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## Global Forum on Competition

### COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

#### Contribution from BIAC

-- Session III --

*This contribution is submitted by BIAC under Session III of the Global Forum on Competition to be held on 27-28 February 2014.*

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## COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- BIAC--

### Introduction/Executive Summary

1. BIAC welcomes the broad scope of the Forum's agenda and the opportunity to provide its views on the functioning of competition in the pharmaceuticals distribution sector. The control of healthcare expenditure is rightly an important issue for both developed and developing countries which have an interest in managing and optimising healthcare spend in the broader societal interest of achieving optimal patient outcomes. BIAC agrees with the recent conclusion from the French competition authority's review of the distribution sector that it is necessary to put competition policy at the service of innovation and value creation, especially at the upstream level, recognising that the innovative sector is a formidable engine of progress, competition, competitiveness and employment.<sup>1</sup> In this sector in particular, competition authorities must be mindful of the need to promote dynamic efficiencies and resist taking a static view that focuses on short-term cost savings to the exclusion of the longer term benefits of innovation incentives.

2. The European Commission Sector Inquiry Final Report noted that in 2007, the total size of the pharmaceutical markets in the EU was € 138 billion on an ex-factory-basis, and € 214 billion at retail level, corresponding to 2% of GDP and an annual per capita spent of € 430.<sup>2</sup> This gap has not diminished in the meantime. The significant difference between ex-factory and retail suggests that there are efficiency gains to be had from improving the distribution chain.

3. The fundamental challenge today is how to ensure that the supply chain is working effectively to ensure early and adequate patient access to medicines. Government and private health insurers have an important influence on demand as their policies on reimbursement can influence a physician's choice of medication and a patient's ability to pay. Patient access must remain at the forefront of the weighing of the pros and cons of all regulatory interventions.

4. In summary, BIAC urges both healthcare regulatory and competition authorities to engage in a risk-benefit analysis of the implications that intervention may have on dynamic competition. Fundamentally, this balance requires the consideration of various factors, including:

- a strong system of intellectual property protection that encourages innovation;
- competitive and efficient generic markets that create headroom for improved patient access to innovative medicines;

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<sup>1</sup> "L'Autorité de la concurrence réaffirme la nécessité de mettre la politique de concurrence au service de l'innovation et de la production de valeur, en particulier en amont de la filière. L'innovation est en effet au cœur de la compétitivité de l'industrie pharmaceutique, laquelle connaît des évolutions rapides : épuisement du business model centré sur les blockbusters et réorientation de la recherche et développement vers le traitement de maladies rares, notamment, et vers les biotechnologies, externalisation de la recherche, essor de la coopération entre laboratoires. Il convient d'accompagner ce mouvement qui est un formidable accélérateur de progrès, de concurrence, de compétitivité et d'emploi." See the Authority's press release of 19 December 2013 on the publication of its sector inquiry into the pharmaceutical distribution system. [http://www.autoritedelaconcurrence.fr/user/standard.php?id\\_rub=482&id\\_article=2282](http://www.autoritedelaconcurrence.fr/user/standard.php?id_rub=482&id_article=2282)

<sup>2</sup> Sector Inquiry Final Report, paragraph 43.

- better data systems to understand supply and demand at the national level, coupled with rigorous enforcement of regulatory obligations on wholesalers and pharmacies to meet local demand to avoid the shortages that many European markets have recently experienced;
- a focus on improving patient access, acknowledging the need to avoid national policy choices that have significant adverse knock-on effects in other markets;
- the elimination of unnecessary state-imposed regulatory restrictions on competition in the supply chain;
- strong consumer protection enforcement to prevent fraud and the dissemination of counterfeit products, particularly in cases of online distribution; and
- subject to the above considerations, consistent application of competition law to ensure that none of the players improperly restricts such competition as the applicable regulatory framework allows in the supply chain.

## 1. Pharmaceutical Supply Chain Actors and the Impact of Regulation

5. The research-based pharmaceutical industry is one of the leading global high technology industries spending more on research and development (R&D) than any other industry.<sup>3</sup> It is a strategically important sector in terms of public health, economic growth and employment. The industry in Europe directly employs about 700,000 people, of which 116,000 work in R&D. According to PhRMA, the chief US biopharmaceutical industry association, direct employment in the US is over 810,000 with an estimated 3.4 million jobs indirectly tied to the sector.

