COMPETITION RULES GUIDELINE

Association of Research-Based Pharmaceutical Companies
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The Competition Rules Guideline (hereinafter referred to as "Guideline") has been prepared by Kaleğası & Gürmen Law Office upon the request for the Association of Research-Based Pharmaceutical Companies (hereinafter referred to as "AIFD"). Information contained in this Guideline is for guidance purposes only and should be used by AIFD and its members to ensure compliance with the competition rules to the highest extent possible. Since it is often difficult to determine whether a contemplated action is compliant with competition rules, and experts on Competition Law should be consulted for advice in case of hesitation regarding compliance.

FOREWORD

To set a model for both its members and its stakeholders, blazed a trail in 2013 and published the first Competition Rules Compliance Guideline to display its seriousness regarding compliance to competition rules, and leave a permanent footprint in the competitive environment in the industry.

The guideline was revised with time and the amendments made in Law No. 4054 on the Protection of Competition ("Competition Law") and in practice were added to the guideline. As a result of the revision of the guideline made following the legislative amendment in 2020, the guideline was transformed into a document reflecting legal rules and AIFD's position and named as "Competition Rules Guideline".

As AIFD, we continue to consolidate the care we have displayed for complying with any kinds of legal and ethical rules including our Competition Rules Guideline. Together with this guideline, AIFD commits to exert utmost effort for achieving full compliance with competition rules.

Compliance with competition rules is a core value and obligation for AIFD. We recognize the importance of this issue together with our employees and members. We understand that not complying with the Competition Law will raise doubts against the entire sector, and lead to the imposition of sanctions against us.

On the other hand, we also recognize that our efforts aimed at achieving compliance with competition rules would not end with the publication of this guideline. We intend to maintain compliance with the competition rules as a lifestyle. We will continue to maintain this as a top item on our agenda, focusing both our efforts and training activities on this issue.

Competition is an ongoing process, and in striving to comply with the rules, we are hoping that a competitive pharmaceutical industry will yield the most beneficial results for both our stakeholders and our economy.

Competition Rules Guideline
Executive Summary

It is very important to ensure that the Competition Rules and the practices of the Competition Authority are properly understood by all businesses operating in Turkey, and the mindset laid down in the Competition Law is communicated to both undertakings and associations of undertakings.

From this perspective, AIFD has defined the following main objective in its charter:

"…to cooperate with the research-based pharmaceutical industry in Turkey, to broaden access to novel medicines, information, and technologies for contributing to health in Turkey, to submit relevant legal applications as may be necessary for this context, and to develop an ethical and open pharmaceutical environment which is found in developed countries".

As described in the above statement, AIFD needs to collaborate both internally with its members and externally with other sector stakeholders to obtain novel drugs, knowledge, and technologies. This means that a major part of AIFD's activities may be assessed within the scope of the Competition Law.

Hence, AIFD views it as a key priority to ensure compliance with competition rules and intends to reinforce its position as a beacon of guidance and a leader on matters relevant to the competition rules, as with all the other areas in which AIFD is involved.

The Guideline primarily provides general information on competition rules. This section should be thoroughly understood by everyone who has a role within AIFD at any level or position, and particularly Article 4 of the Competition Law should be internalized. In fact, detailed information on this matter is provided in the relevant section of the Guideline.

On the other hand, another point specifically relevant to associations is the exchange of information. This topic has been addressed in greater detail under the relevant heading.

One of the most important objectives of the Guideline is to provide AIFD with practical information on following competition rules and assist on operational aspects and practices.

In this sense, an effort was made to describe AIFD's institutional structure and its relevant bodies with the information and recommendations provided in the Guideline. To avoid any conflict with the competition roles from the institutional structure, institutional practices, and operational aspects, each body was defined, and practical rules were laid down, which may a competitive relevance.

To support a practical character, competition rules of particular interest were highlighted, which are considered relevant as regards the ways that AIFD should follow, and the stances AIFD should take while interacting with its members. Furthermore, main guidelines should govern interactions of AIFD with key sectoral stakeholders, including government representatives and other associations, unions, and providers.

The final section of the Guideline discusses ways to assess performance on compliance with the competition rules from a positive or negative perspective. Attentiveness to the points highlighted in this section will not only ensure effective implementation of the recommendations made in the Guideline but also highlight that AIFD is taking this issue very seriously.

The topics described in this Guideline constitute a critical part of the efforts aimed at compliance with competition rules. However, note that compliance to competition rules requires a very disciplined perspective.

As repeated in several parts throughout the Guideline, seeking legal advice is strongly recommended in case of any hesitation.

- Occurrence of non-compliance,
- Concerns that a potential non-compliance may arise,
- Occurrence of circumstances that contradict the explicit warnings provided in this Guideline,
- Inability to determine the extent of a particular issue,
- Occurrence of circumstances that are not described in this Guideline.

To ensure full compliance with the competition rules, AIFD will continue to offer regular competition training to inform their staff are employees or volunteering associates.

The main purpose of AIFD’s effort to support compliance with competition rules is to maximize the awareness of competition both within the association and in the industry.

