain components or products, such as the manufacturing of finished dosages based on APIs provided by Fresenius Kabi. In the context of this Policy, it refers to the contractual relationship between Fresenius Kabi and competitors.

**Anti-trust relevance:** Such contracts may be critical in terms of anti-trust regulation, as by way of such agreements, a competitor may receive capacity or price sensitive data.

#### **Control measure description:**

- Maintain appropriate separation processes and confidentiality between contract manufacturing activities and Fresenius Kabi's own manufacturer.
- Ensure that employees have been trained on confidentiality and anti-trust matters,
- Implement restricted use wordings in contracts with the customers.

### **e) Sales to Distributors:**

**Description:** In certain countries, manufacturers may not restrict their independent distributors, e.g. in their ability to set prices or to sell to customers outside the contractually agreed territories.

#### **Anti-trust relevance:**

Sales to distributors have typically two Anti-Trust Law aspects:

(1) Risk that a distributor facilitates collusion between competitors, if such distributor also acts for competitors.

(2) Risk of competition restraints between Fresenius Kabi as seller and distributor as buyer of our products (vertical restraints). Anti-trust concerns arise when an enterprise with market power (market share of around 30%)/Dominant Market Position imposes vertical restraints.

In Vertical Agreements with distributors, the following practices may **not** be permitted:

- Resale price maintenance: Establishment of a fixed or minimum resale price or a fixed or minimum price level to be observed by the distributors. However, maximum resale prices or non-binding price recommendations may be allowed, provided it is clearly stated that prices lower than those can be charged.
- Tie-in agreement: An agreement requiring a distributor, as a condition of such purchase, to purchase some other goods.
- Exclusivity agreements: Agreements restricting in any manner, the distributor from (a) acquiring/dealing in any goods other than those of Fresenius Kabi, and (b) supplying goods or selling in any area or market.



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- Restriction of passive sales: Restriction of sales by a distributor outside its contractually agreed territory if so requested by a customer (passive sales). However, certain restrictions on active sales (as opposed to passive) into an exclusive territory, i.e. reserved to another distributor or Fresenius Kabi, may be permitted.
- Restrictions on cross-supplies between distributors within a selective distribution system.
- Non-compete obligations for distributors of more than five years.
- Unfairly favoring one distributor over another competing customer.

**Control measure description:** Document selection criteria for distributors and reasons for rejecting requests for supplies by potential distributors (such as rejection for compliance concerns).

- Maintain written price documentation, including back-up for submitted prices and approval thereof.
- Monitor price development by product group and sales region and follow up unusual developments.
- Monitor region-wise market shares.

The Contract Owner of the relevant agreement must ensure that such agreement is legally checked. For details for legal check please refer to Chapter 4.7

### **f) Restrictions in supply contracts:**

**Description:** Supply contracts may generally be entered into if Fresenius Kabi wishes to sell goods and services to another enterprise.

**Anti-trust relevance:** Depending on the market share, restrictions in supply contracts that establish a certain degree of dependency of the supplier from Fresenius Kabi may be critical, such as:

- Indefinite automatic prolongations of the supply contract (without any further requirements for approval by either party).  
Supply contracts combining (i) an exclusivity clause or an obligation to purchase from Fresenius Kabi more than 80% of the individual demand (or 30% of the total demand) and (ii) a long contractual term (a term of more than five years or a further automatic prolongation/renewal), and not easily terminable at the will of the purchaser.
- Supply contracts containing discounts based on supply volumes that represent a high market share may be critical, in particular if such discounts apply retrospectively on all purchases and could result in a buying obligation (also in supply contracts where Fresenius acts as supplier and sets incentives for its customers by granting substantial aggregated rebates).

### **Control measure description:**

- Establish a sourcing process that requires legal review for certain high demand purchases and exclusivity.
- Regular review of supplier's market share and demand and Fresenius Kabi's supply volumes of the respective goods or services for lead buyers.

The Contract Owner of the relevant sourcing process must ensure that any anti-trust requirements which have been identified are complied with.

