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Big Pharma Paradoxes (BPP): Selling simultaneously drugs which Induce and Treat melanomas: "The simple example for complicated Relations!"

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Again we would like to focus the attention to a case of valsartan induced melanoma: a patient who has received two medical products (combined drug of amlodipine and valsartan 10/ 160mg (1-0-0), in the period 2008 to 2018, and additional valsartan 160mg (0-0-1) from 2015 that 1) the suspected primary melanocytic lesion was acquired one and occurred about three years after the start of the treatment with two different sartans 2) progression to cutaneous melanoma was observed when the dose of the valsartan was doubled within a period of 2,5 years, and 3) the exact application of the guidelines of AJCC for surgical treatment of cutaneous melanoma does not protect from melanoma progression (as in the case described by us) unlike the OSMS surgical model in which this progression is absent [3,4]. And what seems to be extraordinary is that 4) the progression of cutaneous melanoma to stage 4 was actually observed in a patient who was initially treated with two different sartans, produced from the same company that produces the Dabrafenib and Trametinib medication : the most widespread medications for treatment of melanoma at the moment [1]! Drugs, which have been subsequently used to treat "our" patient also?!

Analysis of these facts reveals possible or at least at some type of art hypothetical links between cancer development/ carcinogenesis generation and melanoma treatment (1,2)? The role of the so-called "Big pharma" should not be immediately ignored with a “light hand”, and the reasons for that are the FDA/ EMA notifications and the behavior of the Big pharma in this scandal: 1) sartans are carcinogenic (stated by the FDA/EMA), 2) a 6-month grace period is given, so that the production of all companies is “cleared” from possible carcinogenic substances, and 3) not all European companies are screened for carcinogenic ingredients, although there is clinical data for such a connection: drugs, produced in Europe, not sanctioned and even not checked (1,3,4). In short- “Big pharma” is not tested but self-verified and should inform about the results of its final self-inspection? That is what puts one of the enigmatic questions again: who is the regulator of the EMA/FDA- or is this regulator actually “Big Pharma”? A careful analysis of the available data shows that it is precisely the regulatory body that is in the service of “Big Pharma” (2)?!

A simple example of complicated relations is the following one: according to available data the cost of trametinib and dabrafenib scheme is $8,759 per drug per month ($17 518 per month total), which referenced for 1 year treatment leads to amount of $210, 216 (or $630,648 within 3- year therapy) [5]. About the prior antihypertensive therapy, the monthly cost of amlodipine and valsartan 10/ 160mg is fairly $323 per month or $27, 132 for 7- year treatment [6], while for the other drug (valsartan 160mg) is around $120 per month, which generates the price of $4,320 for 3 years of therapy in our patient [7]. The case presented is indicative of how the same pharmaceutical company produces at the same time drugs that are likely to generate cancer and those for its subsequent treatment [1,2]. This opens the question of the role/ position of the so-called “Big Pharma” in the global healthcare empire, its relation to the health care systems and the possible link how money could be earned following the moto: divide and conquer [2].

Another key point is the one step melanoma surgery model (OSMS) which we have introduced in other cases of drug induced melanomas that fill the preferred recommendations without an evidence for metastatic disease at the time of the initial diagnosis establishment [3,4].

We have presented two additional cases of patients with drug induced cutaneous melanomas successfully treated with the OSMS model with absence of any data for recurrence in the two years of follow up period [3,4].

One of the main reasons for the resistance in pharmaceutical and some medical circles about the introduction of this model for surgical behavior –OSMS, is the goal of breaking the mentioned vicious circle.

One step melanoma surgery should be the possible solution that minimises the possibility of mistakes and hence prevents the possibility of melanoma progression [3, 4]. It is precisely because

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of this fact, that it should be noted that the introduction of OSMS as a standard for the treatment of several/some or selected melanoma patients would result in a reduction of patients reaching stages III or IV where the drugs mentioned above are being used.

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