However, it is also a fact that this Guideline, being only a guidance document, is admittedly not exhaustive, and the advice of an expert on competition rules should therefore be sought to clarify any ambiguities, and ambiguous practices should not be implemented.

Hopefully, the points discussed in this Guideline will be internalized and will serve as a model for both our members and stakeholders, for the benefit of the pharmaceutical industry.

I. Introduction

The purpose of this Guideline is to provide a source of reference that may offer information and practical guidance on compliance rules from the perspective of associations. Associations and unions can play a highly productive and competitive role in the development of an industry, and thereby support the effective operation of markets.

However, there have been several cases in precedent Competition Law where some associations operating in other sectors were engaged in practices that resulted in the restriction of competition upon bringing together rivals.

Thus, this Guideline aims to provide guidance so that association activities may be conducted without preventing the emergence of competitive outcomes.

Both AIFD staff and volunteering members who are holding a role with AIFD should carefully read and internalize this Guideline.

If uncertainties or issues warranting further discussion arise, legal advice should be sought to provide clarity and no steps should be taken before the matter is completely elucidated. This approach will be particularly important for maximizing the intended benefit of this Guideline.

It is crucially important that every employee of the Association or "volunteer" expert/AIFD Committee member is knowledgeable in the practical implications of competition rules. Information on competition rules applied in Turkey is provided under the relevant headings in this Guideline, to the extent they are relevant to associations.

To ensure that issues are properly understood, AIFD or its members should attend courses on competition, where necessary, to enhance their knowledge.

For this Guideline to attain its purpose, all information contained herein should be implemented, not by interpreting it from a critical point of view, but by trying to internalize the spirit of the recommendations and actions offered herein, and any deficiencies or errors identified in the Guideline should be improved over time. In conclusion, it should be remembered that complying with the competition rules entails a process where these rules become an internal culture within the association.

II. Purpose and Scope

AIFD has defined the following main objective in its charter:

"…to cooperate with the research-based pharmaceutical industry in Turkey, to broaden access to novel medicines, information and technologies to improve health in Turkey, to make any legal applications, as may be necessary in this context, and to develop an ethical and open pharmaceutical environment which is typically found in developed countries".

As described in the above statement, AIFD needs to collaborate both internally with its members and externally with other sector stakeholders to obtain novel drugs, knowledge, and technologies to improve health in Turkey.

Hence, AIFD views it as an important priority to ensure compliance with the competition rules and intends to reinforce its position as a leader and beacon of guidance on matters relevant to competition rules as with all the other areas in which AIFD is involved.

The Guideline primarily provides general information on competition rules. This section must be thoroughly understood by everyone who has a role within AIFD at any level or position, including representatives of member companies.

One of the most important objectives of the Guideline is to provide AIFD with practical information on the following competition rules and with guidance on practices and operational aspects.

- An effort was made to provide a detailed discussion of competition rules in this Guideline, taking account of AIFD's institutional structure and its relevant bodies. To ensure institutional structures, institutional practices and operational aspects are compliant with competition rules to the highest extent possible, and any potential competitive sensitivities are addressed at all levels, each body was defined, and practical rules with competitive relevance were laid down.

- To support a practical character, competition rules of particular interest, which are considered relevant as regards the ways that AIFD should follow, and stances AIFD should take while interacting with its members, were highlighted.

The matters discussed in the Guideline cover a crucial portion of compliance with competition rules. However, compliance with competition rules involves aspects that entail a very disciplined perspective comprising commercial practices and sectoral experience in addition to knowledge on the economy and a legal perspective.

To ensure full compliance with the competition rules, AIFD will continue to inform its staff, volunteering associates, and committee members via regularly organized competition training.

The main purpose of AIFD's effort to support compliance with the competition rules is to develop and maintain an understanding of competition matters both within the association and in the sector.

Several competition terms are used throughout this Guideline. As it is considered that providing a detailed definition of each term may confound the content and undermine the intent of this Guideline, it is possible to attend training offered by the Association and/or request clarification by seeking legal advice through the Compliance Officer to gain a better understanding of what each of these terms means.

III. Competition Rules

A. Law on the Protection of Competition:

The purpose of the Competition Law is to prevent agreements, practices, or decisions that prevent, disrupt, or otherwise restrict competition in markets for goods and services, and to subject to statutory audit undertakings that have a dominant position in the market from abusing their power, as well as mergers and acquisitions that create a dominant position or solidify an existing dominant position in the markets.

The object of the Competition Law is any natural or juristic persons producing, marketing, or selling goods or services in a market, as well as any entities constituting an economic whole, which is capable of independent decision, that is undertakings, as defined by Law. The scope of the Competition Law also covers entities that bring together undertakings, such as unions and associations.

Hence, the implementation scope of the Competition Law and its secondary regulations ("Competition Legislation") comprise the following main headings.

A.1. Prohibited horizontal and vertical relations between undertakings

Any agreements, concerted practices, or decisions adopted by association of undertakings to restrict competition, or lead to the same effect, are prohibited by Article 4 of the Competition Law.

