

Editorial

France Will No More Reimburse Available Symptomatic Drugs Against Alzheimer's Disease

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Abstract. The French Minister of Health published a decree on May 29th of 2018 removing the drugs used to fight against symptoms due to Alzheimer's disease (donepezil, rivastigmine, galantamine, memantine) from the list of available reimbursed drugs. This follows the advice delivered by the High Authority for Health in 2016 and 2018 stating an "insufficient medical benefit and dangerousness because of significant side effects". The main French scientific and medical societies and professional associations want to state here their deep disagreement regarding this unfair decision. The evidence-based medicine related to these drugs reaches a high level in literature, whereas the clinical relevance of these treatments must be considered with co-prescription of psychosocial interventions and related approaches. As no serious pharmacovigilance signal has been provided by health authorities, the ratio of benefits/risks favors these drugs.

Keywords: Alzheimer's disease, drug, health policy, reimbursement

Alzheimer's disease and related diseases affect about one million of people in France while several million relatives cope with the cognitive and behavioral disorders of these people with progressive loss of autonomy. The Minister of Health published a decree on May 29, 2018 removing the drugs used to

fight against symptoms due to Alzheimer's disease (donepezil, rivastigmine, galantamine, memantine) from the list of available reimbursed drugs. This decree is based on the opinion delivered by the High Authority for Health on July of 2016, October of 2016, and March of 2018 stating an insufficient medical benefit and dangerousness because of significant side effects.

It is a clear misjudgment in as far as all the recently published princeps studies and meta analyses conclude in favor of the effectiveness of the listed

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drugs for a symptomatic treatment of Alzheimer's disease, Lewy body disease, and cognitive disorders of Parkinson's disease. The drug marketing authorization was granted in light of a satisfactory answer to effectiveness criteria established by the regulatory agencies, e.g., the Food and Drug Administration and the European medicines Agency.

Their tolerance profile has been known for almost 20 years, consistent with what is expected, and no negative or dangerous pharmacovigilance signal was reported by the health authorities of Western countries. Furthermore, no national or European health safety agency, the aim of which is to assess the benefits/risks of drugs, questioned the products safety. The positive benefits/risks ratio has been recently confirmed by some meta analyses [1, 2], a Cochrane review [3], and the National Institute for Health and Care Excellence in the United Kingdom (June of 2018); disputed drugs also protect against cardiovascular events. The level of evidence-based medicine related to these drugs is currently not reached by psychosocial interventions [4]. Thus, conclusions of the High Authority of Health constitute an outright spin on the literature review at the time. Symptomatic drugs must only be prescribed by strictly respecting contraindications, especially cardiac contraindications, while monitoring the absence of side effects such as anorexia.

In Western countries, symptomatic drugs against Alzheimer's disease belong to the standard of care planned for many therapeutic trials. This debate is unique in Europe and worldwide. Then, the enforcement of the delisting of these molecules will lead to unequal access to care and research for French patients. Alzheimer Europe consortium (37 associations in 32 countries) also published: "European citizens should have equal rights to protection and access to health care regardless of their country of residence. Alzheimer Europe is therefore convinced that governments and regulators should not further restrict the access to anti-dementia drugs. Treatment should be offered as one part of a care package taking into account the various needs of people with dementia and their carers and anti-dementia drugs should be made available under national reimbursement systems for people with Alzheimer's disease in all Member States of the European Union" (<http://www.alzheimer-europe.org/Policy-in-Practice2/Our-opinion-on/Anti-dementia-drugs>).

The clinical effect of these drugs is significant but mild when considering them alone. However, they build up a synergy with non-drug therapies.

Throughout the last twenty years, France developed an important network of memory clinics thanks to the implementation of several public health plans and a long-term consistent policy beyond any political differences. Many help and support programs are available for the patients and caregivers on the French national territory. The country was able to promote and strengthen the synergy of medical and social approaches in the fight against Alzheimer's disease and related diseases which still represent a major public health problem. The care pathways aim at maintaining or improving the patient's and caregiver's quality of life, preventing complications of severe stages while slowing down the development of dependency. Only an interdisciplinary approach including the general practitioner, the physician specialist of neurocognitive disorders, the paramedical professionals such as the speech therapist, psychologist, occupational therapist, psychomotor therapist, and/or nurse can be efficient. The social services coordinate the home care plan tailored to dependence and family associations support the patients and their relatives. This comprehensive approach enables to reduce the impact of the autonomy loss; the patient's and his/her relatives "well-being" being the goal of all. The use of the listed drugs against Alzheimer's disease is part of this care pathway. **All the therapeutic measures and supports contribute to the slowing down of the patient's cognitive, functional, and behavioral impairments.**

These drugs which are now in the public domain are provided in generic forms. The pharmaceutical industry is no longer developing a commercial approach toward the physicians and their cost is rather small.

This decree is fully inconsistent with the French public health policy and the plans recently established to fight against Alzheimer's disease and related diseases. A new referral to the Health Authority for Health would be possible. It would enable the analysis of recent data from the literature in line with the newly published guidelines. A legal action has been taken by the medical and scientific societies and organizations involved in the diagnosis and care pathways of patients with Alzheimer's disease or a related disease.

DISCLOSURE STATEMENT

Authors' disclosures available online (<https://www.j-alz.com/manuscript-disclosures/18-0843>).

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