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**ANNEX TO THE SUMMARY RECORD OF THE 121st MEETING OF THE COMPETITION
COMMITTEE HELD ON 18-19 JUNE 2014**

-- Executive Summary of the Discussion on Competition and Generic Pharmaceuticals --

This Executive Summary by the OECD Secretariat contains the key findings from the discussion held during the 121st meeting of the OECD Competition Committee on 18-19 June 2014.

*More documents related to this discussion can be found at
www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm*

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EXECUTIVE SUMMARY

*By the Secretariat**

Considering the roundtable discussion and the delegates' written contributions, the following key points emerge:

- (1) ***The existence of originator drugs and innovation by originator companies is vital to develop new treatments against different illnesses and diseases. Following originator innovation, generic substitutes increase competition and result in lower drug prices, which contribute to the reduction of public healthcare expenditure. That is why governments often use a variety of tools to promote generic competition. However, certain regulatory measures may have restrictive effects and should be reformed to promote originator-generic drug competition.***

The pharmaceutical industry is an innovative, high-technology and I.P.-sensitive industry that is essential to public healthcare. Originator pharmaceutical companies play an important role by innovating and developing new or more effective treatments. Originators usually count on patent protection to ensure some return on their investments in R&D. At the same time, it is widely recognised that entry by generic pharmaceutical companies enhances competition in the drug markets, driving prices down to the benefit of consumers and governments.

In many countries, prescribed medicines (both originator and generic ones) are to a large extent reimbursed by the public health system. Medicines therefore weigh on the public budget, which is why governments may intervene in the competition process in order to favour cheaper generic substitutes. The level of penetration of generic pharmaceuticals varies substantively across countries, ranging from countries where it is already high to countries where it is still rather low.

The discussion addressed various forms of government intervention and regulations affecting competition between originator and generic drug companies: while some interventions have in fact promoted entry by generic drug companies, others have hindered the competition process and led to a high(er) ratio of originator drug consumption.

Government measures and regulations reported by delegates to enhance originator-generic competition include the following:

- ***Reimbursement procedures.*** Various countries have eased the administrative procedures for the market entry and reimbursement of generics. In many countries, prescription drugs are reimbursable if they are included on a specific medicine list. So one tool to promote generic competition is to make the listing of generic drugs easier. In some countries conditions are much stringer for originator drugs to be listed and reimbursed than for generic drugs, leading to a very high penetration and consumption of generic pharmaceuticals.

* This Executive Summary does not necessarily represent the consensus view of the Competition Committee. It does, however, encapsulate key points from the discussion at the roundtable, the delegates' written submissions, and the Secretariat's background paper.

- *Ingredient-based substitution.* Generic substitution can be promoted through measures at the prescription and/or delivery levels. Various governments require that doctors prescribe medicines on International Non-proprietary Name (that is a collective name for pharmaceuticals containing the same active substance, thus considered to be substitutes) instead of the brand name. Such measures are particularly relevant where pharmacists have to strictly follow the prescriptions. In other countries, pharmacists have been allowed or even required to provide the cheapest version of any prescribed drug – unless substitution is explicitly excluded by the doctor on the prescription.
- *Compulsory licensing.* There is wide recognition of the importance for governments to address public health needs. Countries that face pressing public health situations, e.g. some developing countries may at times consider compelling an originator company to license its patent rights to a generic drug maker. Compulsory licencing provides consumers with earlier and affordable medicine in countries in which a necessary originator drug is not available at an affordable price. At the same time, forcing early generic entry may create uncertainty and disincentives to innovate on the part of originator firms, so these measures should be applied with particular caution.