A.2. Exemption system

Article 5 of the Competition Law provides that exemptions to prohibitions laid down in Article 4 may be granted for agreements, concerted practices, and decisions between undertakings under specific circumstances, either upon the request of such undertakings or ex officio evaluation of the Competition Board, and for specific types of agreements, either on a case-by-case basis or as a group, by notifications to be issued by the Competition Board. There are two types of exemptions, namely, individual or group exemptions.

A.3. Dominant position and abuse of dominant position

Article 6 of the Competition Law prohibits undertakings, acting either individually or as a group, from abusing their dominant position.

According to the Competition Law, a dominant position exists when one or more undertakings operating in a market are able to set various economic parameters without regard to their

competitors or customers, including price, supply, and production and distribution quantities. The Competition Law aims to prevent undertakings enjoying a dominant position from using their power to eliminate market competition.

A.4. Mergers and acquisitions subject to the approval of the Competition Board

Article 7 of the Competition Law considers it illegal and prohibits any mergers or acquisitions which are aimed at building or further reinforcing a dominant position in a market and which will substantially deteriorate competition in a market for goods or services in all or a part of Turkey.

In the Notification No. 2010/4 on "Mergers and Acquisitions Requiring Approval of the Competition Board," the Competition Board lays down the types of mergers and acquisitions which, to be lawful, must be notified to and approved by the Competition Board.

A.5. Competition Authority

The Competition Authority ensures the formation and the development of markets for goods and services in a liberal and robust competitive environment and oversees the implementation of the Competition Law.

B. Prohibited Practices under the Competition Law

Practices between undertakings are considered a violation of the Competition Law, to the extent they prevent, disrupt, or restrict competition.

Therefore, modern jurisprudence provides regulations for the oversight of practices and unions which may potentially limit competition, in consideration that a competitive environment that must prevail in the markets may be disrupted artificially by certain concerted practices, agreements, and decisions of undertakings.

In order for a practice between competitors to fall in the scope of Competition Law, such relation must give rise to, or have the "potential" to give rise to, a "detrimental effect" on competition in a specific "market for goods".

The Competition Law refers to "a specific market". The market is divided into two, namely the geographical market and the market for goods. Considering the powers of the Authority, the geographical market is limited maximum with the Republic of Turkey; however, there are also examples in which the Board has reduced the geographical market to a city or a region upon observing the nature of that specific case. in such geographical area which were affected by such detrimental effect on competition.

The relevant product market refers to the market composed of the products considered as similar in terms of their price, intended use, or characteristics. It is observed in the assessment of decisions regarding the pharmaceutical industry that the Board has taken as a basis the ATC (Anatomical Therapeutic Chemical Classification System).

It is stipulated in the Law that any concerted act where the intention is to generate a detrimental impact on the existing or potential competition will be against the law.

B.1. Agreements, concerted practices, and decisions

Under the Competition Law, unlawful practices are classified under three categories of "agreements," "concerted practices," and "decisions".

B.1.a) Agreements

The term agreement means that parties have concurred on specific matters. Thus,

a. An "agreement" may be unwritten,

b. Being legally binding is not a requirement (includes gentlemen's agreements),

c. any formal or informal written, verbal, or actual concurrence of intentions may qualify as an agreement, whether or not it has legal implications.

As can be seen, the legal nature or form of a collusive relationship between parties is irrelevant to identifying the existence of an agreement. The relationship between the parties may be written, verbal, explicit, or implied, independent from its form.

B.1.b) Concerted practices

A "concerted practice" signifies a situation where undertakings "deliberately restrict" competition by adopting similar behaviors.

From this general definition, we can derive that a concerted practice is a form of coordination which, without evolving to an agreement, practically amounts to a collaboration, deliberately constructed to mitigate the usual risks of competing against one another.

B.1.c) Decisions and practices of associations of undertakings

An association of undertakings, whether constituting a formal or informal body, platform, or unity and whether operating under the designation of association, union, federation, or confederation, is an entity that brings together natural or juristic persons to voice professional or sectoral needs, to develop on them, and to achieve a common goal. While serving its members

is the primary purpose of any association of undertakings, they may also have a political function, including developing industrial and/or professional policies or developing sectoral/professional policies at both national and international platforms.

Associations are closely watched by the Competition Authority as they not only play an important role in enhancing the functionality and performance of the industry they represent, but they convene competitors as well.

Organizations assembled by undertakings for professional solidarity, discussing sectoral issues, undertaking social events, and other similar functions are also considered an "association of undertakings" and subject to Article 4 of the Competition Law. No decision taken by the association of undertakings through their relevant bodies may involve any practices which are contrary to the Competition Law. As the matter of detrimental effects on competition from such decisions are discussed under the section of this Guideline on concerted practices and restrictive agreements, this section will discuss the admission of members to the association, and dismissal from membership.

