Lenalidomide Krka (lenalidomide) Pharmacy Registration Form

To be completed by the Chief/Superintendent Pharmacist or appointed deputy

Institution name:	
Chief/Superintendent Pharmacist (or appointed deputy):	
Contact telephone number:	
Email:	
Dispensing Pharmacy Address:	**Delivery Address (if different):**
Tel:	**Tel:**
Fax:	**Fax:**
Email:	**Email:**
Ordering Address (if different to delivery address):	

On behalf of . . . . . [institution name], I agree to implement the following risk minimisation procedures when dealing with prescriptions for lenalidomide as specified by Krka in the Lenalidomide Krka Healthcare Professional's Information Guide.

1	I have read and understood the Lenalidomide Krka Healthcare Professional's Information Guide.	TICK
2	All pharmacists who dispense Lenalidomide Krka will have read and understood the Lenalidomide Krka Healthcare Professional's Information Guide.	TICK
3	If supplied with Lenalidomide Krka, it will only be used for the purpose of dispensing the product by the Pregnancy Prevention Programme registered pharmacy to the patient.	TICK
4	Prescriptions for Lenalidomide Krka will be dispensed only if accompanied by a completed Lenalidomide Prescription Authorisation Form.	TICK
5	The pharmacist dispensing Lenalidomide Krka will check each prescription and Prescription Authorisation Form for completeness and countersign the authorisation form prior to dispensing.	TICK
6	Compliance with these procedures will be audited by the chief/superintendent pharmacist or appointed deputy at least annually. Audit results will be made available to KRKA so that their obligation to report to the regulatory agencies on the overall effectiveness of the programme can be met.	TICK
7	Lenalidomide Krka will be dispensed, checked and stored according to our standard documented procedures for oral anti-cancer medicines.	TICK
8	Dispensing will be limited to no more than a 4 week supply for women of childbearing potential, and 12 weeks for males and women of non-childbearing potential.	TICK
9	Dispensing of Lenalidomide Krka to women of childbearing potential should occur within 7 days of the prescription.	TICK
10	After dispensing, Lenalidomide Prescription Authorisation Forms will be kept in pharmacy for a minimum of 2 years.	TICK
11	Pharmacies must undertake the **mandatory** annual self-audit of the PAFs.	TICK
12	I will notify KRKA of any change in contact details.	TICK

I understand that registration to obtain and supply Lenalidomide Krka will only be granted if I agree to items 1–12 described above as supply of Lenalidomide Krka without participation in the required risk minimisation for pregnancy prevention is contrary to the conditions of the marketing authorisation. Registration is valid for 2 years at which point I will confirm that we are continuing to follow the risk minimisation procedures by completing this form and sending to KRKA.

Signature:	
Print:	Date: DD MM YYYY

Email the completed form to KRKA on Info.IE@krka.biz

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