

G-Standaard production schedule for 2021

Over 700 registered manufacturers use the G-Standaard Data Entry Web Portal to add new healthcare products and modify existing ones in the G-Standaard. Z-Index checks and structures these data and compiles information from sources such as the KNMP, the CBG, the Ministry of Health, Welfare and Sport, and health insurance companies. Z-Index releases monthly G-Standaard updates. Software houses integrate these updates into 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 G-Standaard have a clear production schedule and stick to it strictly.

Manufacturers are required to use the G-Standaard Data Entry Web Portal to submit new products and changes to existing products to Z-Index. No alternative methods exist. The following rules apply:

- New products can be submitted at any time during the month.
- New products <u>for the next G-Standaard production run</u> have to be submitted to Z-Index before the new product deadline given in column 3 of the schedule. Keep in mind that Z-Index would rather receive new submissions as early as possible, i.e. well ahead of the date given in column 3.
- Modifications to <u>products already included in the G-Standaard</u> can be submitted up to approximately 3 days before the final production run of the next G-Standaard. See column 5 of the schedule.
- Once the final production run has taken place (column 6) and the updated G-Standaard has been released (column 7), new products and modifications (column 2) can be submitted for the next G-Standaard production run.

Read the description of the production schedule carefully! If you still have any questions, please contact our Information and Data Management department at 070-3737437 or info@z-index.nl..

G-Standaard production schedule for 2021

1	2	3	4	5	6	7
G-Standaard	Opening	Deadline	Test	Deadline	Final	Release
for month	of submissions for the G-Standaard	for new products	production	for submission of modifications	production	of G-Standaard download and
	given in column 1	for the G- Standaard given	run	at 5 pm	run	G-Standaard
	from 8 am	in column 1		αι σ μπ		flex at
		at 5 pm				www.z-index.nl
Jan 2021	Tue 17 Nov	Tue 1 Dec	Sat 5 Dec	Wed 9 Dec	Fri 11 Dec	Tue 15 Dec
Feb 2021	Tue 15 Dec	Tue 5 Jan	Sat 9 Jan	Wed 13 Jan	Fri 15 Jan	Tue 19 Jan
Mar 2021	Tue 19 Jan	Tue 2 Feb	Sat 6 Feb	Wed 10 Feb	Fri 12 Feb	Tue 16 Feb
Apr 2021	Tue 16 Feb	Tue 2 Mar	Sat 6 Mar	Wed 10 Mar	Fri 12 Mar	Tue 16 Mar
May 2021	Tue 16 Mar	Tue 30 Mar	Sat 3 Apr	Wed 7 Apr	Fri 9 Apr	Tue 13 Apr
Jun 2021	Tue 13 Apr	Tue 4 May	Sat 8 May	Wed 12 May	Fri 14 May	Tue 18 May
Jul 2021	Tue 18 May	Tue 1 Jun	Sat 5 Jun	Wed 9 Jun	Fri 11 Jun	Tue 15 Jun
Aug 2021	Tue 15 Jun	Tue 6 Jul	Sat 10 Jul	Wed 14 Jul	Fri 16 Jul	Tue 20 Jul
Sep 2021	Tue 20 Jul	Tue 3 Aug	Sat 7 Aug	Wed 11 Aug	Fri 13 Aug	Tue 17 Aug
Oct 2021	Tue 17 Aug	Tue 7 Sep	Sat 11 Sep	Wed 15 Sep	Fri 17 Sep	Tue 21 Sep
Nov 2021	Tue 21 Sep	Tue 5 Oct	Sat 9 Oct	Wed 13 Oct	Fri 15 Oct	Tue 19 Oct
Dec 2021	Tue 19 Oct	Tue 2 Nov	Sat 6 Nov	Wed 10 Nov	Fri 12 Nov	Tue 16 Nov
Jan 2022	Tue 16 Nov	Tue 30 Nov	Sat 4 Dec	Wed 8 Dec	Fri 10 Dec	Tue 14 Dec



Remember to submit your new products or modifications to Z-Index via the G-Standaard Data Entry Web Portal on time! Keep in mind the deadlines given in the production schedule. If you forget to submit new products or modifications, they will not be added to G-Standaard and, therefore, will not reach users from the G-Standaard.



Description of the G-Standaard Production Schedule

Column 1: G-Standaard for a specific month

Each production cycle of a G-Standaard for the month given in column 1 has six milestones, which are the dates given in columns 2 through 7. As a result, each G-Standaard for each month given in column 1 is published in the middle of the previous month on the date given in column 7.