Other government measures and regulations have had the adverse effect of restricting competition, by raising barriers to entry by generic drug manufacturers:

- *Registration process.* The registration process for market authorisation of generic pharmaceuticals usually require less data, and it is therefore faster and easier than the registration of original medicines. Some jurisdictions, however, do not recognise clinical tests carried out abroad; nor do they admit generic drug applicants to refer to the results of clinical studies carried out for the original medicines. These limitations result in significant delays in the registration process and market entry of new generic drugs.
- *Substitute limitation.* In some countries, the list of authorised generic pharmaceuticals is restrictive and may raise barriers to entry. Where pharmacists are allowed to replace the originator drug with the generic substitute, substitution options are limited if they can only choose from a restrictive list, although other generic substitutes may exist. Such lists may also reduce doctors' and consumers' awareness of the range of available substitutes. In some countries the generics list does not include some frequently used medicines, such as paracetamol and aspirin-based medicines. This contrasts with countries where the lists of authorised generic drugs are more extensive.

Looking ahead, bio-similar medicines may also represent a major competitive pressure in the pharmaceutical sector in respect of biological drugs. Biological drugs are a fast growing industry branch. They are more complex and usually more expensive than the small chemically synthesised molecules, that form the basis of originator drugs and their generic substitutes. Competition authorities have voiced concerns regarding regulations that may restrict bio-similar entry and competition against reference biologic drugs. Such regulations consist notably in restricting the principle of substitutability or therapeutic equivalence of bio-similars, or disproportionate authorisation and registration conditions.

Competition authorities across jurisdictions shall use advocacy to raise the attention of other parts of government on the possible anti-competitive effects of certain measures regulating the pharmaceutical industry. In addition to raising awareness, competition authorities should urge the adoption of regulatory reforms that would eliminate barriers and obstacles to competition in the sector. Experience in some jurisdictions reveal that competition authorities sometimes face resistance from health authorities, despite the substantial public savings that generic drugs may

generate. Competition authorities' co-operation with other agencies (e.g. IP agencies or health authorities) could also provide useful synergies towards effective competition enforcement and advocacy in the pharmaceutical sector.

- (2) ***Competition enforcement plays an important role in preserving and promoting competition to stimulate innovation and reduce prices in pharmaceutical markets. Entry by generic drug companies does not only reduce prices of existing medicines, it also stimulates originator companies to innovate and develop new drugs. The pharmaceutical industry features a number of characteristics that are worthwhile bearing in mind when assessing the conducts of pharmaceutical companies.***

The following industry features are worthwhile bearing in mind in assessing pharmaceutical companies' behaviours:

- Regarding the price effects of generic entry, empirical studies show that the price of pharmaceuticals falls moderately upon entry by one generic competitor, and dramatically upon entry by more than one competitor. It generates an obvious incentive for originator companies to try to restrict generic entry in order to keep maximising their profits.
- Assessing the quantitative effects of pharmaceutical companies' strategies is important, too. For most consumer goods, quantities generally rise where prices fall, but this may not be true for pharmaceuticals. Pharmaceuticals are highly regulated products, the principal drug purchaser is the government, and the level of medicine consumption is to a large extent determined by doctors' prescription based on medical conditions. This raises the question as to whether a competition authority should address higher prices for a prolonged period where they might not have appreciable quantitative effects on consumer welfare.
- The pharmaceutical industry heavily relies on patents, which guarantee profits and returns on R&D investments for the originator companies. While the patent holder enjoys a monopolistic power over its patent, that does not necessarily mean market power. In assessing relevant pharmaceutical markets, competition authorities should also consider the heavily regulated environment in which drug makers operate and the fact that switching from a product to another is rarely decided by consumers, rather by doctors and governments.
- Experts have also pointed to the absence of a unified patent enforcement system, and to the difficulty, in many jurisdictions, for originator companies to get adequate compensation for the loss they incur from generic drug companies infringing on their valid patents. Certain practices adopted by originator companies call in question the effectiveness of IP law enforcement mechanisms and the relevance of competition law enforcement in this context.

- (3) ***Antitrust cases against unilateral conducts reveal that originator companies can adopt diverse and creative strategies to delay or prevent generic entry. Such strategies include misuses of the patent system (e.g. ever-greening or patent clustering), spreading misleading information, inducing product switching and refusal to licence an essential patent. Competition enforcement in this context is essential, but it also seems to be sometimes compensating for the failures of the IP and regulatory systems.***

Competition authorities and experts have addressed a variety of strategies adopted by originator companies to exclude or delay generic drug competition, such as product hopping, patenting tactics, disinformation tactics, and refusal to give access to essential patents.