Membership in or dismissal from an association may be considered a violation under the Competition Law even if it does not have a particularly detrimental effect on market competition. Therefore, any association of undertakings which brings together competitors must remain at an equal distance to all undertakings operating in an industry. Particular care must be taken to ensure that the admission and dismissal procedures are compliant with the Competition Law. In this context, membership admission and dismissal procedures should be free from any arbitrary elements, and care must be taken to avoid procedures that are inconsistent with current regulations, in particular the competition rules. In other words, the criteria must be clear, objective, fair, and equally applicable for everyone. Membership in an association should be accessible to everyone who meets the membership criteria, and anyone whose membership application has been declined should be given a rationale for the decision, based on objective criteria, and allowed a recourse for objection. Also, no restriction should be imposed on individual decisions of members throughout their membership; the association's practices should not influence individual commercial decisions of its members, and any dismissal decision must be based on objective criteria – as with during admission – applied equally to all members, and on reasons which mustnot be objectionable under the Competition Law.

B.1.d) Examples of "De minimis" agreements not imposing a substantial restriction on competition

Within the scope of the concept of "agreements not imposing a substantial restriction on competition" introduced into the Law on 16.06.2020, agreements under a specific volume in the market, except for explicit and severe violations, may not be subject to the investigation of the Competition Board.

The designation of the agreements that will be subject to this rule is to be made decided by the Board. The Competition Board is expected to introduce with a Notification the arrangement stipulating that in the agreements to be made between competing undertakings, such agreements will not substantially restrict competition provided that the total market share of the relevant parties does not exceed a given rate (in any of the markets impacted by the agreement) and that non-competing undertakings do not exceed a certain portion of this rate. However, the right of the Competition Board to subject the relevant agreement to an investigation, where deemed necessary, even if designated thresholds of market shares are not exceeded is reserved.

B.1.e) Examples of agreements, decisions, and concerted practices restrictive of competition

Certain types of agreement are considered a "severe violation" and are thus always prohibited, including mainly:

- Direct or indirect fixing of prices,
- Designation of purchase and sale terms,
- Exchange of sensitive confidential information of competitive relevance between competitors,
- Partitioning, controlling, or limiting markets,
- Partitioning sources of procurement,
- Controlling or limiting production.

(B.1.e.1) Designation of prices and other purchase and sale terms

In Competition Law, "price-fixing agreements" are considered the most typical and objectionable type of restrictive arrangement.

The provisions of the Competition Law cover not only the direct fixing of prices, but also other factors that have an indirect bearing on the price, such as costs, margins, and even the transaction terms.

It is a most essential rule of a market economy that prices can be formed freely according to market dynamics, without any outside intervention.

Therefore, from a perspective of the relations between competitors, no doubt competing undertakings' coming together to designate prices or other terms of purchase and sale, or to adopt a common set of behaviors, will have restrictive implications on the competition.

(B.1.e.2) Partitioning of markets

Another case of a restrictive arrangement, addressed in the Competition Law, is "partitioning markets for goods or services, and sharing or controlling all kinds of market resources or components."

The same provision regulates not only the partitioning of markets for goods or services but also sharing of any market resources or elements. For instance, partitioning of commodity markets or customers or geographical markets between undertakings may qualify as an act of partitioning market components.

And partitioning of sources of procurement occurs when undertakings collude to maintain control of channels, such as those of raw materials or semi-products, through which a product can be procured. For example, any instance of undertakings joining forces to control the entry of raw materials, or agreeing on carrying out production, distribution, or selling activities of products through specific undertakings is typical acts that constitute partitioning.

(B.1.e.3) Controlling supply and demand

The third restrictive act addressed in the Competition Law is "controlling the amount of supply or demand concerning goods or services, or determining them outside the market," which relates exclusively to lateral relations.

Economic science requires prices to form freely, depending on supply and demand dynamics in a free market.

Thus, any outside intervention in these factors will represent an intervention in the price and the functionality of free competition.

Therefore, from the perspective of Competition Rules, any exposure of supply and demand, and indirectly the price, to intervention by undertakings will constitute a clear violation of free competition in that market.

(B.1.e.4) Discriminatory practices

It is considered "discrimination" when multiple undertakings collude to apply different terms and conditions to persons of equal standing, for equal entitlements, obligations, and liabilities.

If an undertaking is not in a dominant position, such an undertaking may certainly make discriminatory practices through an individual decision; what is prohibited by the Competition Law is several undertakings' colluding to discriminate against persons of equal standing.

The Law concerns situations where multiple undertakings collude to artificially create differences in terms of competitive conditions for other undertakings with whom they engage in a commercial relationship.

(B.1.e.5) Demanding unusual obligations

It is considered a violation of the Competition Law when competitors collude against other undertakings whom they engage in a business relationship, in order to force them to purchase other goods or services alongside a specific product or service, against agreement and common commercial practice, or to make it a condition to showcase other products or services, for selling a product or service to a reseller which such reseller wishes to purchase or to impose conditions on the resale of supplied products or services.

(B.1.e.6) Human Resources Practices

In recent years, the Competition Board, which has evaluated the cases concerning labor markets, published a specific guideline on labor markets in 2024. The Guidelines emphasize that agreements among undertakings that restrict the transfer of employees, without justifiable reasons (e.g., "no-poach" "no-hire" or "no transfer" agreements), may result in anti-competitive consequences. Such agreements are regarded as restrictive to employees' career opportunities and may diminish competitive behavior regarding wage levels benefits.

