



Introduction to the G-Standaard Production Schedule for the year 2019

Z-Index releases a new G-Standaard update every month. Software houses integrate the G-Standaard updates in the information systems used by pharmacies, general practitioners, hospitals and health insurance companies. It is in the interests of all end users that all parties submitting information to the Z-Index (including 700 manufacturers) have a clear production schedule and stick to it strictly.

The Internet application data entry web portal is not fully functional during 3 working days around the G-Standaard final production run. You can modify product packaging data but cannot publish these modifications. In other words, during these timeouts, Z-Index does not take your modifications into account, which means they will not appear in the following G-Standaard update. For further information, please read the explanation of the production schedule.

Read the explanation of the production schedule carefully! If you still have any questions, please contact the Information and Data Management department (phone no.: +31(0)70-3737437; e-mail: info@z-index.nl).

G-Standaard (GS) production schedule for 2019

1	2	3	4	5	6	7
GS for month	Opening of "publish" online option at 8:00	Deadline for <u>new</u> products at 17:00	<u>Test</u> production run	Deadline for the "publish modifications" online option at 17:00	<u>Final</u> production run	<u>Release</u> of update to GS download and GS Flex (on www.z-index.nl)
Jan 2019	Tue Nov 13	Tue Nov 27	Sat Dec 1	Wed Dec 5	Fri Dec 7	Tue Dec 11
Feb 2019	Tue Dec 11	Tue Jan 8	Sat Jan 12	Wed Jan 16	Fri Jan 18	Tue Jan 22
Mar 2019	Tue Jan 22	Tue Feb 5	Sat Feb 9	Wed Feb 13	Fri Feb 15	Tue Feb 19
Apr 2019	Tue Feb 19	Tue Mar 5	Sat Mar 9	Wed Mar 13	Fri Mar 15	Tue Mar 19
May 2019	Tue Mar 19	Tue Apr 2	Sat Apr 6	Wed Apr 10	Fri Apr 12	Tue Apr 16
Jun 2019	Tue Apr 16	Tue May 7	Sat May 11	Wed May 15	Fri May 17	Tue May 21
Jul 2019	Tue May 21	Tue Jun 4	Sat Jun 8	Wed Jun 12	Fri Jun 14	Tue Jun 18
Aug 2019	Tue Jun 18	Tue Jul 2	Sat Jul 6	Wed Jul 10	Fri Jul 12	Tue Jul 16
Sep 2019	Tue Jul 16	Tue Aug 6	Sat Aug 10	Wed Aug 14	Fri Aug 16	Tue Aug 20
Oct 2019	Tue Aug 20	Tue Sep 3	Sat Sep 7	Wed Sep 11	Fri Sep 13	Tue Sep 17
Nov 2019	Tue Sep 17	Tue Oct 1	Sat Oct 5	Wed Oct 9	Fri Oct 11	Tue Oct 15
Dec 2019	Tue Oct 15	Tue Nov 5	Sat Nov 9	Wed Nov 13	Fri Nov 15	Tue Nov 19
Jan 2020	Tue Nov 19	Tue Dec 3	Sat Dec 7	Wed Dec 11	Fri Dec 13	Tue Dec 17

Explanation of the 2019 G-Standaard Production Schedule

General

- There are five milestones in each monthly production cycle, represented by the data in columns 2, 3, 4, 5 and 6. Example: the milestones in the production process for the G-Standaard of February 2019 are December 11, 2018, and January 8, 12, 16 and 18, 2019.

Column 2/3: listing/delisting new product packagings

- **New**: a product packaging that has never been listed in the G-Standaard before.
- You can register new products only via the aforementioned Internet application.
- Product packagings will only be included in the following G-Standaard if you have filled in all the mandatory fields. Attention: The pharmacy purchase price (and, where relevant, the recommended sales price) must be greater than zero.
- Manufacturers of medicinal products can speed up the approval process by submitting the extract of the CBG or EMA registration dossier as soon as possible.
- Manufacturers of medical devices can speed up the approval process by submitting extra information as soon as possible: product characteristics, comparable products marketed by themselves or competitors, and the name of a contact person with content knowledge.
- Manufacturers of compounded drugs can speed up the approval process by submitting a patient information leaflet and/or a summary of product characteristics and/or a preparation protocol as soon as possible.
- Manufacturers of experimental drugs speed up the approval process by submitting a declaration from the Dutch IGJ (The Healthcare Inspectorate) that they are authorized to distribute their products in the Netherlands.
- If we deem the quality of the information provided to be unsatisfactory or the data are incomplete, we reserve the right not to include a product packaging in the G-Standaard (provisionally).
- Reactivate: reactivating a product packaging of which the expiration date in the G-Standaard has passed.

- If you wish to submit **more than 30 new product packagings** to the G-Standaard in a given month, please contact the I&DM department (070-3737437) by phone beforehand. Depending on available capacity, the submittal method and the product group(s) to which the new packagings belong, it may be impossible to process all of them in one go. Should this happen unexpectedly, the I&DM department will be happy to set new appointments with you.

Column 4: test production run objective

- For us, it is the first opportunity to check the G-Standaard.
- For the Ministry of Health, Welfare and Sports, it is the basis used to determine GVS limits.

Column 5: modifications

- **Modification**: changing a field or invalidating a product packaging that has already been included in the G-Standaard at least once. Therefore, changing data on a product packaging that has never been included in the G-Standaard before is not considered a modification.
- Modifications that can be entered via the Internet application may only be submitted by these means.
- There are **two types of modifications**:
 1. modification of a field regarding a product packaging. E.g.:
 - modification of a price (changing price x to price y, where x is greater than zero euros);
 - modification of the number of an own article; or
 2. Expiring a product packaging or removal of an expiration date the has not passed in the G-Standaard.

Column 5 (for a given month) and column 2 (for the following month)

- The "**publish modifications**" online option is unavailable for 3 working days every month (from Wednesday at 17:00 to Monday at 17:00, not counting holidays). In other words, modifications can be made but not published. N. B.: modifications that have not been published yet are stored in the system!
- The aim of making the "publish modifications" option temporarily unavailable is twofold:
 1. Preventing you from publishing modifications during the period between the modification deadline and the final production run, as this could result in modifications being deliberately or inadvertently included in the G-Standaard update without Z-Index checking their quality.
 2. If, when controlling the final production run, it is found that the G-Standaard does not meet the quality standards, the final production run can be repeated on Monday morning without including deliberate or inadvertent modifications added after the modification deadline.

Column 7

- If you are subscribed to the G-Standaard download and/or the G-Standaard Flex, you can download the update to the G-Standaard from www.z-index.nl on the aforementioned date provided that Z-Index has approved the final production run, i.e. the new G-Standaard update. If this is unexpectedly not the case, it will be announced on www.z-index.nl.