Product switching. Product switching cases have proliferated during the last years. At first sight, product switching may seem good as it involves bringing into the market a new, likely more advanced or improved version of an existing drug. This practice starts raising concerns if the new version of the originator drug enjoys stronger, longer lasting patent protection, whereas the older originator drug will soon go off-patent. This may provide an incentive for the originator company to induce a switch by doctors and patients from the original drug to the new one. Such product switch may be induced by the originator company through e.g. promoting the new drug differentially, raising the relative price of the old drug, or withdrawing the old drug from the market. Competition enforcers face the challenge of drawing a line between beneficial innovation and switching strategies that would harm consumers. Recent decisions have found that product hopping amounted to an antitrust violation when the older product was withdrawn from the market. Pharmaceutical companies question, however, how they can keep innovating and improving their products without facing the risk of antitrust enforcement.

Patenting tactics. Ever-greening and patent clustering are two types of patenting tactics raising antitrust concerns. Ever-greening refers to an originator company introducing minor changes to its soon-off-patent medicine (e.g. a slightly different composition) in order to obtain additional or a divisional patent protection, and thereby delay or deter generic entry. Abuse cases establish that seeking additional protection, such as a divisional patent or supplementary protection certificate, is abusive where the sole purpose was to delay generic entry without bringing any new product or development on the market. The question was debated as to whether seeking a divisional patent required that a new or revised product be introduced. Patent clustering (i.e. when an originator company obtains multiple patents covering various aspects of the same product) makes it difficult for potential generic competitors to know for which part of the product and when market entry is possible. As reported by experts, the number of listed patents per drug has increased significantly over the last decades, and most of these patents are not active ingredient patents, but secondary patents.

Caution is required when dealing with the inherent conflicts between competition law and IP rights. It was questioned, in the context of patenting tactics, whether antitrust enforcement is warranted in the use of the regulatory process by companies. Some would rather call for the revision of the patent regulations that allow pharmaceutical companies to obtain patents in such circumstances.

Disinformation tactics. Pharmaceutical companies sometimes intentionally provide false or misleading information to regulators (such as IP agencies), drug providers (hospitals, doctors, pharmacists) or consumers in order to hinder competition or entry of generic substitutes. Disinformation can prove anti-competitive where a pharmaceutical company did not own the patent it claimed, in order to obtain a preliminary injunction against a generic drug competitor. Originator companies can also mislead doctors regarding the quality, efficiency or side-effects of their drugs as opposed to the generic version, to influence doctors' decision and induce them to deny generic substitution. Competition authorities have established that disinformation is anti-competitive where doctors are not knowledgeable enough about medicines to make an independent decision. Others found that there was no competition infringement where doctors had sufficient knowledge and where it was not clear whether the disinformation tactic actually influenced their decisions.

Essential patents. Antitrust claims by generic drug challengers against the refusal by an originator company to license its patent, have generated controversy and important questions: What is an 'essential' patent? Under what conditions does an originator company's refusal amount to an abuse? Who should be entitled to be a licensee? Should refusals rather be addressed through regulatory intervention when it is a matter of public health?

Consumer welfare requires not only cheaper drugs, but also newer and better pharmaceuticals. It is also thanks to the pre-existence of originator drugs that generic substitutes can be developed. The main goal and challenge is therefore to strike the right balance between maintaining high incentives for innovation while promoting the benefits of generic competition. Most abuse cases trigger ‘borderline’ questions pertaining to IP law enforcement, competition law enforcement and/or regulatory intervention. Competition enforcement appears sometimes to be compensating for the failures of the IP or regulatory systems. Competition authorities should therefore cooperate with regulators and their advocacy efforts should be encouraged where competition cases reveal that reforms are needed.

