European Federation of Pharmaceutical Industries and Associations

Response to the European Commission's public consultation on evaluation of procedural and jurisdictional aspects of EU merger control

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The European Federation of Pharmaceutical Industries and Associations (EFPIA) brings together 33 European national pharmaceutical industry associations as well as 41 leading companies undertaking research, development and the manufacture in Europe of medicinal products for human use.

EFPIA is pleased to contribute to the European Commission's public consultation on evaluation of procedural and jurisdictional aspects of EU merger control. EFPIA will focus on those aspects specifically affecting the pharmaceutical sector, namely a potential new complementary jurisdictional threshold based on the value of the transaction.

1. Executive Summary

EFPIA understands that the Commission is contemplating a new threshold for pharmaceutical transactions[1] that would trigger notification if:

(1) the global deal value (sales price) exceeds a given monetary threshold;

(2) one party generates revenue in the EU of at least €250 million;

(3) the ratio between the price of the target and the target's worldwide revenue exceeds a certain ratio yet to be determined; and

(4) an EU nexus test is satisfied such as, for example, the target having a product that is in late stage approval processes somewhere in the EU.

Before any changes are made to the current framework, EFPIA urges the Commission to undertake a robust empirical analysis to quantify the need for an additional threshold in light of potential theories of harm assessed against the specific regulatory framework that shapes the pharmaceutical sector and limits individual companies' freedom of action.

There is a real risk that any additional threshold will capture too many non-problematic deals, causing undue delays to investments in innovation capable of improving the lives of patients. This

[1] As per the discussion between an EFPIA delegation and the case team at a meeting on 13 December 2016.

would create significant and unnecessary transaction costs and administrative burden for little added benefit (potentially in violation of the fundamental principle of proportionality set out in Article 5 of the Treaty on the European Union).

The Commission should also consider the international spillover effects of other competition authorities) following suit. If regulators in other jurisdictions similarly added requirements for review based on transactional value, delays could multiply and potentially inhibit needed medicines being developed.

If the Commission nonetheless determines that there is a significant enforcement gap that merits an additional threshold, EFPIA submits that:

- a transaction value threshold would in any event not cover pure pipeline acquisitions since such transactions do not qualify as "concentrations" under the Merger Regulation (defined in the Consolidated Jurisdictional Notice as an acquisition of control over assets which "*constitute whole or a part of an undertaking, i.e. business with a market presence, to which a market turnover can be clearly attributed*");

- transaction value thresholds are unsuitable for determining whether a given transaction will have an impact on a specific jurisdiction - in any event, the value threshold should be materially higher than the €400 million in the new German merger control law to ensure that EU review is reserved for sufficiently large transactions that are likely to have a sufficient effect on the conditions of competition within the single market;

- a ratio threshold will always be triggered where the target generates little if any revenue (zero revenue will be equated to €1): coupled with an insufficiently high value threshold, this casts the net much too wide;

- a robust local nexus test will be an essential filter: it should be clear, precise and draw a bright line test for when the EU Merger Regulation is applicable so that the Commission does not review transactions outside of its jurisdiction – submission of a marketing authorisation application in more than one EU Member State would be an appropriate standard;

- a truly simplified procedure beyond what is available today (no pre-notification discussions or other undue delays) should be made available to avoid undue hold up absent a clearly articulated theory of harm in any given case that would justify a closer look.

In sum, EFPIA urges the Commission not to pursue a value-based threshold on the basis that there is no identified enforcement gap. The current rules are sufficient and the referral rules are an adequate safeguard.

2. The current system works well

The Commission asks whether EFPIA has encountered significant transactions in the pharmaceutical industry in the past five years that have had a cross-border effect in the EEA but that were not captured by the current revenue thresholds. An example cited is the 2015 USD 21bn acquisition of Pharmacyclics by AbbVie.

The acquisition of Pharmacyclics by AbbVie is in fact not a relevant example of a "pipeline acquisition" which would fall below a pure turnover threshold: indeed, Pharmacyclics' product (Imbruvica) had already been approved in the U.S. for certain indications by February 2014, and was also further approved in nearly 50 other countries at the time the transaction closed. Similarly, Shire's acquisition of Dyax was notified to the US agencies and granted early termination of the HSR waiting period which clearly indicates that this transaction raised no issues whatsoever and does not reflect any "gap". Hence, neither transaction revealed any potential restrictions to competition falling beyond the reach of the Commission and cannot serve as an illustration that there is a "gap to be filled".