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**g) Rebates and discounts:**

**Description:** Rebates and discounts can generally be granted to customers.

**Anti-trust relevance:** Anti-trust concerns may arise when an enterprise with Dominant Market Position is granting certain rebates and discounts. Rebates and discounts applied by an enterprise in a Dominant Market Position should be the same for all (potential) customers, transparent and based on objective criteria.

- Quantity rebates: It is acceptable to offer a discount or rebate to a customer where the reduction is justifiable on the basis of genuine cost savings. Quantity rebates, which reflect cost savings in economies of scale, which are made available to all buyers and do not restrict the customer's choice of supplier, are permitted.
- Loyalty / fidelity rebates: On the other hand, a dominant enterprise may not grant fidelity (or loyalty) rebates or discounts that have the effect of tying that customer to the dominant supplier and thus preventing the customer from obtaining his supplies from competing suppliers (foreclosure effect). This includes retroactive rebates, i.e., on condition that a volume threshold is reached, offer a customer lower prices on units provided and to be provided.

**Control measure description:**

- Maintain transparent discount scheme based on objective criteria.
- Grant rebates on economically sound reasons rather than loyalty aspects.
- Do not set prices below cost without proper documentation and approvals.
- Regular review of Fresenius Kabi's market share.
- Mandatory local legal review of the discount and rebate scheme in place.

The Contract Owner of the relevant rebate agreement must ensure that any anti-trust requirements which have been identified are complied with.

**h) Refusal to supply:**

**Description:** In general, and within the constraints of its contractual obligations, Fresenius Kabi has the right to decide with whom it will – and will not – do business, provided that it does so independently and the decision is not part of an agreement with another enterprises.

**Anti-trust relevance:** Anti-trust concerns may arise when Fresenius Kabi has a Dominant Market Position and refuses to supply. A dominant enterprise is required to have some reasonable and fair objective commercial reason for cutting off or reducing supplies to a customer. Objective justifications might include real concerns about the customer's credit worthiness or a shortage of the relevant product.

**Control measure description:**

- Regular review of Fresenius Kabi's market share.
- In a Dominant Market Position, only refuse supply if objective reasons are obvious and document such reasons
- Seek legal advice when in doubt.

The Contract Owner of the agreement must ensure that any anti-trust requirements which have been identified are complied with.

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### i) Non-discrimination:

#### Description:

In general, Fresenius Kabi is free to negotiate different sales conditions with its distributors and customers.

#### Anti-trust relevance:

Anti-trust concerns may arise when Fresenius Kabi has a Dominant Market Position and applies different sales conditions to similar distributors and customers under comparable circumstances or similar sales conditions to dissimilar distributors and customers. A dominant company cannot grant different sales conditions (prices, rebates etc.) to distributors and customers meeting the same requirements. However, a dominant company can grant different sales conditions for objectively justified reasons (e.g. granting different sales conditions to customers active on different distribution levels wholesale/retail or to certain customers which provide additional services that others do not provide).

#### Control measure description:

- Regular review of Fresenius Kabi's market share.
- Compare sales conditions for similar and dissimilar customers.
- In a Dominant Market Position, only grant different sales conditions if objective reasons are obvious and document such reasons.
- Seek legal advice when in doubt.

The Contract Owner of the relevant agreement must ensure that any anti-trust requirements which have been identified are complied with.

### 3) Sourcing:

#### a) Sourcing partnerships with other enterprises:

**Description:** This would mean the bundling of purchasing activities with other enterprises.

**Anti-trust relevance:** The mere fact that Fresenius Kabi bundles purchasing activities with its competitors does not infringe Anti-Trust Laws; however, such partnerships should not be used to improperly exchange price or other market-sensitive information, or result in agreements on sales prices to end consumers, etc.

#### Control measure description:

Mandatory legal review for purchasing co-operations with other enterprises, irrelevant of the form of such co-operation:

- Control measures regarding information sharing (Chapter 4.2, Section d) should be undertaken.