6. The innovator model of pharmaceutical competition is characterized by costly upfront investments in R&D and clinical trials, limited prospects of new products reaching the market and producing a return, strict price controls imposed by state buyers that fail to reward innovation in most European markets and beyond, as well as reimbursement policies that delay market access, strong patent protection and legal certainty as to the enforceability of patents are a prerequisite to ensure that the incentives that lead to this innovation are maintained.

7. The generic industry plays an important role: increased competition on prices when products lose exclusivity enables sustainable treatment of more patients at lower cost, and creates financial headroom for the funding of better patient access to innovative medicines.<sup>4</sup> Generic entry requires access to lower levels of capital and does not entail the same degree of investment risk, although, increasingly, generics are developing new patented formulations, dosage forms and delivery methods since such products are more likely to receive rapid regulatory approval at higher reimbursement rates. The boundaries are further blurred by the tendency of innovative companies to introduce their own generic product upon patent expiry.

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<sup>3</sup> European Commission 2013 EU Industrial R&D Investment Scoreboard. page 45. The scoreboard contains economic and financial data for the world's top 2000 companies ranked by their investments in research and development (R&D). The sample consists of 527 companies based in the EU and 1473 companies based elsewhere (<http://iri.jrc.ec.europa.eu/scoreboard13.html>). According to this and other estimates, the industry spends about 16.4% - 17.5% on R&D as a percentage of total sales.

<sup>4</sup> "... la concurrence liée à la mise sur le marché de médicaments génériques entraîne des économies de coût pour l'assurance-maladie qui permettent, dans un contexte budgétaire difficile, de dégager des ressources pour financer à leur juste valeur des médicaments réellement innovants." Conclusions from the French competition authority press release of 19 December cited at footnote 1 above.

8. Generic entry is actively facilitated by the legal framework once the innovator's exclusivity period expires.<sup>5</sup> However, some national health systems impose barriers that limit the introduction or adoption of competitive off-patent markets.<sup>6</sup> BIAC supports a framework that encourages swift generic entry on originators' loss of exclusivity and policies that facilitate generic uptake (without discrimination between generics and off-patent originals) and effective competition among generic producers.<sup>7</sup>

9. The remainder of the supply chain is also highly regulated in many jurisdictions. Pharmaceutical wholesaling, brokering and pharmacy sales often are subject to separate licensing regimes. While economic operators are, in principle, free to carry out multiple activities, they must have the appropriate licence for each. Although regulations vary significantly from one jurisdiction to another, they are essentially designed to ensure that medicines are received from and supplied to duly authorised players that fulfil their respective regulatory obligations. Where such obligations exist, marketing authorisation holders (originators and generics) as well as wholesalers and pharmacists are required to ensure sufficient stocks to meet local demand.<sup>8</sup>

10. Pharmacies typically are the primary source of availability of prescription drugs although, in some countries such as Canada, doctors are also free to sell prescriptions. Some markets have opened up OTC markets to greater retail competition (the US and the UK are notable examples). Many European countries including UK, Poland, Croatia, and most recently France are in favour of a mixed approach with authorisations to sell some OTC medicines in retail stores under a pharmacist's supervision.

11. Some market actors, including pharmacies, are turning to new business methods such as online sales. There are clear benefits to internet sales but also potential risks for consumers, which means that many jurisdictions are currently considering how to ensure the safety and security of delivery required for pharmaceutical products.<sup>9</sup>

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<sup>5</sup> Extensive pre-clinical and clinical trials are not required. Marketing authorisation can be obtained on the basis of an abridged data package demonstrating that the copy is accurate (with the same qualitative and quantitative composition in active substances and same pharmaceutical form) and bioequivalent to the reference product. There are other measures to facilitate speedy generic approvals, see by way of example, Article 10, Directive 2001/83 on the Community code relating to medicinal products for human use (as amended) [2004] OJ L 311/67.

<sup>6</sup> Generics are attracted to commercial opportunities: the value of the market per capita and population size are drivers of the number of generic entrants. A regression analysis carried out as part of the European Commission's sector inquiry in 2009 demonstrated that price caps and mandatory discounts correlate with a lower number of entrants and, in the longer run, lead to higher prices in comparison with non-cap schemes (Final Report, paragraphs 1478 – 1480).

<sup>7</sup> For example, calls for minimum quotas in terms of generics dispensed should cover all low cost medicines to avoid discriminating against original off-patent products. Experience shows that the primary aim of regulatory measures or incentives introduced to encourage generics often appears to be to achieve short-term cost savings rather than to develop dynamic and sustainable competition in the off-patent segment.

<sup>8</sup> In the EU, they are required to ensure "within the limits of their responsibilities, appropriate and continued supplies of medicinal product[s] to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered" Directive 2001/83/EC on the Community Code relating to medical products for human use [2001] OJ L 311/67, Article 81, Recital 38.