B.2. Exchanging Information

B.2.a) Introduction

Information exchange is a most delicate matter under the Competition Law, right next to agreements, concerted practices and decisions, and practices of association of undertakings. In undertaking or planning their activities, undertakings are prohibited from sharing information that reduces or eliminates market uncertainties (especially related to the future) or which have or may have an impact on independent decision-making of undertakings, with implications detrimental to competition.

The main reason why competition authorities focus on information exchange is that such arrangements facilitate collusive conduct, by enabling monitoring of competitors' activities, between competing undertakings.

Information exchange between undertakings may take place mainly in two ways; in the first form, the exchange takes place directly between undertakings, while in the second form, information is collected by a central sectoral organization or a professional undertaking, and then distributed indirectly.

Information exchanged between undertakings may be individual or collective. Individual information means data relating to a single undertaking whose identity is specified or who is otherwise identifiable, and collective information means collective data on at least three undertakings. Data on only two undertakings and data exchanged through a system where, although the data relates to a larger number of undertakings, participants can extract data of individual undertakings is considered individual information.

Under the Competition Law, serious differences exist between cases of information exchange which are adjunct to prohibited activities, and situations where the exchange of information solely involves sharing of statistical data on a sector. Competition authorities prohibit and harshly penalize information exchange conducive to practices that disrupt competition,but they encourage exchanges for statistical purposes.

B.2.b) Exchange of information – Evaluation criteria

Under competition rules, the exchange of information depends on three major factors, namely, (1) market structure (2) content and qualification of the information exchanged, and (3) frequency of exchange of information.

We understand that competition authorities are not seriously opposed to the distribution of statistical information collected by professional organizations or research companies, even if they contain detailed information, to the extent such information is anonymized to exclude any possibility of identifying individual information of undertakings. However, exchange of individual information relating to undertakings' value creation or quantities or sales, price and discount terms and general terms of sale, delivery or payment, and particularly relating to the removal of future-oriented uncertainties is prohibited, as it involves elements and effects that may restrict or diminish competition in practice. In recent years, the dissemination of information regarding labor markets has been included within the category of sensitive data. Currently, it is regarded that information pertaining to employee wages, side benefits, or working conditions is considered "competition sensitive". The sharing of such data among enterprises may adversely impact competition and refrain employees from acting freely and exercising their autonomy.

In summary, when exchanging information, details on the relevant market structure, relevant product market, nature of the information, method of transfer of information, the time interval of the information (past, present, future), and with whom information is shared should be evaluated case-by-case.

C. Dominant Position and Abuse of Dominant Position

The Competition Law defines the dominant position as "the ability of an undertaking to prevent effective competition and determine price, supply, demand, distribution, and technological development in a market, without regard to its competitors and customers".

The Board designates the dominant position upon assessing the numeric size and market shares of the undertakings on the market. However, the outcome is considered as the initial phase in the designation of the dominant position. In many of its assessments, the Board cannot decide on the dominant position based solely on numeric data, and also explores whether undertakings have some qualitative powers defined as "market power" in the relevant product market.

In high market shares, it is presumed that undertakings hold a dominant position if these shares are generally above 50%, whereas, in lower market shares, some indicators are evaluated together to determine whether the undertaking is in a dominant position.

Furthermore, another comparison as important as the absolute market share is the relative market share. Market shares that enable undertakings to act in a substantially independent manner from their competitors, suppliers, and customers are regarded as sensitive in terms of competition legislation. In other words, undertakings that hold a substantial superiority over their competitors in terms of market share may be regarded to hold a dominant position upon consideration of other criteria even if their absolute market share is relatively low.

Although market share is the first consideration in determining whether a dominant position exists, it certainly is not the sole determinant. It should also be explored whether the undertaking possesses a certain degree of market power in the product market concerned.

Competition authorities take the following criteria into account in determining the market power:

- The ratio of their market share with that of the competitors, especially in the last 3 years,
- Although they have a higher market share, the ratio of their market share with that of the closest competitor,
- Competitive advantages preventing the competitors to gain market share; for instance, distinct technological advantages, brand superiority, financial superiority of group companies in case of affiliation with a group, wide penetration and superiority of distribution channels, variety of product range, and whether they are included in the distribution as well.
- Potential competitive environment in the market,
- Whether there is an entry barrier; privileges granted to industrial property right holders. Entry barriers may also originate from the market structure, such as availing of a certain technology, difficulties in accessing raw materials. Furthermore, competitors may also give rise to such barriers with their stance, such as in cases in customer retention efforts of the competitors and the requirement for high-budget advertisements.

Article 6 of the Competition Law prohibits not the dominant position but abuse of the dominant position. Following this general prohibitory statement, the Law provides a list of examples of major cases of "abuse".

Examples of practices that restrict competition, directly and indirectly, are presented below.

- Preventing market entry, and making it more difficult for competitors to operate,
- Discrimination,
- Conditional selling,
- Abusing a dominant position one has in a market, in another market,
- Limiting production, marketing, and technological development to the detriment of consumers,
- Refusing to supply goods or services,
- Applying unfair pricing,
- Applying discount systems, exclusivity – loyalty premiums, and other binding agreements.

Notably, the above examples resemble examples of agreements made among undertakings that are disruptive of competition, the difference being that it is now a single undertaking, rather than a group of undertakings, that enjoys a dominant position.