In the USA where a value threshold has been in place for many years, it would seem that very few transactions in the pharmaceutical area have led to substantial objections from the Federal Trade Commission (in particular the *Pharmacyclics/AbbVie* transaction was cleared without commitments).

The current thresholds seem to have worked well in terms of capturing relevant transactions as well as delineating EU versus national review. Any EU reform should be based on a critical mass of cases in relation to which there is empirical evidence of a failure to prevent competitive harm. EFPIA is not aware of any indications that this may indeed be the case.

The Commission's investigation into the *Facebook/WhatsApp* acquisition demonstrates the absence of any gap in the system due to existing referral mechanisms. And the availability and appropriateness of the Commission's enforcement powers under Articles 101 and 102 of the EU Treaty act as a final net if one were needed.

Where there is an overlap that is part of a larger transaction involving both marketed and pipeline products (which is more often the case than not), the Commission has been able to address any potential concerns under the current thresholds as was the case in *GSK/Novartis (oncology)*. Similarly, Pfizer's acquisition of Hospira was reviewed because both companies have multiple products on the market which generate revenue and could have created a market impact.

With respect to the pharmaceutical industry, the proposed deal value threshold is presumably mainly aimed at capturing acquisitions by established players of highly valued biotech companies that own products under development that have not yet been marketed and therefore do not generate turnover (and *a fortiori* no significant turnover). In fact, many of the products under development, especially early stage products, may not reach the market at all due to scientific factors such as lack of efficacy or safety concerns. Thus to place any significant weight on these early stage products would be inappropriate.

The mere fact that pharmaceutical companies are willing to pay a high price to acquire the "chance" of bringing a product to market (despite the high failure risk associated to them) does not mean that the acquisition of pipeline assets should be treated as "market presence" or as "turnover".[2]

[2] Should capturing these transactions be the ultimate objective of the envisaged reform, then the first key hurdle the Commission would meet is that such transactions do not qualify as "concentrations" to start with (a fact that will be unaffected by merely changing the notification threshold). Indeed, it is clear from the Consolidated Jurisdictional Notice that the Merger Regulation applies to acquisition of control over assets which "*constitute the whole or a part of an undertaking, i.e. business with a* ***market presence****, to which a market* ***turnover can be clearly attributed***".

Contrary to certain new industries, the R&D based pharmaceutical industry has been subject to EU merger control since its inception and has not dramatically changed. Furthermore, EFPIA submits that there is no detection gap in relation to the pharmaceutical sector. Smaller or "pipeline" deals are generally announced in the press and information about the status of companies' research pipelines (be it biotechs or multinationals) are both public and detailed.

It should not be forgotten that the application of EU Member State merger rules apply and may capture transactions where the target has little revenue in Europe. Referral mechanisms remain in place to allow upward referral to the Commission either at the request of the parties or by national authorities in consultation with the Commission should potential concerns arise.

Finally, if a transaction is not subject to prior clearance by any antitrust authority in the EEA, the transaction will remain subject to potential *ex post* scrutiny under Articles 101 and 102 TFEU and/or the equivalent national provisions.

Given the difficulties in crafting a jurisdictional test that does not capture too many unproblematic transactions in the pharmaceutical sector, EFPIA suggests the Commission assess any potential theories of harm in the light of the real world regulatory and economic environment in which the EU pharmaceutical industry operates today. We are convinced that such an assessment will come to the conclusion that there is no genuine risk of harm to competition or to consumers justifying a new value-based threshold.

3. Which theories of harm justify more intervention?

EFPIA understands that the Commission is considering the following theories of harm:

1. dampening of innovation: the risk that the acquirer will discontinue the research and development or that an overlapping pipeline product will be taken out of the market;

2. dampening of price competition: the risk that more concentration in the hands of one company could confer market power and increase prices.

3.1 Dampening of innovation: this theory is unfounded

No single pharmaceutical company has such a rich pipeline that it would be prepared to pay a high price to simply take a potential competitor off the market (or halt its own promising research lines) in order to reduce competition in innovation. Buying off one potential competitor will not protect against competition from others. In addition, we fail to see how any pharmaceutical company could arbitrate between the two and bet on which is most likely to come to market.

Nor is it practically feasible to simply stop a promising line of research in the absence of robust scientific and cost concerns after an acquisition. Doctors conducting the research publish their studies, patient organisations are becoming very active in monitoring ongoing clinical studies, and independent data monitoring committees determine whether to stop a study on scientific grounds. To stop R&D for anti-competitive reasons would be noticed by specialists and patient groups and would generate complaints and significant negative publicity.