#### b) Insourcing from competitors:

**Description:** Insourcing of products from competitors means that Fresenius Kabi buys raw materials, API or finished products from a competitor.

**Anti-trust relevance:** Insourcing of raw materials, APIs or finished products (attending tender business in stock out cases), could also lead to anti-trust infringements if such

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contracts or behavior are intended to unduly influence the relevant market by way of exchanging market relevant information.

### Control measure description:

- Maintain appropriate organizational and process separation to ensure confidentiality between Fresenius Kabi's sourcing and sales departments.
- Ensure that employees have been trained on confidentiality and anti-trust matters
- Implement restricted-use wordings in contracts with the suppliers (for e.g., clauses imposing confidentiality obligations on the supplier (including persons who would receive such information) from using the information provided in any manner other than that specified in the contract terms (such as to gain an unfair advantage). Also, clauses to ensure firewall protocol within the supplier organization can be considered to limit the access to information to key people bound by confidentiality).

### 4) Other:

#### a) Participation in industry associations:

**Description:** Fresenius Kabi is a member of several industry associations and participates in relevant meetings.

**Anti-trust relevance:** Meetings with competitors during industry association events may provide a forum for improper exchange of highly sensitive and market relevant information or verbal agreements with competitors on anti-trust relevant issues.

### Control measure description:

- Identify all Legal Entity's representatives in industry associations
- Provide regular trainings to the representatives in industry associations
- For meetings, an appropriate documentation (agenda, meeting minutes) shall be maintained.
- **Annex 1** to this Policy contains more detailed guidance for meetings

#### b) Bidding co-operations:

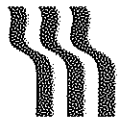
**Description:** A joint bidding with another enterprise may be required where Fresenius Kabi is unable to offer the requested volumes or product mix.

**Anti-trust relevance:** The fact that the bidding process or specification requires competitors to align their bids does not result in an exception from the general anti-trust restrictions. Such bidding co-operation needs to be cleared by the legal department in accordance with Sec. 4.7 before any activity in this regard.

**Good practice control:** The Contract Owner of the relevant agreement must ensure that the activities have been approved legally.

#### c) Benchmarking:

**Description:** Benchmarking is a comparison of enterprise related information, e.g. cost structures, organizations or processes in order to improve or evaluate Fresenius Kabi's own efficiency.



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**Anti-trust relevance:** Anti-trust concerns can arise where benchmarking is conducted with data and/or information received (directly or indirectly) from other enterprises, in particular if sensitive information is exchanged that can be used to coordinate market strategies and/or otherwise restrict competition.

**Control measure description:**

Ensure that either Benchmarking is conducted by Fresenius Kabi itself or with help of an independent consultant without receiving any information from other enterprises or, if the Benchmarking potentially involves data and/or information provided by other enterprises, the requirements listed under (d) below are complied with.

**d) Information exchange and industry statistics:**

**Description:** Information exchange between enterprises can occur in many forms/ways and might be conducted directly or indirectly, by third parties such as industry associations or independent consultants, research centers etc. Such third parties may publish general industry reports, periodicals etc., and establish standards, but also may compile industry statistics or conduct benchmarking exercises based on company data of individual members or participants.

**Anti-trust relevance:** The compilation of industry statistics is often pro-competitive as it allows industry participants to make better informed choices to adapt their strategy more efficiently to market conditions. However, in particular information exchange between competitors may result in a restriction of competition (and thus be unlawful) if such information exchange includes sensitive information.

For example, the exchange or discussion of future or current data, including in particular future sales prices, production capacity or sales information is critical and certain control measures must be put in place.

**Control measure description:** The responsible person in-charge of the project shall:

- ensure that only past data which is not commercially sensitive is exchanged, never future or current data
- ensure that the input information does not flow back or is discussed between the participants of the data gathering,
- ensure that the resulting report sufficiently aggregates and anonymises the data and does not allow a tracing back of the source of information (i.e. by a sufficiently large number of minimum participants)
- in cases of any doubt share the intended actions with local legal anti-trust counsel prior to any implementation or data exchange.