D. Implementation of the Competition Law by the Competition Board

D.1. Application of Exemption

The Competition Law authorizes the Competition Board to evaluate and grant exemption – whether on an individual basis, or through a notification – for a relationship where, although prohibited or may be prohibited under the general rule, the restriction in question is favorable to consumers, and for market and technological development.

D.1.a) Individual exemption

Individual exemption is granted by the Competition Board upon the request of concerned parties (the request is made using the "Negative Clearance / Exemption Notification Form") or upon a self-assessment of the Board, concerninga relationship which is restrictive of competition and fulfilling all the conditions required for granting exemption.

By a decision to grant individual exemption, the Board exempts a specific agreement, concerted practice, or decision for a penalty, which the Board has been notified on, or has otherwise become aware of.

With the granting of an exemption in this manner, invalidation, administrative fines, and compensation defined in Competition Law under the legal sanctions regime are no longer applied against the agreement, decision, or concerted practice for which an exemption had been granted.

Individual exemption decisions may be granted indefinitely or for a limited period.

D.1.b) Block exemption

In addition to individual exemption, the Competition Law also provides for block exemption, regulated with Notifications from the Competition Authority.

Agreements and/or decisions that meet the criteria of block exemption notification issued by the Board automatically enjoy exemption, without having to submit a specific notice to the Board.

Thereby, the system grants protection for these types of agreements from regulatory sanctions, including invalidation, compensation requirement, and administrative fines.

The Board avails of secondary legislation related specifically to the relations between some sectors and undertakings subject to a block exemption from the enforcement of the Law. Examples of block exemption notifications specific to the pharmaceutical industry include Vertical Agreements (distribution chain-agreements between wholesalers and pharmacies, etc.), Technology Transfer Agreements, Research and Development Agreements, and Specialization Agreements.

D.2. Structural Measures

Another crucial point introduced in Law No. 7246 amending the Competition Law is the arrangement entitling the Competition Board to adopt structural measures. The referred arrangement authorizes the Competition Board to adopt decisions on structural sanctions such as “transfer of partnership shares and/or assets” of undertakings. It is underlined in the Law that structural measures may be applied as a last resort, that the structural and behavioral measures should be proportional with the violation and be necessary to effectively terminate the violation.

D.3. Investigation Process

D.3.a) Directly launching of an investigation

The Competition Board may directly launch an investigation when it receives a notification or complaint regarding a situation disruptive of competition, or when it identifies a violation ex officio.

D.3.b) Preliminary investigation

The Competition Board may decide to directly launch an investigation or to undertake a preliminary investigation to determine whether the circumstances warrant launching an investigation.

If a decision is taken to conduct a preliminary investigation, a rapporteur is appointed to conduct the preliminary investigation, and to report his or her opinion to the Competition Board in writing together with all the information and evidence obtained and his/her views on this matter.

Following the submission of the preliminary investigation report, the Board convenes and evaluates the information submitted to decide whether launching an investigation is warranted.

D.3.c) Investigation procedure

When a decision is taken to launch an investigation, the Board appoints the rapporteur(s) who will conduct the investigation under the supervision of the relevant department head. An investigation must be completed within six months. Where necessary, the Board may grant an additional six-month extension for one time only.

The Competition Law grants the investigation subject the right to submit three written and one oral statement of defense. The clock on the first written defense statement starts when the Board sends the relevant parties a notification, attached with sufficient information on the type and nature of the allegations.

D.3.d) Commitment and reconciliation

Relevant undertaking or association of undertakings may provide a commitment during an ongoing preliminary investigation or investigation procedure for the settlement of competition issues. Should the Board be convinced that violation may be remedied via commitment, a decision may be adopted for not initiating an investigation or terminating an investigation that has been initiated based on the commitments submitted. It is not possible to submit a commitment for any kind of violation; no commitment can be submitted for severe commitments such as cartel structures, price-fixing between competitors, regional or customer partitioning, or restricting the amount of supply.

Likewise, after initiation of an investigation, the Board may choose upon the request of relevant parties or based on its own accord to reach an agreement with the undertaking or union of undertakings that accepted the presence and scope of the violation for achieving procedural economy. In case of termination of an investigation by agreement, a discount of up to 25% may be applied on the applicable administrative fine.

D.3.e) Information request

In fulfilling its mandate under the Competition Law, the Board may require any public agency or institution and private undertaking or union of undertakings to submit information needed by the Board. Undertakings are required to present the Board with the requested information within the prescribed deadline. Otherwise, the Board is entitled to impose an administrative fine for every day of delay based on the turnover of the undertaking.

D.3.f) On-site audits

On-site Auditing Authorization of the Competition Board
According to Article 15 of the Competition Law, in fulfilling its mandate the Competition Board is authorized to perform "on-site audits" when it deems necessary.

Under this mandate vested in the Board by the Competition Law, experts and assistant experts appointed by the Competition Authority (hereinafter referred to as "Experts") may conduct on-site audits in connection with:

- A preliminary investigation, or
- An investigation, launched by the Competition Board.

To perform an on-site audit, Experts may visit:

- Undertakings, or
- Associations of undertakings.