- (4) *Pay-for-delay agreements have attracted increasing antitrust attention around the world. Action has been taken against such agreements where the originator would obtain from the generic drug competitor to delay entry to the detriment of consumers. In addressing pay-for-delay, competition enforcers face key questions pertaining to the applicable legal test, to whether the nature of the patent (i.e. the level of innovation) and the nature and size of payment are relevant in assessing the competition harm.*

Pay-for-delay settlements, a.k.a. reverse payment agreements, have captured increased antitrust attention, and competition enforcement actions have been taken on both sides of the Atlantic. Pay-for-delay settlements consist of agreements whereby the originator manufacturer tries to avoid the risk of early generic entry by paying a generic drug company for -delaying the launch of its generic version.

Competition concerns arise where both the originator and generic drug manufacturers benefit from delaying generic entry to the detriment of consumers - that is when the originator company shares its patent revenue with the generic challenger while preventing customers from early access to cheaper generics.

Pay-for-delay agreements have raised a number of debated questions:

- What theory of harm and legal test apply to pay-for-delay: How to distinguish between originator-generic agreements that restrict competition and the ones that may be lawful? Is pay-for-delay restrictive by object, per se, by effect, subject to the rule of reason, or based on other tests or presumptions?
- What sort of “payment” is problematic: Does the nature of the payment matter: cash or other types of advantages or value transfers? Does the size of the payment matter?
- What “delay” is problematic: Where entry is delayed beyond the validity period of the patent or beyond the likely end date of the patent litigation?
- Is pay-for-delay relevant and worrying only in the context of a patent litigation? Is the likely outcome of the patent litigation relevant?
- Is the nature or strength of the originator’s patent relevant? Does competition enforcement against pay-for-delay invalidate a patent at stake?

Pay-for-delay occurs where a generic drug company has entered, or threatens to enter the market, while the patent on the originator drug has not expired. This may lead to various types of litigations: e.g. the originator suing the generic company for patent violation (seeking an injunction and compensatory damages) or the generic drug company challenging the validity of

the originator patent in court (seeking to secure its early entry). To avoid the risk of early competition, patent invalidation, or costly and lengthy litigation, the originator company may reach a settlement with the generic challenger. How much the originator would pay, and how long the delay would be for, depend on the bargaining power of the parties and the likely outcome of the litigation they are trying to avoid. Expert statistics show that the strength of the patent plays an important role in the outcome of the litigation: the originator company wins in most cases involving a strong patent, i.e. a primary patent on the active ingredient, whereas the generic challenger is more likely to succeed in case of a weak or secondary patent at stake (e.g. on the formulation or process). Statistics further reveal that most pay-for-delay agreements relate to secondary patents. Competition concerns generally arise if the payment by the originator company delays generic entry later than it would otherwise be.

The regulatory environment – especially IP laws and enforcement mechanisms - also plays a role in pharmaceutical companies' decision to enter into reverse payment agreements. Major differences in the regulatory systems of the EU and the US were identified: in Europe, the IP litigation and enforcement system is highly fragmented and often requires costly and complex patent litigations in multiple jurisdictions. There is limited availability of effective preliminary injunction in the EU, and originator companies virtually never receive adequate compensation for the loss resulting from unlawful generic entry. Also once an originator drug with a valid patent has faced generic entry (even if invalidated), the originator price would rarely reach its initial level back; this drawback may also have a spill-over effect across jurisdictions. This was referred to as 'irreparable harm' by the business and experts. There was a general agreement on the necessity of a unified European patent litigation court to eliminate the current pitfalls. It remains unclear, however, whether and how antitrust enforcement and legal standards take these regulatory burdens into account in assessing originator-generic agreements.

Pay-for-delay has so far been approached as a restrictive horizontal agreement. It remains to be seen whether such agreements could also be caught under abuse of dominance rules, or under merger control. The latter may be particularly relevant where the payment takes place through co-operation or joint activities.

Originator-generic competition can also be hampered by other types of restrictive agreements: competition authorities reported antitrust actions taken against trade association decisions and against horizontal agreements among generic manufacturers, which restricted competition and raised generic drug prices collectively.