### **5.3 Dawn raid guidelines / searches by authorities:**

If there is a dawn raid or a search by authorities please bear in mind the following principles:

Do:

- Review the search warrant and the identity cards of the DG officials.
- The DG officials are required by law to ensure that two "independent and responsible" inhabitants of the locality in which the place to be searched is situated are present as witnesses. Please verify the identity of the two witnesses.



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## **Local Anti-Trust Policy**

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- Ensure the examination of records by the DG officials is confined to the subject matter of the investigation (if any) stated in the search warrant.
- If a document which the DG officials have requested cannot be found, explain what happened to it (if you are able to) and indicate that Fresenius Kabi will provide it in due course, if it can be located.
- Contact the company's internal legal team and external counsel immediately, and follow instructions from the legal team at all times
- Cooperate with the officials (e.g. open a cupboard when asked)
- Accompany the officials at all times
- Make an accurate written record of every aspect of the inspection, including copies of everything the officials searched, took or copied, and any questions asked
- Keep every aspect of the inspection, including the fact that it has occurred, confidential
- Comply with any preventative measures adopted by officials including in respect of IT, such as the suspension of external email communication
- Remain calm and polite
- Seek as much information from the officials about the investigation as possible
- Where any documents/devices (hard copy or electronic) are seized, the DG officials are required by law to make a list of such documents and the location where they were found. This list, is called a panchnama and is required to be signed by Fresenius Kabi, the two witnesses and the DG officials. Please verify this list before signing it. A copy of the same must be provided to Fresenius Kabi.
- Copies of all documents or information seized have been retained, to the extent allowed by the DG officials. If copying was not permitted, make sure you have registered this as a protest in the panchnama.

### **Do Not:**

- Leave the officials to search through files or offices on their own
- Over-cooperate or volunteer information or documents that have not been requested
- Obstruct the officials in any way
- Hide, destroy, delete or alter any documents (electronic or hard copy)
- Discuss the inspection with anyone outside or inside the company, unless authorised by the legal team
- Tamper with any seals affixed by the officials to computers, offices or cabinets
- Provide any false or misleading information to the officials
- Refuse to provide access to your PC/laptop/phone and any other device used for business purposes , even if it falls under a bring your own device policy

### **5.4 Trainings / communication:**

Compliant acting requires a broad knowledge of anti-trust requirements and their importance for business transactions. Practical examples may help support the understanding of the law and its application.

Fresenius Kabi has rolled-out an anti-truste-learning which is available for every employee assigned to a sensitive function in the Legal Entity. Participation in such anti-truste-learning is compulsory for all employees in sensitive functions (as explained below) as well as for nominated staff members.



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## Local Anti-Trust Policy

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The E-Learning Coordinators of each Legal Entity shall define a list of sensitive functions for their entities. Such sensitive functions are typically:

- Regional saleshead
- Tender office employees
- Key account management
- Distributor management
- Sourcing management
- Representatives in industry associations
- Legal team

The Hotelkeeper shall regularly review the list of sensitive functions for its Legal Entity(s) and shall review the training status of staff members.

In addition, regular class-room trainings shall be conducted for sensitive functions.

### **5.5 Monitoring in each Legal Entity:**

The Hotelkeeper shall monitor the implementation of and ensure compliance with this Policy. The Hotelkeeper shall also evaluate the impact of any change in the legal environment and adapt this Policy as required. This Policy will regularly be reviewed by the Hotelkeeper for potential improvements and required adjustments.

### **5.6 Reporting:**

Anti-trust cases shall be reported by each employee to supervisors, the respective compliance officer or the compliance hotline. Any such report will be managed in accordance with the **U 20 "Case Management Policy"**.

Potential misconduct may be reported via multiple channels (e.g. whistleblowing hotline, internal/external audits, media coverage). A central ombuds panel undertakes a pre-assessment by checking plausibility and analysing initial severity of the case report and determines the respective task force to investigate the case based on an investigation mandate issued by the ombuds panel. The case will be administered in the central case management tool. The investigation shall then be performed by the task force to verify the substantiation of the case and the involved participants.