If the purchaser already has a competing product on the market, it will likely be facing the threat of generic competition to its existing product (given the average 10 years of exclusivity available once a

product is on the market) before the pipeline product reaches the market (if it ever does). It will have every incentive to ensure its investment in a promising innovative product is successful, not only to refresh its product portfolio but also to utilise the expertise and resources already developed in the relevant therapeutic area in order to ensure an effective and quick uptake of the new medicine.

The high risk of failure associated with pharmaceutical R&D and the increasingly differentiated needs of subsets of patients mean that companies pursue many R&D pilots in any given therapeutic area. It is common to have multiple targets in phase I-II development. Companies will continue R&D as long as a compound is likely to bring a benefit over and above existing therapies to a set of patients. The advance of personalised medicine will increase further the variety of individual products a pharmaceutical company will need to bring to market in order to serve its patients' needs.

A healthy R&D pipeline is critical to the success of any pharmaceutical company, a factor that is clearly reflected in the rise and fall of share valuations in response to information on pipeline developments. Fundamentally, the development, regulatory and commercial risks involved in bringing a new medicinal product of market are high which is in fact the driving reason for acquisitions in the innovative pharmaceutical industry.

The fact that, on average, only one or two of every 10,000 substances synthesized in laboratories will successfully pass all stages of development to become a marketable medicine means that pharmaceutical companies must pursue many diverse projects at the same time in order to have a realistic chance of success.

In the latest study from **Di Masi, Grabowski, and Hansen (2016)**, the overall probability of clinical success (probability that a drug entering clinical testing will be eventually approved) was evaluated at 11.83%. The transition probability between the phases were the following: 59.2% between Phase I and phase II, 35.2% between phase II and phase III, 61.95% between phase III and new drug / biologic license applications.[3]

This is why many pipeline acquisition deals are done. Pharmaceutical companies are under great pressure to research and develop innovative medicines to generate the revenues required to keep innovating. They will buy in promising lines of research if they have a gap in their portfolio or if their own research has failed or has revealed itself to be less promising than originally anticipated.

3.2 Pricing power concerns are misguided

Once a medicinal product has received regulatory approval, the originator is in a challenging situation. It has invested heavily in the development and has only a limited exclusivity period during which to recover the investment. In addition, it is usually in competition with other innovators so has every incentive to start marketing the product as quickly as possible. Moreover, if the product is

[3] "Innovation in the pharmaceutical industry: new estimates of R&D costs" published in the Journal of Health Economics. The authors estimate that *"The distribution of clinical period failures for the study were 45.9% for phase I, 43.5% for phase II, and 10.6% for phase III/regulatory review".*

sufficiently innovative, there will be significant pressure from patients and physicians to have the product available as soon as possible.

Prices for medicines in the EEA are by and large set by the Member States, pursuant to different mechanisms. Health technology assessments (HTA) are increasingly used by healthcare providers and payors to assess the value of new medicines. They identify those pharmaceuticals which offer the highest value for money and inform decisions about which drug should be reimbursed and the degree to which payers fund a medicine. The outcome of the HTA forms the basis for negotiations which then also involve budget impact assessment.

In addition, a significant number of EU Member States apply international reference pricing (IRP). IRP is one of the most commonly used instruments to control prices of patented pharmaceuticals. It consists of using the prices of a pharmaceutical product in a group of other countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the domestic price. This regularly leads to the lowest prices being used, independent of any value assessment that has been undertaken. The countries included are often significantly less wealthy and have different healthcare challenges. Sometimes the referenced countries extend well beyond the EU to countries further east and south, making the comparison even more problematic. Recent pressures have also increased payors' interest in therapeutic referencing that may include off patent and parallel traded products.

These various mechanisms mean that the originator has limited bargaining power over any single innovative product let alone over any portfolio of products. The fact that an originator has an approved oncology product on the market and purchases a research line into another oncology product does not come with any assurances that the pipeline product will make it through clinical development, obtain regulatory approval as well as pricing and reimbursement and will ultimately be commercially successful. This is likely why remedies in merger control proceedings for medicinal products that are not yet approved are rare.

