

Key Performance Indicators in 2013

LICENSING OF HUMAN MEDICINES	Number of licensed medicines until 31.12.2013	57 978
	Number of procedures until 31.12.2013	6 892
	Number of applications	8 201
	Number of marketing authorisations for new medicines	509
	Number of new SIDC codes	3 751
MEDICAL DEVICES	Number of registered and notified medical devices until 31.12.2013	75 073
	Number of new codes	1 663
	Number of updated codes	2 691
	Number of incidents of medical devices made available on the SK market	1 205
PHARMACOVIGILANCE	Number of suspected adverse reactions reported to SIDC	1 038
	Number of suspected serious adverse reactions reported to SIDC	568
QUALITY CONTROL	Number of medicines analysed	225
	Number of magistraliters analysed	1 456
	Number of analytical batch certificates controlled	463
	Number of medicines recalled from market	22
CLINICAL TRIALS	Number of applications for clinical trials	144
	Number of approved applications for clinical trials	148
	Number of rejected applications for clinical trials	5
	Number of applications for new clinical facilities regarding clinical trials	53
INSPECTIONS	Inspections of Good Pharmacy Practice	887
	Inspection of Good Manufacturing Practice	22
	Inspection of Good Distribution Practice	71
	Inspection of Good Practice for Preparation of Blood Products	22
	Inspection of Good Clinical Practise	5
	Inspection of Good Pharmacovigilance Practise	1
AVAILABILITY OF MEDICINES	Number of nofications for reexport of medicines	14 618
	Number of medicines planned to be reexported	577
	Number of packs of medicines planned to be reexported	3 139 238
	Number of medicines reexported	512
	Number of decisions not approving reexport	113
	Number of medicines not approved for reexport	24
	Number of packs not approved for reexport	85 875
DRUG PRECURSORS	Number of approved licences to dispense drug precursors	150
	Number of newly authorised medicines containing drug precursors	3
ADVERTISEMENT OF MEDICINES	Number of notifications concerning advertisement activities	1 605
	Number of controlled advertisement activities	27
FINANCIAL BALANCE	Revenues transfered to state budget	11 942 752
	Expenditures	4 372 652
	Number of SIDC staff	169