Amsterdam, June 12th 2018

Subject: Our position on the general debate Medicines policy, June 21st 2018

Dear Member of Parliamentary Committee on Health,

With this letter we wish to inform you about our position concerning access to medicines prior to the general debate on Medicines policy on Thursday June 21st 2018.

Since the Dutch Presidency of the European Union, the debate on access to medicines has become heated. The Netherlands has made forward-thinking proposals thanks to its vision on medicines, and has therefore put the issue of affordable medicines on the national and international agenda [1]. In addition, Minister Bruins (Medical Care) aims to take measures to guarantee access to affordable medicines, now and in the future.

Conditions on public investments

The Council for Health and Society (RVS) [2], Universities Allied for Essential Medicines (UAEM), License to Heal and the Centre for Research on Multinational Corporations (SOMO) were among the organizations that held presentations at the Wemos meeting about conditions on public investments in medicines in the Dutch House of Representatives. We would like to point out again that it is of great importance to set conditions on public investments for the development of medicines.

In financial terms, The Netherlands invests substantially in biomedical research that is fundamental to new and innovative medicines [3]. Yet, manufacturers are not expected to offer anything in return when the medicine has obtained market approval, such as reasonable pricing or socially responsible licensing. These licenses make medicines (more) accessible and increase the health care sector's financial sustainability. Public financing for medicines cannot benefit public health without reasonable medicine prices and responsible licensing [4].

We also want to express our support for key proposals made by the RVS to make and keep medicines more affordable: 1) Tackle power abuse by manufacturers, 2) Stimulate pharmacies to produce medication, 3) Allow patients to order medicines online with doctor prescriptions, and 4) Grant compulsory licenses.

At the general debate on Medicines policy on November 22nd 2017, Minister Bruins made several commitments regarding the abovementioned points. For example, he vowed to ensure that the Netherlands Federation of University Medical Centres will conduct research on public investments in medical research in the Netherlands. He also announced that a pilot project on socially responsible licensing will be initiated. The status of this project remains unknown at the moment.

Recently, the Dutch daily newspaper Algemeen Dagblad stated: 'Promising treatments, new medical technology *and* medicines must be made available to patients more quickly.' Minister Bruins endeavors

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to make 105 million Euros available to achieve this goal. Research that is necessary to include new technologies or medicines in the basic health insurance package is complicated, expensive and time-consuming [5,6]. We are keen to know how the implementation of the announced similar scheme for medicines would look like. Are conditions attached to these investments with public money, guaranteeing access to medicines or medical technology? For example, are reasonable prices or profits determined in advance, so that society can benefit from this investment? Also, will the scheme leave room for investment in the early stage of development in particular, so that researchers will be in a better position to enforce compliance from pharmaceutical companies to issue socially responsible licenses?

Compulsory licensing
Civil society organizations have stated in a letter that supplementary protection certificates for medicines are a risk to access to medicines because they delay the approval of cheap generic medicines. One option would be to make these certificates dependent on the true costs of research and development. This would make transparency a key requirement.

At the general debate on November 22nd 2017, Minister Bruins also vowed to conduct further research on possible compulsory licensing. We are also interested in the Technopolis Group's research results on supplementary protection certificates, which is complementary to research conducted by Copenhagen Economics, commissioned by the European Commission.

Competition law
The Authority for Consumers & Market (ACM) wants to investigate whether the competition law can be applied to patented medicines [7]. Several European governments have made resources available to counter abuse of monopoly power. The call of the Board of the ACM stresses the potential of enforcing stringent oversight of market abuse that negatively affects public health. We fully support this call.

Independent research
Research on new medicines in clinical trials must be independent. Such research not only leads to better research results, but is also beneficial to the added therapeutic value of medicines (read our position paper for our recommendations) [8]. The EMA's move to the Netherlands next year in April will be an excellent opportunity for the Netherlands to encourage independent research on medicines.

Transparency and new calculation model
Most cancer medicines are too expensive, according to recent research by Carin Uyl de Groot and Bob Löwenberg (Erasmus University). They have proposed a new model to determine the price of cancer medicines [9]. This is in line with Zorginstituut Nederland's (Netherlands' National Health Care Institute) alarm call. Zorginstituut feels blackmailed by pharmaceutical companies as they are not transparent about how they determine their medicine prices. At the same time, pressure from the side of politics and society to reimburse medicines is high. Zorginstituut wants Minister Bruins to stop reimbursing expensive medicines if manufacturers refuse to clarify why certain medicines are priced the way they are. Another suggestion is that the government could penalize unreasonable pricing with compulsory licensing.

We are extremely interested in the position of the Minister regarding Zorginstituut's advice and its follow-up. We would also like to know whether the Minister would consider applying the Erasmus University's new calculation model. Will the Minister take the opportunity to control and lower medicine prices?

If you have questions regarding the abovementioned points, please contact Ella Weggen (ella.weggen@wemos.nl) or Tom Buis (tom.buis@wemos.nl). We are glad to talk with you.

Yours sincerely,

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