<sup>9</sup> According to LegitScript (The Leading Source of Internet Pharmacy Verification) which monitors 365,647 health-related websites, among 37,939 active Internet pharmacies, 35,956 (94,8%) are not compliant for a host of different reasons (no pharmacy license, domain name registration, controlled substances, location, prescription validity irregularities). Coordinated international actions against unlawful online sales of medicines started in earnest in 2008. There are annual operations involving INTERPOL in cooperation with the World Customs Organization (WCO), the Permanent Forum on International Pharmaceutical

12. For the reasons set out below, a key challenge in the current climate, particularly in Europe, is to ensure that pharmacists and wholesalers prioritise their public service obligations over short-term arbitrage activities that undermine supply security. There are many issues related to competition in the distribution sector where there is room for improvement. They include:

- regulations that maintain inefficient distribution chains such as pharmacy margins that favour generics over originators at the same price
- understanding the extent of below the line or non-transparent discounting of generic companies to pharmacists so that demand-side incentives to encourage generic up-take ensure that at least some of the cost savings from increased competition are passed on to payers and patients
- patients, asked to act more rationally through demand-side measures such as the requirement that they make co-payments, should be empowered to make informed decisions in conjunction with their physician as to available treatments
- increased vigilance to avoid excessive buyer power.<sup>10</sup>

13. The plethora of state controls operating on both the supply side and demand side have long been a cause for concern in relation to innovation and competition.<sup>11</sup> Regulatory measures may have unanticipated negative effects on the functioning of competition in distribution markets, particularly where price controls have extraterritorial effect as the result of (i) wholesaler arbitrage, and (ii) international price referencing.

## 2. Arbitrage and Product Shortages

14. The economic crisis has forced deep price cuts to pharmaceutical products as governments attempt to reduce healthcare spending. This has fuelled parallel trade and created supply shortages<sup>12</sup>

Crime (PFIPC), Europol, and the EU's Heads of Medicines Agencies Working Group of Enforcement Officers (HMA WGEO). In 2013, 99 countries participated, 13 763 web sites were shut down, 10 192 274 medicines were seized and 213 people arrested.

<sup>10</sup> Wholesaling activities are generally recognised as a separate market in Europe, the US and elsewhere. On this basis the US FTC has successfully challenged "four to two" mergers in this sector. The US has also been active in assessing consolidation at the level primarily of pharmacy benefit management firms. For example, in an acquisition by CVS of a rival chain, Revco, the FTC required the divestiture of 120 Revco drug stores or pharmacy counters in a number of local markets "in order to maintain a level of competition that otherwise would have been substantially reduced" by the merger. In this case the FTC took note of the fact that the "customer" is typically not the patient but an intermediary third party, and competition occurs at the level of pharmacy chains competing for sales to pharmacy benefit management firms. See: <http://www.ftc.gov/enforcement/cases-proceedings/971-0060/cvs-corporation-revco-ds-inc>.

<sup>11</sup> The WHO has observed that the "unpredictable lottery" of price controls in Europe "has a direct effect on which medicines are produced by innovator companies". Priority Medicines for Europe and the World, World Health Organisation, November 2004, p. 104.

<sup>12</sup> Causes for drug shortages are many and complex, including manufacturing, quality and/or compliance issues, epidemics triggering additional demand, natural disasters disrupting supply chains and the globalisation of manufacturing and distribution activities leading to fewer supply sites and less flexibility. Simply the process of pricing and reimbursement decision-making can delay market entry for both originator and generic products for as long as 18 months in some countries, to be contrasted with those countries where no formal bar to accessing the market exists (e.g., the US, Germany and the UK).

resulting in market distortions that negatively affect the availability and accessibility of innovative medicines in low-income countries.<sup>13</sup>

15. Government imposed temporary export bans are a legitimate response to genuine shortages in circumstances where there is a real and immediate threat to security of supply and/or patient safety. But these are short-term measures that do little to solve the distortions caused by exporting the effects of national price regulations to other countries.

16. In some of the worst hit countries in the EU for example, the innovative pharmaceutical industry contributed, through a combination of price cuts and discounts, more than €7 billion between 2010 and 2011 alone. Companies continued to supply markets despite delays in payment, significant write-offs and claw-back mechanisms, while at the same time enduring parallel trade triggered by emergency local price cuts. In this climate, the situation for patients has deteriorated.<sup>14</sup> Spain, for instance, recently cracked down on pharmacies found illegally selling price controlled drugs destined for patients to wholesalers for export in breach of their supply obligations.

