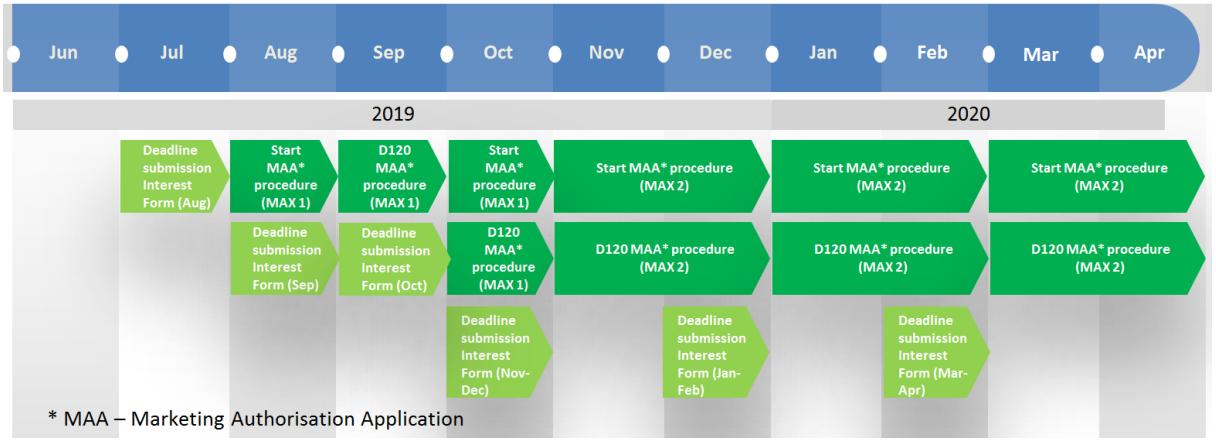
Explanation of the Interest Form, CBG-ZIN Parallel Procedures pilot

If you are interested in participating in the CBG-ZIN Parallel Procedures pilot, let us know by submitting the 'Interest Form CBG-ZIN Parallel Procedures'. The form asks you to provide information on various matters, such as the therapeutic indication of the product, expected date of submission (EMA) and requested reimbursement status. This information is to help us draw up an inventory of the type of product, the expected submission data and type of reimbursement procedures. The project leaders also use the information to determine within which timeframe parallel procedure could start and to decide whether the product complies with the inclusion criteria. This inventory is intended solely to help us estimate which type of product could be eligible for the pilot, and does not guarantee that the product will actually be included in the pilot procedures.

One of the inclusion criteria concerns the starting date of the marketing authorisation procedures for the product. A product can only be accepted into the pilot if the marketing authorisation application procedure starts (i.e. is accepted by EMA) between August 2019 and April 2020. Further, through experiences and questions on the criteria for inclusion and exclusion, it has been decided that products for which the marketing authorisation application has already started and day 120 is between August 2019 and April 2020 can also be included. This is to ensure that both the marketing application authorisation procedure and the procedures for national reimbursement can be finalised during the course of the pilot.

The period in which products can be accepted (August 2019 to April 2020) is further divided into 6 phases, whereby at most 1 or 2 products can be included per phase. To guarantee an efficient and effective pilot, for the moment in total 3 to 4 products will be included in the pilot. This means that not all slots may be filled and no further products will be added to the pilot. There is a deadline for each of the 6 phases within which the interest form must have been submitted. In general, the deadline is one month before the start of the centralised marketing authorisation application procedures (MAA) (see also the table and figure below. After receiving your interest form, the project leaders will contact you as soon as possible to further discuss the possibility of inclusion or exclusion and, in the event of acceptance into the pilot, to schedule a follow-up meeting, if the product complies with the criteria listed below. However, the possibility remains that, if there are too many applications, for a variety of reasons (e.g. marketing authorisation procedures start during the same period), only a select number of products will be included, in order to guarantee the efficient and effective running of the pilot. In the follow-up meeting, the project leaders will elaborate further on various aspects of the pilot procedures, expectations, conditions, the benefits and risks, and concrete plans will be made for formal inclusion in the pilot. A few weeks after the follow-up meeting, the pharmaceutical company will be expected to formally commit to participation in the pilot.

Figure 1: Overview start period MAA CBG-ZIN Parallel Procedure



Deadline submission Interest Form Parallel Procedures CBG-ZIN	Start centralised marketing application authorisation procedure (EMA)
15-7-2019	15-8-2019 (August)
3-9-2019	3-10-2019 (October)
30-9-2019	31-10-2019 (November & December)
2-12-2019	2-1-2020 (January & February)
27-1-2020	27-2-2020 (March & April)

Deadline submission Interest Form Parallel Procedures CBG-ZIN	Dag 120 marketing application authorisation procedure (EMA)
19-8-2019	19-9-2019 (September)
17-9-2019	17-10-2019 (October)
14-10-2019	14-11-2019 (November)
14-10-2019	12-12-2019 (December)
30-12-2019	30-1-2020 (January)
30-12-2019	27-2-2020 (February)
26-2-2020	26-3-2020 (March)
26-2-2020	30-4-2020 (April)

Tables 1 & 2: Interest Form submission deadlines per phase for the CBG-ZIN Parallel Procedures pilot

Inclusion criteria for products in the Parallel Procedures pilot

- The marketing authorisation application is classified as a 'regular' centralised marketing authorisation application (Not a major type II variation; extension of the indication).
- The marketing authorisation application has been accepted by EMA and will start between August 2019 and April 2020.
- Day 120 of the marketing authorisation application is between August 2019 and April 2020.
- Placement of the product has been requested on 'List 1B' of the standard health care package. In other words, a reimbursement assessment is needed (not a 'marginal assessment or a 'report in the form of a letter' [*briefrapport*]*)*
  or
- It is almost certain that the product will be placed in the so-called ' geneesmiddelensluis' ("waiting room").
- The participating pharmaceutical company is expected to participate proactively during the pilot procedure (including consultation meetings, one-on-one evaluation moments) to help shape the parallel procedures.

Exclusion criteria

- Products cannot be included that participate in the Beneluxa- or Eunetha project, 'Subsidieregeling Veelbelovende Zorg' or 'Nieuwe Regeling Weesgeneesmiddelen'.
- Products for which there is a relatively high chance that a marketing authorization will not be granted - meaning that it is likely that a reimbursement procedure will not start - can in principle be excluded.
- If within the same period two equivalent products are eligible for inclusion in the pilot (competing resources, overlapping indications), both products may be excluded from the Parallel Procedures pilot.

If you are interested in participating in the CBG-ZIN Parallel Procedures pilot, you can communicate this by submitting the 'Interest Form Parallel Procedures CBG-ZIN'.