Any inquiries or information requests from local anti-trust authorities addressed to the Legal Entity must be reported immediately and prior to the disclosure of any information to the legal department of Fresenius SE & Co. KGaA.

### **5.7 Legal Support:**

The Hotelkeeper shall ensure that all business operations of the respective Legal Entity are made in compliance with current legal requirements. For legal advice in relevant transactions, Fresenius Kabi has retained a Panel Law Firm that will assist the Hotelkeeper and any employee of Fresenius Kabi Oncology Limited. Requests for legal advice to the Panel Law Firm may only be made by Mr. Nikhil Kulshreshtha, Director & Secretary.

## Local Anti-Trust Policy

Contact Details of the Panel Law Firm are attached as **Annex 7** to this Policy.

### 5.8 Remedies:

The remediation of concrete non-compliant behaviour in respect of anti-trust provisions follows the **U 20 "Case Management Process"**.

Should an investigation of a case result in the conclusion that any relevant Fresenius anti-trust policy (including this Policy) has been violated, the task force shall set-up a remediation plan, which shall consist of disciplinary sanctions of the respective participant, training measures, process adjustments or organizational changes to prevent future violations. The remediation shall be monitored by the regional/divisional compliance co-ordinator.

### 6. References:

- gSOP LE 004 "Compliance Risk Management Process" [Fresenius Kabi Antitrust Policy]
- Fresenius Kabi U20 Case Management Policy
- Fresenius Kabi K 1 Policy on Hotelkeeper Responsibilities
- U 14 Fresenius Kabi Antitrust Compliance Policy
- INGD-002 "Tender Management"

### 7. Document Change History

this Policy replaces:           None

Version	Reason for Change	Effective Date
00	Document newly established	27 August 2018

### 8. Publication & Distribution

#### 8.1 Publication:

Locally at Fresenius Kabi Oncology Limited, Gurgaon. The information for the publication of new or revised documents shall be given by Legal Function to all the concerned departments through distribution and retrieval procedure.

#### 8.2 Distribution:

FKOL Local Standard Distribution List including Management.



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## **Local Anti-Trust Policy**

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### **Annex 1: Short guidance when attending meetings of industry associations:**

#### **Do's**

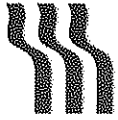
- Review whether the association you are active in has its own compliance code and adequate processes to avoid any anti-trust concerns.
- Insist on an agenda to be circulated prior to the meeting and check the agenda for items that may raise anti-trust concerns (if in doubt, check with your local anti-trust legal advisor and/or the Hotelkeeper).
- Insist that official meeting minutes are kept and review these minutes after the meeting (if you identify language that may raise anti-trust concerns check with your local anti-trust legal advisor and/or the Hotelkeeper).
- Document each meeting (written agenda should be followed and minutes of the meeting prepared).
- Object immediately if there is any inappropriate discussion (e.g. exchange of confidential and sensitive business information)
- If the inappropriate discussion continues, leave the meeting and insist that this is reflected in the minutes. On the same day, make a note about the discussion and the steps you took and share the same with the Hotelkeeper, and decide on the measures to be taken.
- Be aware that Anti-Trust Law extends not just to discussions during the meeting itself, but also to all conversations in the course of a meeting, and in a social context before and after meetings e.g. over coffee during a break.
- Not only in industry meetings but in general be always cautious in what you say and what you write in e-mails in particular in those markets with high entry barriers and where company has a strong position/considerable market share.

#### **What must not be discussed (formally or informally) in a meeting...**

- prices, price policies, industry price levels, margins, discounts, allowances, credit terms, costs of production or distribution, cost accounting formulas, or methods of computing costs, other current terms of trade, etc.
- individual production capacities and quotas, individual sources of supply, costs, production, inventories, or sales, etc.
- information as to future plans concerning technology, investments, or the design, production, distribution or marketing of particular products including proposed territories or customers, etc.
- matters relating to individual suppliers or customers, particularly in respect of any action that might have the effect of excluding them from the market.
- strategy in relation to or responses in respect of tenders, or other contracts, other matters which would otherwise be regarded as company confidential.

