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Minister of Medical Care and Sports PO Box 20350 2500 EJ THE HAGUE

2021012702

Date 4 May 2021

Subject Advice on the clustering of combination products and ghost clusters in

GVS

Dear Ms van Ark,

I hereby offer you the report "clustering of combination products and ghost clusters (part 1)".

In preparation for the modernisation of the medicine reimbursement system (GVS), you have asked the National Health Care Institute questions about the clustering of two categories of medicinal products, namely the combination products and the ghost clusters. Because your question is about a large number of medicinal products, it has not been possible to discuss all medicinal products in one report. We will therefore advise you on these in several parts.

In this report (part 1), the National Health Care Institute provides a general approach to systematically grouping the combination products into clusters. The starting point of the assessment for interchangeability (clustering) is the system of the current legislation and regulation. It is assumed that clustering of combination products becomes legally possible after adaptation of Articles 2.40 and 2.47 in the Health Insurance Regulation.

In your letter of 12 May 2020, you also specifically asked questions about two specific groups of combination products, namely those for antiretroviral medicinal products (HIV-inhibitors) and medicinal products for the treatment of chronic hepatitis C infection. These questions have been covered in this report.

With regard to the ghost clusters, we have done an initial exploration of the list of 64 substances with 121 article names. Ghost clusters are clusters on List 1A with only one product left. Each ghost cluster has its own context: the reasons for its existence can be diverse. This leads to an assessment per situation of how the ghost product should be replaced in the GVS after the ghost cluster has been discontinued. The discussion of (most) ghost clusters requires an individual assessment.

In this advice, we have discussed a number of products in this category. The report contains our advice on the clusters for children and combinations with medical devices or utensils. We have also denominated two medicinal products which, in our opinion, do not belong in the GVS; they are better suited to medical care as specialist medicinal products. The financial consequences of this proposal are limited.

National Health Care Institute

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Your letter of 12 May 2020 In the course of 2021, we will draw up a plan for the evaluation of the remaining (groups of) medicinal products. Given the limited capacity of the National Health Care Institute, we will do this in stages. We will coordinate this with the Ministry's Department of Medicinal Products and Medical Technology.

Yours sincerely,

National Health Care Institute

Care I

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Sjaak Wijma Chair of the Executive Board