Instructions on the working method for manufacturers when supplying information for the Horizon Scan

1. Introduction

1.1 Since 1 January 2017, *Zorginstituut Nederland* (the National Health Care Institute, hereafter the *Zorginstituut*) is responsible for managing and further development of the Medicinal Products Horizon Scan (hereafter: the Horizon Scan).

1.2 The Horizon Scan is an integral, public summary – as unbiased as possible – of medicinal products that can be expected on the market over the next 2 years, and of relevant developments in this field.

1.3 The *Zorginstituut* has ultimate responsibility for the contents of the Horizon Scan.

1.4 The parties involved in the administrative outline agreement on care provided by medical specialists have agreed to work together on realising the Horizon Scan. These agreements have been recorded in a letter to the Lower House of Parliament, dated 29 January 2016, in the 'integral package of measures for guaranteeing the affordability and accessibility of expensive medicines'. These parties form the Medicinal Product Horizon Scan Steering Group (hereafter: the Steering Group).

1.5 The *Zorginstituut* puts the contents of the Horizon Scan to the Steering Group, and asks for its ratification.

1.6 The Steering Group is comprised of representatives of the following parties:
- The Federation of Medical Specialists (FMS)
- Dutch Federation of University Medical Centres (NFU)
- Dutch Association of Hospitals (NVZ)
- The Dutch Healthcare Authority (NVZ)
- Dutch Patients' Federation (PN)
- Dutch Nurses and Care givers (V&VN)
- Dutch Independent Clinics (ZKN)
- Ministry of Health Welfare and Sport(WVS)
- Zorginstituut Nederland (the *Zorginstituut*)
- Association of Dutch Healthcare Insurers (ZN)

1.7 By ratifying the Horizon Scan, these parties are endorsing the Horizon Scan as the best possible estimation for proposed developments regarding medicines in the fields mentioned.

1.8 The *Zorginstituut* assesses whether procedures have been adequately followed and whether the estimation was arrived at expertly. The *Zorginstituut* also takes the Steering Group's ratification into consideration during its deliberations. The *Zorginstituut* confirms the contents of the Horizon Scan based on its assessment and deliberations.

2. Tasks of the working groups

2.1 In principle, there are seven working groups, i.e.:
- Oncology and Haematology;
- Metabolism and Endocrinology;
- Chronic Immune disorders;
- Infectious diseases;
- Lung diseases, general;
- Neurological disorders (incl. behaviour);

- Cardiovascular disorders.

2.2 A working group is comprised of the following members: medical specialists, (hospital) pharmacists, representative(s) of health care insurers and representative(s) of patients.

2.3 Representatives of the Ministry of Health, Welfare and Sport (WVS) and of the *Zorginstituut* also participate in the working groups. Their input relates to content and they do not have a casting vote in the working groups. Both parties can in the meantime use draft information from the Horizon Scan while carrying out their statutory tasks.

2.4 The key task of a working group is to detect and analyse developments surrounding medicines in the relevant field of the working group and to determine the clinical impact of these new medicines (or extensions in indications) on the Dutch situation.

2.5 The working groups are responsible for the contents of the Horizon Scan, making use of basic lists drawn up by the *Zorginstituut*. Missing information is incorporated and, where necessary, information that has already been included is corrected or supplemented.

2.6 Ultimate responsibility for the content of the Horizon Scan is with the *Zorginstituut*, not with the working groups. Working groups are accountable only to the *Zorginstituut*.

2.7 The working method of these working groups has been recorded in the 'Explanation of the working method of Medicinal Products Horizon Scan working groups'. This working method can be found on the website www.horizonscangeneesmiddelen.nl under downloads.

3. Information supplied by a manufacturer

3.1 Twice a year, manufacturers are asked to supply information for the Horizon Scan. The request to supply information can in any case be found on the website www.horizonscangeneesmiddelen.nl, or via the Innovative Medicines Association [*Vereniging Innovatieve* Geneesmiddelen] and HollandBIO.

3.2 Information supplied by manufacturers is sent directly to the *Zorginstituut* via the e-mail address horizonscan@zinl.nl.

3.3 The information supplied is regarded as one of the sources available to the Horizon Scan. The *Zorginstituut* and the working groups are at liberty to prioritise sources or to decide whether or not sources will be included in the Horizon Scan. In general, preference is given to information from the manufacturer regarding actual prices and actual introduction dates, as long as the factuality of the information has been sufficiently established.

3.4 Information can be supplied by making use of a specially designed form. This form should be completed as fully as possible, preferably per substance name and corresponding indication. If a medicinal product is being developed – or as the case may be, registered – for different indications, then a separate form should be completed per indication.

3.5 The *Zorginstituut* can publish all information supplied by a manufacturer in the Horizon Scan. The manufacturer's permission is not required. By supplying the information, the manufacturer has given permission to publish the information.

3.6 In principle, the *Zorginstituut* can also use information supplied for the Horizon Scan when carrying out its other tasks.

3.7 The information supplied can be requested via the Government Information (Public Access) Act [*Wet openbaarheid van bestuur,* WOB]. Information supplied for the Horizon Scan will not be regarded as company and manufacturing data that were supplied to the Zorginstituut in confidence.

3.8 The manufacturer is responsible for ensuring that information is only supplied if it can actually be published. Any statements of manufacturers, e.g. 'confidential', will not be respected if the information is supplied within the framework of the Horizon Scan.

3.9 The *Zorginstituut* is not bound to include a manufacturer's input or to provide the manufacturer with a reply.

3.10 The working group assesses the manufacturer's input for the domain concerned. The working group is not bound to include this input nor to send a reply.

3.11 Information that the manufacturer supplies will only be used prospectively (for future publications) and not to update past publications.

3.12 Communication about the contents of the Horizon Scan takes place via the *Zorginstituut*. The working groups may not be approached directly within the framework of their tasks for the Horizon Scan.

Diemen, 8 December 2017