Experts may:

- Review any written papers and documents of undertakings or association of undertakings, and take their copies, where necessary,
- Require them to provide a written or oral clarification on specific matters, or
- Visit any physical premises of undertakings to audit their assets, including any virtual media where data and information are stored (computers, external disks, servers, etc.), and take their copies and physical samples.

The arrangement introduced with the "Guideline Regarding Inspection of Digital Data in On-site Audits", published within the scope of the amendment made in 2020 in the Law, authorizes the experts of the Authority to conduct a digital inspection on the information systems of the undertaking containing any kind of data, such as servers, desktops/laptops, and portable devices, storage devices such as CDs, DVDs, USB sticks, external hard disks, backup records, and cloud services as well as any kind of portable communication devices (mobile phones, tablets, etc.). It is stipulated that the experts of the Authority may benefit from digital forensics software and hardware enabling the conduct of a qualified search in the digital data during such inspections.

D.3.g) Administrative fine

The ability to enforce the Competition Law for ensuring competition requires the adoption of an acceptable sanction system. Such sanctions should deter undertakings from restricting competition or not complying with the mandates of the Competition Board. Hence, administrative fines related to the agreements and practices violating the Law *in limine* and limiting competition and behavior violating the Law in form have been introduced.

The fines are lower for procedural crimes and at higher for fundamental crimes and their code of practice is governed with the Regulation on the Fines to be Charged in Case of Competition-Restricting Agreements, Concerted Actions and Decisions, and Abuse of Dominant Position.

In addition to adopting behavioral and structural measures, the Competition Board may impose a fine of up to 10% of the turnover of the undertakings in case they are involved in violations qualified as severe violations such as competition-restricting agreements, decisions, or concerted behavior or abuse of the dominant position.

However, legal arrangements have been introduced for preventing undertakings subject to a cartel from being fined. The most important reason for introducing such an arrangement was that cartels, regarded as a most severe type of violation, are composed in consequence to a secret agreement and may be unveiled with extreme difficulty. Therefore, the Competition Board introduced the Regulation on the Active Cooperation for Detecting Cartels, to encourage denouncement of this severe violation. Within the scope of the referred regulation, those that submit an application of repentance and denounce a cartel may be exempt from being subject to administrative fines.

IV. Corporate Structure and Operations

As of 2021, AIFD is operating via the following committees and working groups.

All groups and committees operating within AIFD fully recognize the importance of complying with the competition rules and are obliged to act according to these rules.

As the said groups and committees operate within and work for AIFD, their work and the content they create may in any case undergo revision by AIFD.

AIFD will ensure the following:

- In case of a change of role in the committees, AIFD monitors that the new job descriptions and practices are compliant with competition rules.
- In case of the formation of new committees, AIFD ensures that the duties and practices of these committees are compliant with competition rules.

The following groups and committees are currently operational within AIFD:

- Board of Directors and General Managers Meetings
- Strategic Management Committees
- Specialist Committees
- Working Groups

The duties of the Board of Directors are composed of the components specified in the Charter of the Association. For instance, the Board of Directors, that is the second-most authorized board after the General Assembly, agrees not to take up and discuss topics of a sensitive nature for competition rules.

The chairs or specifically appointed members in other committees and groups are responsible for ensuring compliance with the competition rules.

V. Competitive Relations

A. Internal Governance and Relations with Members

Associations hold a special position in terms of competition rules as they bring together competing undertakings. AIFD acts in line with its purpose and vision in its activities and strives to ensure compliance with competition rules to the greatest extent possible.

Relations with members constitute an important part of the practices that are based on this essential principle.

As regards compliance with Competition Rules, relations with member companies can be classified under three main headings:

- Admission and dismissal
- Exchange of information
- Concerted acts

Under no circumstances may the conduct of an association be non-compliant with the rules in performing any of the above functions. Otherwise, it may expect to face accusations and penalties if a violation is established.

Main rules to be considered for in the relations with members:

- Every member must maintain its independence, particularly on commercial matters, and independently take commercial decisions, as competition rules require them to make their decisions as independent entities.
- Internal competitive behavior within the association can be discussed under two main headings:
  - Non-commercial Matters: Examples of non-commercial matters include issues that do not directly impact on dynamics of competition, such as technical regulations or standards. In so far as it remains at a technical level and excludes any information on competitors, such discussions are unlikely to trigger any competitive sensitivities. However, it may not be possible to categorize every specific issue, in which case legal advice must be consulted.
  - Commercial Matters: Under no circumstances should commercial matters be discussed among competitors (association members). However, since the pharmaceutical industry is regulated by law, there may be cases where a government agency directly asks for disclosure of opinion on a commercial matter. In that case, it must be ensured that any action taken is guided by appropriate legal advice.

B. Relations with Other Associations

By virtue of its position, AIFD is in contact with other sectoral organizations. The lateral engagements include other associations or unions representing undertakings that may qualify as a competitor, and the vertical engagements includes unions representing distributors of goods or services.

These engagements include, often with the involvement of government agencies, discussion of government regulations and/or forming of and contributing to a position, and exchanges on the current situation of the sector or potential future concerns.

