

**HRA Pharma**

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**TO WHO IT MAY CONCERN**

Laboratoire HRA Pharma as the legal manufacturer, the responsible for the quality of Compeed product and the holder of Russian Registration Certificates expresses its respect to all concerned parties and inform about the following:

It was discovered during routing control of first produced batches of updated Compeed SKU for Russia that one additional line was printed on back label of the secondary packaging/plastic holder.

The concerned SKUs are listed below (all information meets the label and should be considered as correct):

SKU	Russian Registration Certificate	LOT number (LOT: XXXXXX)	Shelf life (X years)	Expiry date (🕒:Year – Month)
Compeed Blister Small 6s	FSZ 2011/10240 from 27.07.2020	<b>7812669</b>	<b>3 years</b>	<b>2023-12</b>
Compeed Mixed Blister 5 Pack	RZN 2015/2935 from 27.07.2020	<b>7806406</b>	<b>3 years</b>	<b>2023-09</b>
		<b>7812663</b>	<b>3 years</b>	<b>2023-09</b>

HRA Pharma confirms about following:

- The products meet the current Russian regulatory requirements, requirements of the registration dossier (including technical documentation delivery set, packaging labelling, etc).
- There is no impact on the quality, safety, and efficacy/performance on the Compeed products manufacturer for the Russian market. Products can be released and commercialized on the Russian Market.
- The additional line was printed accidentally and does not mean the production date.
- The production site was informed, and appropriate correction actions were taken in order to remove the additional line from the label for other Lots. Additional line will not appear for any other Compeed products.

*Signed at Chatillon, on 28 February 2021*



Gaëlle DAUDE  
Head of Quality



Tanguy CORADIN  
Head of Regulatory



Paul CARTER  
Chief Scientific Officer  
Responsible Person for Medical Devices

Laboratoire HRA Pharma