Media Release

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Commission non-refers Doctors Without Borders complaint

The Competition Commission has non-referred its investigation into complaints of alleged anticompetitive conduct against Aspen Pharmacare Holdings Limited ("Aspen"), Mylan Laboratories Limited ("Mylan Laboratories"), Mylan South Africa Incorporated ("Mylan South Africa") and Mylan Incorporated ("Mylan Inc.").

On 12 September 2012, the Commission received a complaint from Medecins Sans Frontiers/Doctors Without Borders ("MSF") against Aspen, Mylan Inc. and its affiliates for entering into exclusive supply agreements regarding the introduction of fixed dose combination anti-retroviral products ("ARV-FDCs") in the South African public health sector. These are drugs used in the treatment of AIDS and/or HIV. In 2008, Mylan Inc. appointed Aspen as the exclusive supplier in South Africa of an active pharmaceutical ingredient ("API") that is used to produce what are known as finished dose anti-retroviral products ("FDFs"). Aspen was also licensed by Mylan Inc. as an exclusive supplier in South Africa of FDFs. The parties agreed that Mylan Inc. and its affiliates would not directly or indirectly market or sell FDFs and the API to any other firms registered or incorporated in South Africa, besides Aspen.

MSF further alleged that the API Agreement and the FDF Agreement endure until 2016 and respectively prohibit Mylan Inc. from entering the South African market, directly or indirectly to supply the ARV-FDCs or any other products that Aspen supplies to the South African market as licensed by Mylan Inc. MSF alleged that the conclusion of the agreements would have the effect of preventing or lessening completion in the market. MSF also alleged that on-going negotiations between Aspen and Mylan Inc. regarding the pricing of ARV-APIs would influence the final price of ARV-FDCs and was possibly price fixing that would negatively affect the prices of ARV-FDCs.

In addition to the MSF complaint, the Commission also initiated its own complaint against Aspen, Mylan Inc., Mylan Laboratories and Mylan South Africa for market allocation on the basis that the API Agreement and the FDF Agreement possibly constituted a division of markets between competitors. For convenience, the MSF complaint and the complaint initiated by the Commission were investigated together as they both related to the same set of agreements.

In assessing the two complaints, the Commission identified two relevant markets. The first was the *upstream market* for the manufacture and supply of ARV-APIs used to manufacture ARV-FDCs for the treatment of HIV/AIDS. In this market, Mylan Inc. (through its wholly owned subsidiary Mylan Laboratories) is one of the world's largest producers. The second was the *downstream market* for the manufacture and supply of ARVs to the public sector through a tender process.

ARVs are categorised into different types, the multiple dose combination drugs (which entail patients taking for example up to three pills a day) and ARV-FDCs (which combine different drugs into a single pill). The investigations focused on the latter, specifically two combinations, one that contains tenofovir, emitricitabine and efavirenz ("T.E.E") and the other containing tenofovir, lamivudine and efavirenz ("T.L.E"). The individual drugs in these two combinations were previously marketed separately in South Africa, before they were introduced as ARV-FDCs, first in the private sector and later in the public sector through the 2012 ARV tender that was issued by the Department of Health.

The 2008 set of agreements gave Aspen a reliable and secure supply of APIs and FDCs which enabled it to manufacture and develop ARVs that it supplied to the South African market. Aspen's ARVs were largely supplied to the public sector through its participation in the 2008 and 2010 ARV tenders that required multiple dose combination drugs, as well as later in the 2012 ARV tender for the supply of ARV-FDCs.

The Commission investigated the price-fixing allegation and subsequently dismissed the allegation due to lack of supporting evidence.

On allegations of prevention or lessening of competition in respect of the API Agreement, the Commission found that the exclusionary effects of the API Agreement in the downstream market, whilst it temporarily prevented Mylan Inc.'s entry into the South African ARV market, did not substantially lessen or prevent competition in the market. Aspen's competitors could access ARV-APIs from other manufacturers and were not excluded from competing with Aspen in the ARV tender market. The Commission also found that there were efficiencies that emanated from the API Agreement that would outweigh any anti-competitive effects. Aspen had been awarded a large portion of the 2008 ARV tender and needed to ensure that it had guaranteed access to the ARV-APIs in order to meet its obligations in terms of the tender.

On allegations of market allocation in respect of the FDF Agreement (read together with the API Agreement), the Commission found that there was a clause in the FDF Agreement (the so-called "non-compete clause") which temporarily prevented Mylan Inc.'s entry into the South African market and was inextricably linked to the exclusive license. The Commission's interpretation of the agreements was not sufficient to categorize them as a contravention of the Competition Act No. 89 of 1998, as amended. Furthermore, the Commission found that it is common practice in the pharmaceutical industry for owners of intellectual property to license to a particular entity the use of their intellectual property either on an exclusive or non-exclusive basis. In cases where the license is on an exclusive basis, the Commission will closely examine the effects of the exclusivity on competition in the relevant market and assess any claimed efficiencies. As pointed out, in this case the Commission found that Aspen's competitors could reasonably access alternative sources of supply. In appropriate cases, exclusive supply agreements may promote efficient production, planning and stock maintenance.

On the whole, the Commission found that there were efficiencies that emanated from the agreements. Aspen was able to supply the large volumes of the ARV-FDFs that were required by the government in the 2008 and 2010 ARV tenders. Also, due to its guaranteed supply of ARVs from Mylan Inc. on several occasions, Aspen had to increase its volumes of supply of ARVs to the State because other parties were unable to provide the required volumes. Aspen may possibly not have been able to meet its supply obligations and increase its volumes to meet shortages if it did not have guaranteed access to ARV-FDFs manufactured by Mylan Inc.

Despite its decision to non-refer the complaints, the Commission had concerns with the 2008 set of agreements that may have had the effect of lessening competition in the market and restricting access to APIs and FDFs manufactured by Mylan Inc. However, the Commission took into account the fact that the conduct is largely historical as the agreements were mutually terminated by the parties on 14 February 2013. In fact, Mylan Inc. subsequently participated in the 2012 ARV tender issued by the Department of Health for ARV-FDCs and was awarded a portion of the tender.

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