#### **What may be discussed...**

- Policy development.
- Industry public relations or advocacy activities.
- Publicly available information on market trends (provided this does not lead to collusion concerning the future).
- Non-confidential, technical issues relevant to the industry such as court judgments, proposed new legislation; regulatory codes of conduct etc. (provided this does not lead to collusion concerning the future).



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## **Local Anti-Trust Policy**

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- Information exchanges concerning non-public data which relate only to:
  - General, historical and non-confidential data (ie cannot be expected to have an impact on competitors' future business) or
  - aggregated data of at least 3 independent producers; and individual enterprises cannot be identified from the data or the data is processed by an independent third party and confidentiality is ensured.



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### **Annex 2: Short guidance on R & D Agreements:**

#### **1. Do's**

- Always check with the Legal & Secretarial team before entering into any R & D Agreement.
- Provide the Legal & Secretarial team with detailed information on scope and participants of planned R&D project in order to allow for comprehensive antitrust review.
- Determine the exact scope of the planned R&D project, the identity and current business activities of the R&D partner enterprises, and the scope of Kabi IP rights affected by R&D project.
- Identify the markets potentially affected by the R&D project and the participating parties' position on this market.
- Define the goal of the R&D project with regard to the use (exploitation) of the R&D results.

#### **2. Behavior and terms to be avoided (formally or informally)**

- Do not enter into R&D Agreements without prior consulting and consent of the Legal & Secretarial team.
- Prohibition to use results of R&D project for further, independent R&D activities by each party to the R&D project.
- Prohibition to conduct R&D activities beyond scope of R&D project and, after the present R&D project has been completed, within the scope of this R&D project.
- Parties to R&D project may generally not determine sales prices for products arising out of R&D project as well as license fees or similar conditions for IP rights arising out of R&D projects.
- Restriction of parties' possibilities to challenge the validity of IP rights of the other parties in the R&D project with relevance for the R&D project and, after the end of the R&D project, of IP rights protecting the results of the R&D project, respectively.

#### **3. Non-critical terms**

- Agreements on distributing R&D work between parties to R&D project.
- Agreements concerning distribution of costs for R&D project subject to additional conditions.
- Provisions on communication between participants of R&D project, including project meetings etc. Agreements should however ensure that R&D project-internal communication is restricted to R&D project-related topics and communication does not go beyond what is necessary for achieving R&D project's goals.



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### **Annex 3: Short guidance on Sales:**

#### **1. Do's**

- Always determine autonomously and independently prices and price-related conditions.
- Always compete for all customers vigorously on the merits of your products/services.
- Always negotiate autonomously and independently with customers and suppliers.
- Always check with the Legal & Secretarial team before:
  - Entering into exclusivity agreements with customers and suppliers
  - Refusing to supply certain customers
  - Granting rebates or discounts to customers
  - Imposing any pricing restriction

#### **2. Behavior and terms to be avoided (formally or informally)**

- In relation to competitors (horizontal aspects):
  - Do not agree on prices, price-related conditions or other commercial terms with competitors.
  - Do not arrange any market sharing or allocation of customers with competitors
  - Do not engage in an information exchange with a competitor concerning sensitive sales information.
  - Do not engage in bid rigging or collusive bidding.
  - Do not enter into agreements with competitors to limit or control production, supply, markets, technical development etc.
- In relation to distributors (vertical aspects), if Fresenius Kabi has market power (market share of around 30%):
  - Do not fix or set the resale price to distributors for any product.
  - Do not oblige, force or incentivize the distributors to follow a certain resale price.
  - Do not prevent distributors from accepting orders from outside an agreed territory (i.e. no restriction of passive sales).
  - Similarly, do not refuse orders from distributors exporting the products with the argument of territorial restrictions.
  - Do not restrict sourcing of competing products by the distributor for a duration of more than five years from the start of the agreement.
  - Do not enter into agreements with distributors, where the distributor is required to purchase goods, as a condition to purchase some other goods.
- In case of a Dominant Market Position:
  - Do not impose unfair and discriminatory sales conditions and/or prices to similar buyers without objective justification.
  - Do not set price below costs.
  - Do not refuse or reduce supplies to similar buyers without objective justification.
  - Do not make the supply of a dominant product conditional upon the obligation to buy another product.
  - Do not grant rebates or discounts causing or incentivizing the buyers to source all or most of their requirements from the dominant supplier.



