VITAMIN D
UpDates

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EDITORIAL

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Up to 2019, a progressive increase in the consumption of vitamin D in Italy was noted, with a consequent rise in expenditures borne by the National Health Service (SSN) [Rapporto OsMed (Osservatorio Nazionale sull'impiego dei Medicinali – National Database on the Use of Medicines Report), Agenzia Italiana del Farmaco – Italian Medicines Agency (AIFA)]. The extent and growth in the consumption of Vitamin D led to speculation of possible inappropriate use. With the declared intention of reducing this consumption, in late October 2019 AIFA published Note 96 identifying reimbursement criteria for Vitamin D supplementation for the prevention and treatment of deficiency states in adults [1].
In the first 20 months of application of the Note, compared to previous periods, there was a decrease in consumption and related expenditure for Vitamin D covered by the Note [2] (Fig. 1). However, whether this was due to an improvement in the appropriateness of use is not known.
In this issue we are publishing two contributions that raise doubts and concerns as to whether Note 96 has led to a deterioration in appropriateness of use, at least in some respects, rather than an improvement.

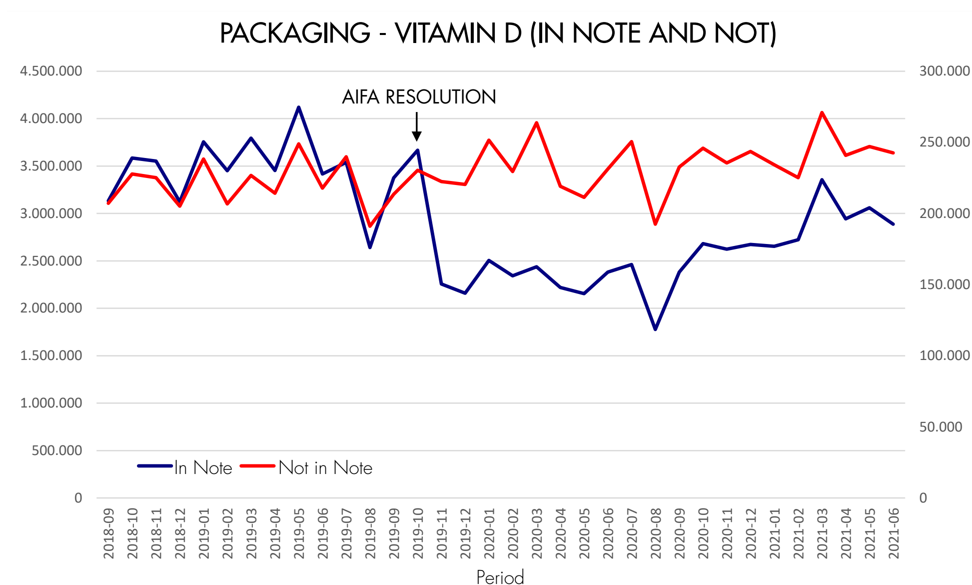

FIGURE 1.
(Source: https://www.aifa.gov.it/documents/20142/1030827/NOTA_96_20mesi_22.10.2021.pdf) [2].

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The first article summarises the role of vitamin D in the prevention of osteoporosis, considering its physiological action, and updates the subject in light of some recent publications, sometimes critically highlighting its limitations, which might explain some inconsistencies or discrepancies. Furthermore, the article expresses concern that the fall in consumption among the elderly, which is at risk of vitamin D deficiency and osteoporosis, may have compromised appropriate and often necessary supplementation of this age group. Recall that immediately after the publication of Note 96, in April 2020, it was I, as President of the Italian Society of Osteoporosis, Mineral Metabolism and Skeletal Diseases (SIOMMMS), who reported this risk to AIFA, communicating my concern in view of the preliminary results of an AIFA monitoring report three months after the introduction of Note 96 [3]. In particular, it was noted that the available data did not truly allow any assessment of whether the reduction in consumption and related expenditure on vitamin D could be attributable to improved appropriateness. We were particularly concerned about the significant reduction in the use of vitamin D in the elderly, who are known to be most at risk of deficiency. This is also because it has been known for some time [4], though ignored by Note 96, that there is a reduced ability of the skin to produce adequate amounts of vitamin D despite exposure to sunlight, the main source for meeting requirements, in people over the age of 60. Since Note 96 overlooks this aspect and specifically does not include advanced age as a risk condition for hypovitaminosis D, it does not adequately protect the elderly from the risk of vitamin D deficiency.

The second article analyses some very interesting aspects of the impact of Note 96 on the appropriate use of vitamin D in Italy. Specifically, using administrative flows for examinations and drug prescriptions at a ULSS (Local Health Service), an attempt was made to verify whether or not a reduction in the consumption of vitamin D was accompanied by greater appropriateness of use after Note 96 went into effect. Actually, after Note 96 was published, there was observed a reduction in the appropriate and recommended combination of vitamin D with drugs for the treatment of osteoporosis, which in my opinion was due to the lack of clarity in the text of Note 96 on this point and to its consequent often erroneous interpretation by doctors. Therefore, from this point of view, the observed drop in vitamin D consumption did not coincide with an improvement in appropriate prescription but rather with its worsening. Furthermore, the above analysis showed no improvement in the other indicator assessed, namely the proportion of patients treated with vitamin D without ascertained hypovitaminosis in the last 12 months. This, even though, in my opinion, those conditions for which the same Note does not provide for serum 25(OH)D dosage or for those patients for whom the continuity of treatment or the persistence of well-known previous risk conditions of vitamin D deficiency should be considered. Frankly, to require said dosage to be entitled to supplementation covered by the National Health Service would be superfluous, inconvenient, inapplicable or even unethical.

The need to better assess the actual impact of Note 96 on the appropriateness of vitamin D use, is also further borne out among the conclusions of the foregoing AIFA 2 monitoring report by the following:

- "From the data presented, after 20 months the effects of the Note seem to begin to wane, if compared with the first months of its application…"
- "Assess an awareness campaign on proper prescription addressing primary care general practitioners".

What are your thoughts?

Happy reading!

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