Columns 2/3: opening/deadline for new products for the next G-Standaard production run

- A new product that has not been previously delivered with the G-Standaard will be delivered with the next G-Standaard
 provided that all the mandatory fields have been filled in and the product has been submitted to Z-Index on time. The
 G-Standaard Data Entry Web Portal states which fields are mandatory.
- You can speed up the approval process by linking the following documents to the new article before you submit them in the G-Standaard Data Entry Web Portal.:
 - o Medicinal products: Marketing Authorisation and Summary of Product Characteristics (SmPC).
 - o Medical devices: additional information such as product characteristics or a mock-up of comparable products.
 - o Compounded drugs: a patient information leaflet, a product specification sheet and/or a preparation protocol.
 - Experimental products: a certificate from the Dutch IGJ (The Healthcare Inspectorate) that states that you are authorized to distribute this product in the Netherlands, a patient leaflet, a product specification sheet or a SmPC of a reference product in Dutch, English or German.
 - Medicines with temporary permission: a reference to the decision of the Dutch IGJ (The Healthcare Inspectorate) that states that temporary permission is given to import the medicine and a patient leaflet, a product specification sheet or a SmPC of a reference product in Dutch, English or German.
- Do not wait until right before the date given in column 3 to submit new products. Please submit them as early as possible to ensure a smooth process.
- Z-Index will contact you if the provided information is not sufficient to approve the product. If this happens to a new product submitted shortly before the deadline for new products (column 3), it may result in insufficient information at the time of the deadline, preventing the inclusion of the product in the next G-Standaard. Z-Index therefore advises you to submit new products well ahead (at least several working days) of the deadline given in column 3 whenever possible.
- The assignation of a ZI-number only becomes effective after you receive the corresponding e-mail from Z-Index. A newly submitted product can therefore be rejected. Keep this in mind with factors such as the artwork.
- An expired product (one whose expiry date has already passed) can be reactivated by deleting its expiry date and submitting
 the product to Z-Index again.
- Name changes fall under column 3. Change requests can only be made by e-mail.



If you wish to submit more than <u>30</u> new products to G-Standaard in a given month, please call our Information and Data Management department (070-3737437) beforehand. Depending on the available capacity, the submission method and the product group(s) to which the new products belong, it may be impossible to process all of them in one go. Should this happen, our Information and Data Management department will set new appointments with you.

Column 4: Test production run

- Z-Index checks for the first time the G-Standaard for the month given in column 1.
- Based on the test production run, the Ministry of Health, Welfare and Sport assigns GVS limits that are integrated into G-Standaard by Z-Index.

Column 5: Deadline for submission of modifications

- Every month, submission of modifications to Z-Index is disabled for 3 working days after the date given in column 5 (from Wednesday at 5 pm to Monday at 5 pm, not counting holidays). There are two reasons for this:
 - 1. To prevent the deliberate or inadvertent inclusion of modifications that have not undergone the required Z-Index quality checks in the next G-Standaard production run.
 - 2. If, when controlling the final production run, it is found that the G-Standaard does not meet the quality standards, the G-Standaard production run can be repeated on Monday morning without including deliberate or inadvertent modifications added after the modification deadline.
- You can make modifications to products already included in the G-Standaard and submit them to Z-Index for the G-Standaard production run given in column 1 up until the date given in column 5. There are several types of modifications:
 - Changing product fields. The G-Standaard Data Entry Web Portal states which fields can be changed.
 - Expiring a product by entering an expiry date. In keeping with the sales period, the expiry date must be at least
 6 production months in the future.
 - Deleting expiry dates in the future.

Column 6: Final production run

The test production run is followed by the final production run for the month given in column 1. Z-Index carries out the necessary quality checks:

- Over a thousand checks are automatically carried out.
- Over sixty checks are actively monitored, often following the four-eyes principle.

A production run can be rejected. If this happens, a new G-Standaard production run will be launched once the necessary corrections have been made.

Column 7: Publication of G-Standaard download and G-Standaard flex at www.z-index.nl

- Following the approval of the final production run (column 6), the G-Standaard for the month given in column 1 is released to clients via the Z-Index website. In the event of a deviation from the schedule (cf. quality checks), a notification will be posted on the Z-Index website.
- Furthermore, the source of G-Standaard flex is now refreshed with the most recent version of G-Standaard.