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- Do not leverage your dominant position such as force buying, or "tie in" sales, to gain or protect sales in other product groups where Fresenius Kabi is not dominant.
- Do not limit or restrict production of goods, provision of services or technical/scientific development relating to the goods. (for e.g., refusal to license a product which is an essential ingredient in the manufacturing process, or licensing a product which may be an essential ingredient in the manufacturing process at an unfair/excessive price).

### **3. Non-critical terms**

- Communicating non-binding price recommendations to distributors (provided no direct or indirect pressure is exercised or any incentive is offered to enforce such recommendation).
- Stating maximum resale prices (provided it is clearly stated that lower prices may be charged).
- Preventing the distributor to source and resell competing products during the first five years of the duration of a distribution agreement (non-compete clause), if no Dominant Market Position exists. Granting of exclusive distribution rights for a certain territory and prohibiting an *active* marketing policy outside the agreed territory, if no Dominant Market Position exists.

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**Local Anti-Trust Policy**

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**Annex 4: Short guidance on Sourcing:****1. Do's**

- Always negotiate autonomously and independently with suppliers.
- Always check with the Legal & Secretarial team before entering into exclusivity agreements with suppliers.
- Always try to obtain price quotes from more than one potential supplier.
- Always report any incident of similar prices/quotes in tenders by the suppliers to the legal department.
- Always include confidentiality obligations in the procurement/bid conditions.
- In general, determine sources and conditions of supply autonomously and independently of other competitors. Exceptions apply in case of sourcing cooperation with competitors which, however, must be subject to prior Anti-Trust review and approval by the Legal & Secretarial team and the Procurement team.
- In case of a sourcing cooperation with other enterprises:
  - Verify that cooperation partner does not qualify as actual or potential competitor. In case of doubt, do check with the Procurement team and the Accounts & Finance team.
  - Determine product/service market affected by sourcing cooperation and cooperating parties' position in this market.
  - Restrict communication and exchange of information to the level strictly necessary for purchasing cooperation. Engage with the Legal & Secretarial team and the Procurement team for prior review on scope and level of information to be exchanged with cooperation partners.

**2. Behavior and terms to be avoided (formally or informally)**

- Do not use insourcing co-operations with competitors as means to resale price fixing, output limitation or market allocation.
- Do not accept supply terms that restrict the possible scope of use for the supplied product without prior review by the Legal & Secretarial team and the Procurement team.
- Do not accept supply terms excluding supply of products by other parties (exclusivity agreements) without prior review by the Legal & Secretarial team.
- Do not disclose or receive any commercially sensitive information such as prices, capacity, etc. during the negotiations.

**3. Non-critical terms**

- Use of standard purchasing/sourcing conditions of Kabi and supplier, respectively.
- Acceptance of supplier's standard rebate/discount system (e.g. quantity discounts).





