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Fixed dose combination in Argentine Pharmaceutical Market

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Considering WHO criteria for selection of essential medicines, it is recommended that they should be formulated mainly as a single active principle (AP). Fixed-dose combinations (FDC) are acceptable only when the dosage of each ingredient meets the requirements of a defined population group and when the combination has proved to be advantageous over the AP administered separately, in terms of therapeutic effects, safety, patient adherence to treatment or delay in resistance development -malaria, TBC or AIDS treatments¹. There are not conclusive studies supporting the facts that treatment with FDC are superior than single principles for patient adherence ²

A study hold in 2006 in the Argentinean pharmaceutical market ³, showed that 1905 active principles were commercialized, 60.4% of them were FDC (1151) (See Fig A). This market is made up of 9635 pharmaceutical products from which 3428 (35.6%) corresponded to FDC. These included products made up of two or three AP (2689) and up to four or more AP (729) (See Fig B)

This irrational market is evenly found in every pharmacological/therapeutic group. Just to give an example, in the case of NSAID´s there are in the market 29 different brands, from which 55.5% are FDC and only 5.4% have a high intrinsic value ⁴

It is important to mention that only 12 FDC are the same as are found in the WHO EML(2005) – 23 is the total number of FDC in the WHO EML – The situation becomes even more complicated because doctors are obliged by argentine legislation (law 25.649) to prescribe by their generic names.

It is shown by the data here presented that: 1- there is a high number of AP and in FDC in relation with the public health needs as regards chronic and prevalent pathologies existent.; 2- not all medicines available in the market have been studied enough to prove their efficacy and safety; 3- a high percentage of FDC (64%) have doubtful, null or unacceptable therapeutic value ⁴.

It is necessary to claim to regulatory agency (ANMAT) to change regulations and to avoid the incorporation and/or to remove from the market most of the FDC, which do not add any benefit and , on the contrary increase the risk of side effects, contributing to the irrational use of the therapeutic resources without any link to the health needs.

References:

¹The selection and use of essential medicines. Report of the WHO Expert Committee,2005. World Health Organization.

²Connor J, Rafter N, Rodgers A. Fixed dose combination pills or unit-of-use packaging improve adherence? A systematic review. *Bull World Health Organ.* 2004 ;82(12):935-939.



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