17. The problem is not confined to crisis-stricken countries such as Greece and Spain. Recently, the UK has suffered from systemic shortages and supply disruptions. The UK authorities have responded by introducing legislation requiring pharmacists to acquire a wholesale licence before they can engage in any parallel trade.<sup>15</sup>

18. The French sector inquiry into the distribution of medicines notes the phenomenon of wholesalers abusing the regulatory system by registering as full line wholesalers in order to benefit from product quotas delivered by innovators at the local regulated prices which are then resold into higher price countries.<sup>16</sup>

19. Some national schemes incentivise parallel trade even at the direct expense of the exporting country. Denmark references the price of imported parallel traded products in setting the reimbursement price. In Sweden, parallel traded products comprise an estimated 15% of the total pharmaceutical market, driven largely by the fact that pharmacists reap the benefit of the price differential.<sup>17</sup> In Germany, parallel imports must account for at least 5% of quarterly sales of pharmacies. The German pharmaceutical market is estimated to have an ex-factory value of approximately €27 billion and the parallel distribution market

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<sup>13</sup> Drug shortages are not a European phenomenon. A study of shortages in the US published by IMS in November 2011 found that the supply of drugs on the shortages list had been stable or increasing over a 5 year period but there was significant volatility in the supplies of the drugs in question leading to the conclusion that the problem of shortages is complex requiring more systematic research across the total supply chain. IMS noted that more rigorous monitoring and sophisticated demand forecasting may help prevent future shortages.

<sup>14</sup> The Belgian Presidency published an analysis at the end of 2010 showing a 10:1 access differential per capita between Germany, France and Luxembourg on the one hand, and Romania and Bulgaria on the other. That gap mirrors a growing divergence in GDP and living standards across Europe and beyond.

<sup>15</sup> See reports from a UK all party parliamentary pharma group ("APPG") (<http://www.bbc.co.uk/news/health-18022148>).

<sup>16</sup> Op cit., paragraph 134.

<sup>17</sup> Research shows that the profits enjoyed for parallel traders can be as much as 20 times the net savings to the national healthcare system. See Kanavos and Kowal, Does pharmaceutical parallel trade serve the objectives of cost control?; Eurohealth Vol 14 No 2, page 25; see also Kanavos P, Costa-Font J. Pharmaceutical, Parallel Trade in Europe: stakeholder and competition effects. Economic Policy 2005;20(44):751–98.

alone is valued at almost €3 billion.<sup>18</sup> This demand is equivalent to a substantial part of many smaller states' national healthcare budgets.

20. Economists recognise that arbitrage in pharmaceutical markets does not tend to increase the intensity of price competition but merely allows the middlemen to take part of the profit that would otherwise accrue to the originators, with knock-on effects on R&D investment into innovation.<sup>19</sup> Unfettered arbitrage opportunities can harm economic welfare by undermining the dynamic efficiencies that efficient price differentiation would encourage in the form of additional markets/patients being served. In addition, there are a number of straightforward steps that would enable authorities to better assure the efficient functioning of the supply chain and anticipate and identify potential supply shortages at an early stage. Better monitoring and rigorous enforcement of existing regulatory obligations on all actors in the supply chain, coupled with further measures to enhance transparency within the supply chain, would considerably improve the status quo. Such improvements can be done at a national level and can be facilitated by the sharing of best practices and closer consultation with stakeholders.

21. Greater transparency across the supply chain to make it easier for national authorities to identify distortions, predict when and where shortages are likely to occur, and devise suitable regulatory responses before patient access is affected. For example, recent amendments to Czech pharmaceutical regulations require pharmacy operators, who also act as distributors, to declare whether they receive stock in their capacity as a pharmacy operator or a distributor; if stock is declared for resale in pharmacies, it cannot subsequently be distributed by the pharmacy operator on a wholesale basis. This system also allows the relevant actors to ensure that they are meeting their respective supply obligations based on accurate data.

### **3. The Effects of International Reference Pricing**

22. Since the start of the economic crisis, the practice of countries linking their regulated medicines prices to those of other countries, including those countries in crisis that have taken emergency containment measures, has created significant risks for patient access and innovation.<sup>20</sup>

23. International reference pricing restricts competitive conditions from determining product availability and market prices and thereby risks leading to greater price convergence among markets to the detriment of patients in the least affluent countries. It further exacerbates health inequalities, ultimately threatening investments in R&D funding into future treatments.