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## **Local Anti-Trust Policy**

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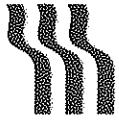
### **Annex 5: Short summary of general points to remember in Anti-Trust Law:**

#### **1. Do's**

- Determine all your business activities autonomously and independently of competitors.
- Be always careful in the presence of competitors, e.g. in trade association meetings, at industry fairs, social events, in particular in connection with the discussion of market-related topics.
- In case of any doubt whether a certain behavior is in line with Anti-Trust Laws, do check with the Legal & Secretarial team before entering into any agreement.
- Anti-Trust Authorities usually base their evidence of Anti-Trust Law infringements on internal and external documents of the undertakings involved.
- In order to avoid any misunderstandings with respect to the interpretation of memoranda, contracts and internal or external correspondence, it should be ensured that clear, unambiguous wording is always chosen.
- When making oral statements (e.g. by telephone) or when drafting letters, emails and notes, every Fresenius Kabi employee should carefully check whether the chosen wording could be misunderstood as being an indication for anti-competitive behavior.
- As a rule of thumb and for checking correct wording, ask yourself how a document which is to be sent will look to an outsider.

#### **2. Behavior and agreements to be avoided (formally or informally)**

- Do not exchange sensitive information on prices, sourcing and supply conditions, sales volumes or customers with competitors.
- Avoid aggressive language (e.g. *"We will force X out of the market."*, *"We are unassailable market leader."*).
- Do not speculate in written documents or emails about the question whether a specific strategy is compliant with Anti-Trust Laws. Should it turn out later that the strategy is unlawful, the doubt expressed by you may serve as an indicator for the relevant Anti-Trust Authority that the infringement has been committed intentionally (with the potential to form an encumbering circumstance when imposing sanctions).
- Never include language in documents or emails which can create the impression that the action described in such document or email is prohibited (e.g. *"Destroy after reading."*, *"Everybody is requested to keep it a secret as it would cause serious damage if caught"*, and *"Delete immediately"*, *"let's not discuss on email, this can create anti-trust concerns"*).



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### **Annex 6: Short Guidance on Scope of Legal Privilege (Investigation by the CCI):**

#### **1. Do's**

- Internal correspondence with the legal department of Fresenius Kabi may be inspected, seized and used by the DG officials.
- A differentiation is to be made with respect to correspondence with external lawyers:
  - Any correspondence with external lawyers prior to the start of the investigation (e.g. legal opinions, results of compliance investigations) are statutorily recognized as privileged and confidential. However, it can be difficult to define the limits concerning legally privileged documents. The DG officials may take the view that legal privilege only prohibits the use of the document, meaning that during the inspection the officials themselves may read and check the documents in question. The DG officials may also take the view that mixed documents, in which comments of an internal nature as well as advice from external legal advisors are repeated, are not wholly legally privileged".
  - Legal privilege may also be claimed on:
    - written communications obtained by in-house lawyers or employees from third parties in contemplation of or in connection with litigation and communicated to external lawyers, for advice; and
    - documents brought into existence by in-house lawyers and communicated to external lawyers for enabling external lawyers to advise on prospects of making or resisting a claim, even if litigation has not commenced or not imminent but is reasonably in prospect. Mark correspondence with external lawyers as "*Legally Privileged/Attorney-Client Privileged*"
- If in doubt, check with the Legal & Secretarial team or your legal counsel whether documents are deemed protected before handing these over to the DG officials.
- If the DG officials insist that the documents are handed over, seal the documents in an envelope marked "*legally privileged documents – inspection by authorities is only permissible with a court decision*". Do register a protest regarding the same in the panchnama.

#### **2. Behavior and agreements to be avoided (formally or informally)**

- Do not hinder the investigation by the DG officials in any way, in particular, do not remove or destroy any documents.



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**Annex 7: Contact Details Panel Law Firm:**

<b>Contact Persons</b>	<b>Mr. Naval Satarawala Chopra / Ms. Manika Brar</b>
Position	Partners, Shardul Amarchand Mangaldas & Co.
Address	Amarchand Towers, 216, Okhla Industrial Estate, Phase III, New Delhi - 110020 India
Telephone No.	+91 (11) 26920500
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Fax No.	+91 (11) 26924900
E-mail Address	<a href="mailto:naval.chopra@AMSShardul.com">naval.chopra@AMSShardul.com</a> <a href="mailto:manika.brar@AMSShardul.com">manika.brar@AMSShardul.com</a>