AIFD is aware that it should avoid any conduct which may violate any rules governing relations with competitors, or which may constitute a prohibited act under the Competition Law. To outline, the following types of relations with other associations must be avoided, on both the horizontal and vertical plane. Especially concerning its relations with other associations and/or unions representing the industry:

- Any communication which may be construed as a direct or indirect fixing of prices (or data and information containing commercial components) should be avoided,
- Information considered commercial and strategic should not be shared,
- Topics such as prices, cost components (payment terms, discounts, bonuses, free goods, etc.), commercial terms, production, stocks, partitioning of regions or products, or exclusion of specific competitors should not be discussed,
- Participating in tenders or boycotts, or similar actions and behavior should be avoided,
- Appropriate legal advice must be consulted for any projects involving a joint transaction of purchase, sale, or commercialization.

Particular care must be taken when forming an opinion through meetings with other, potentially competing associations operating in the lateral plane, ensuring always that any correspondence with such associations remains within the confines of the competition rules.

C. Relations with Service Providers

An association may purchase services from several providers to achieve its vision and mission. However, the association must remain within the confines of the competition rules when receiving services and in the output generated.

For AIFD, there are two types of particularly important service providers. The first type is vendors who collect information and data from the market on AIFD members and commercialize such information. The activities of these types of vendors are important from

a competitive perspective, since in some cases the information compiled may include commercial or non-commercial information of competitors.

While the responsibility for how a vendor collects and uses or distributes such sensitive information and data primarily rests with the vendor, AIFD should nevertheless take account of the following considerations when dealing with such vendors.

- AIFD should never and under no circumstances have any role in the distribution or sharing of data collected by such vendors,
- AIFD may purchase data/information from such vendors to achieve its purpose and vision, provided such information includes no individual company details. In some circumstances, the referred data may contain individual company data related to the members. In case of the presence of data including such details, AIFD provides legal clarity on whether to collect such information in the first place, retain them at the association, or whether to use them and does not share such information with its members in any form or under any condition.

The second type is vendors are generally those who prepare opinions and proposals from whom AIFD purchases consultancy services. These vendors usually support AIFD on benchmarking, ideation and content development, and strategy development. AIFD should take into account the following considerations in anypurchase of services from these vendors:

- The scope of the services procured must be specified clearly and explicitly, and this scope should be observed,
- Only public information of members must be shared during relations with those entities,
- When it becomes necessary to disclose nonpublic information, legal advice must be sought, and how this information will be used and where it will be stored should be clarified.
- If the information must be published, first it should be ensured that nonpublic information is collected and stored by third parties and that any data to be published should be sufficient solely to provide a general picture of the issue in question, never including any data on individual members upon being anonymized and/or masked.

D. Relations with Government Agencies

The pharmaceutical industry operates in an environment where relations with government agencies carry utmost importance under a structure established and regulated by the government. The government uses its regulatory power to closely supervise both sectoral activities and most competitive dynamics and leverages its position as the largest buyer and consumer of goods and services when negotiating with the pharmaceutical sector.

From a regulatory perspective, AIFD conducts its relations with the state based on cooperation, giving its opinion, where appropriate, regarding the regulations the government has put into force or intends to do so. And developing such opinions may involve collecting data and information from member companies. In such cases, AIFD is aware of the importance of observe competition rules and shares the importance of compliance with these rules at every phase with the stakeholders in the industry.

Considering that many competitive dynamics are controlled and regulated by the government, it should be considered natural for AIFD to engage in some lobbying activities on these issues. AIFD is aware that competition rules are applicable also when conducting lobbying activities.

Any decision and/or stance taken against government control of competitive dynamics must be compliant with the competition rules.

- The opinion of AIFD is of an advisory nature under any circumstance whatsoever. AIFD does not take any action aimed at influencing the decisions of its members.
- Member companies are independent in their decisions and actions; in case the decisions of member companies deviate from the views of AIFD, AIFD may not question the reason or impose any sanctions on its members,
- When the association and its member companies happen to agree on a specific matter regarding relations with the government, AIFD receives legal advice and acts in line with competition rules.

VI. Conclusion

It is very important to ensure that the Competition Rules and the practices of the Competition Board are properly understood by all businesses operating in Turkey and that the mindset laid down in the Competition Law is communicated to both undertakings and association of undertakings.

AIFD Competition Rules Guideline is intended for providing guidance. AIFD will continue to operate with due prudence and respect for all applicable laws to ensure compliance with the competition rules. Hence, the staff, management, and member companies are unquestionably resolved to implement the competition rules.

AIFD Competition Rules Guideline lays down essential information on competition rules and practices using basic and comprehensible language to aid both AIFD and its members in their efforts to harmonize their business practices and culture with the competition rules and practices.

It is a fact that the Competition Rules Guideline is not exhaustive, and thus AIFD is aware that the advice of an expert in Competition Law should be sought at any phase of indecision/dilemma, and that ambiguous practices should not be implemented under any circumstance.

We hope that the points discussed in AIFD Competition Rules Guideline may be internalized and serve as a model for both our members and sector stakeholders for the benefit of the pharmaceutical industry.