24. A seminal 2008 OECD Study underlines how international reference pricing affects prices and availability of medicines outside the country undertaking the benchmarking practice by reducing manufacturers' willingness to set prices according to national market conditions. It recognises that this may have a negative effect on affordability and availability of medicines in smaller markets and lower-income countries.<sup>21</sup>

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<sup>18</sup> "The parallel distribution industry: a closer look at savings", EAEPC report of January 2013 at p. 21.

<sup>19</sup> See, for example, Jan Peter van der Veer of RBB Economics on the Kluwer blog "Entering uncharted territory: the Commission's thinking on territorial supply constraints". <http://kluwercompetitionlawblog.com/2013/06/04/entering-uncharted-territory-territorial-supply-constraints/>

<sup>20</sup> A 2013 study was carried out by CRA on the international impact of Swiss drug price regulation on behalf of Interpharma and Novartis. It concluded that a 10% across the board price reduction in Switzerland would reduce industry revenues by €430 million on the domestic market, but an additional €495 million in the rest of the world, a multiplier of 2.15.

<sup>21</sup> OECD Health Policy Studies, Pharmaceutical Pricing Policies in a Global Market, 2008, p. 18.

25. A 2012 CRA report<sup>22</sup> shows that the most significant costs of price-referencing and parallel trade fall on low-price countries that face higher prices and reduced access. This is observed in longer delays prior to launch, shortages in some cases and, in a worst case scenario, no access at all to new medicines. To resolve these problems, prices of medicines should factor in the value of the product, patient benefits, and affordability considerations. Last but not least, they must exclude emergency cost containment measures that may have been imposed in other markets which, inherently, incorporate market distortions and magnify the effect of those distortions.

26. Fundamentally, any effective policy response to the problem of patient access will require greater solidarity between countries, acknowledging that national policy choices can and do have significant adverse knock-on effects in other markets. This worked successfully with schemes designed to improve patient access to HIV medicines in Africa whilst avoiding significant international trade distortions.<sup>23</sup>

27. Instead of fuelling market distortions leaving patients in lower income, lower price countries, worse off, the objective should be to focus on an affordable price in each market based on objective criteria. The basis for that discussion is the principle of the non-extraterritoriality of national price controls which was accepted in Recommendation VI of the G10 Medicines Report and in Recommendation 9.2 of the Final Report of the High Level Pharmaceutical Forum.<sup>24</sup>

28. This approach is fully in line with the OECD 2010 Report which recognised that "...Economists and policy makers generally agree on the fact that cross-country price discrimination for patented pharmaceuticals is a win-win situation in which companies earn the revenues they need to invest in R&D while people in lower-income countries access the medicines they would not access at a high price".<sup>25</sup>

#### **4. Competitive Issues in the Supply Chain**

29. Compliance with the competition rules is required from each and every supply chain operator. Across the OECD and elsewhere, those rules prohibit anti-competitive agreements and unilateral conduct amounting to an abuse of market power. These rules should be rigorously enforced in relation to conduct that can be identified as causing material competitive harm.

30. It is paramount that the competition rules are enforced in such a way as to ensure a level of legal certainty, particularly as regards rules dealing with unilateral conduct, that avoids chilling effects on pro-competitive conduct.

31. Competition agencies should be reluctant, in the absence of a clear theory of competitive harm, to impose regulation that would dictate the structure or functioning of the pharmaceutical supply chain.

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<sup>22</sup> The implications of international reference pricing and parallel trade on social welfare and patient access, CRA, September 2012.

<sup>23</sup> The value of differential pricing as a means of ensuring affordable access to vital medicines has long been acknowledged in the context of serious communal diseases such as HIV/AIDS, TB and malaria. The concept underpins Council Directive No 953/2003 to avoid trade diversions into the EU of certain key medicines [2003] OJ L. 135/5. Recital 5 confirms that "Price segmentation between developed country markets and the poorest developing country markets is necessary to ensure that the poorest developing countries are supplied with essential pharmaceutical products at heavily reduced prices. Therefore, these heavily reduced prices cannot be understood as a reference for the price to be paid for the same products in developed country markets". These underlying principles have also been acknowledged by Member States in the Bremen Declaration (ensuring patient access to life-saving HIV/AIDS medicines).

<sup>24</sup> High Level Group on Innovation and the Provision of Medicines - Recommendations for action ("G10 Medicines Report"), published 7 May 2002, and High Level Pharmaceutical Forum 2005-08, Final Conclusions and Recommendations, October 2008.

<sup>25</sup> Value for Money in Health Spending, OECD (2010), p. 164.