EFPIA is well aware that in the recent past, there have been investigations into excessive pricing in the pharmaceutical sector. These complaints seem to relate to older generic drugs that do not face competition and without there being any apparent reason for such an increase, and of such a magnitude. None of these (limited) cases have anything to do with a company having acquired pipelines products in order to prevent the appearance of competition (on the contrary, the Aspen case, for example, followed the acquisition of mature products which had been generating sales for decades and had long ceased to benefit from any patent protection and which had not been the object of any new R&D or developments) .

Complaints about excessive pricing in relation to innovative drugs at launch have not been investigated by competition authorities that recognise the broader societal value of rewarding innovation that lowers overall costs of care in the system.

By way of example, the competition authorities declined to investigate whether Gilead's pricing for its Hepatitis C product (priced higher than its biotech creator anticipated charging prior to the acquisition) was abusive. The Commission recognised that there is significant competition in innovation, including a number of recent new market entrants, and that Member States have the tools to control pharmaceutical pricing. Article 102 is available to regulators in the case of evidently abusive conduct. This is not an issue to be dealt with prospectively through merger control.

4. A deal value based threshold would be arbitrary and burdensome

Thresholds based on net present value (NPV), share value, and deal value are all inherently uncertain - values can change materially over short periods of time. They are subjective and subject to market volatility, especially given the failure rate as referenced at footnote 3 above.

As a result, it is common to see transactions where the purchase will take the form of an initial down payment to be completed with milestone payments or other types of contingent payments (triggered upon reaching certain regulatory or clinical stages) which make the determination of the "value" of the transaction quite complex.[4]

So transaction value is only a rough and imprecise proxy for marketability. The more advanced the R&D being purchased is, the more expensive it will be. The sale is often done through an auction process that can artificially drive up the price. Even if a new product is in phase 3 clinical trials, there is still a risk that it will not come to market

Relative values also diverge across industries, and setting an arbitrary deal value threshold may have the perverse effect of increasing the burden for some sectors whilst allowing others to escape intended scrutiny.

The Commission should also be aware of the specific features of deals in the biotech sphere. Often start-ups are starved of cash and cannot and will not progress to clinical trials without guaranteed upfront funding and the other support that well-established acquirers can bring. Often timing is of the essence to close a transaction quickly in order to progress the R&D and bring new life-saving products to market ahead of the competition in this space, and also to share the risk of discovery and development. It is imperative that such deals be closed rapidly and with minimum disruption. Changes to the current clearance structure could thus delay access to impactful medicines for patients in need.

Should a clearly identified enforcement gap merit an additional threshold, EFPIA considers that:

- a transaction value threshold would in any event not cover pure pipeline acquisitions as such transactions do not qualify as "concentrations" under the Merger Regulation;
- transaction value thresholds are unsuitable for determining whether a given transaction will have an impact on a specific jurisdiction – at the very least, any EU law threshold should be materially higher than the €400 million in the new German law;
- a ratio threshold will always be triggered where the target generates little if any revenue (zero revenue will be equated to €1) – coupled with an insufficiently high value threshold, this casts the net much too wide;

[4] In this respect, as an illustration, the US agencies devote substantial resources only to respond to questions received that relate to how the size of transaction test should be interpreted and applied in specific cases. The FTC's Premerger Notification Office hence has a staff of ten full-time people (including six staff attorneys) dedicated solely to responding to questions from parties considering their filing obligations. This is not even considering the burden linked to handling the actual notifications generated by this threshold.

- a clear local nexus test is critical – given the failure rates cited above, we suggest that application for a marketing authorisation would be an appropriate test;
- a truly simplified procedure should be made available to avoid undue hold up absent a clearly articulated theory of harm in any given case that would justify a closer look.

Use of the Simplified Procedure is by no means a "box-ticking exercise", and our recent experience has been that a Simplified Procedure case can still incur considerable legal costs and administrative burden for clients. Circumstances that may give rise to increased cost include cases involving new, undefined or previously unconsidered plausible markets where there is a veritable lack of reliable market data.

In particular, the pre-notification procedure can still be relatively lengthy and complicated, with significant time spent demonstrating to a case team that the relevant provision of the Simplified Procedure Notice is met. The administrative burden was increased by the 2013 reforms (in particular by the new Short Form CO, and by the requirement to produce certain internal documents under the new Section 5.3). Companies that had never produced documents to the Commission previously are now required to do so in relation to transactions that will not raise competition concerns. The HSR filing process for non-problematic transactions is significantly less burdensome and time-consuming in comparison.

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In sum, EFPIA urges the Commission not to pursue a value-based threshold on the basis that there is no identified enforcement gap. The current rules are sufficient and the referral rules are an adequate safeguard.