

Key Performance Indicators in 2014

LICENSING OF HUMAN MEDICINES	Number of licensed medicines until 31.12.2014	47 763
	Number of procedures until 31.12.2014	6 887
	Number of applications	8 580
	Number of marketing authorisations for new medicines	389
	Number of new SIDC codes	3 289
MEDICAL DEVICES	Number of registered and notified medical devices until 31.12.2014	76 734
	Number of new codes	1 661
	Number of updated codes	2 553
	Number of incidents of medical devices made available on the SK market	1 208
PHARMACOVIGILANCE	Number of suspected adverse reactions reported to SIDC	1 059
	Number of suspected serious adverse reactions reported to SIDC	600
QUALITY CONTROL	Number of medicines analysed	332
	Number of magistraliters analysed	544
	Number of analytical batch certificates controlled	418
	Number of medicines recalled from market	28
CLINICAL TRIALS	Number of applications for clinical trials	139
	Number of approved applications for clinical trials	142
	Number of rejected applications for clinical trials	7
	Number of applications for new clinical facilities regarding clinical trials	69
INSPECTIONS	Inspections of Good Pharmacy Practice	998
	Inspection of Good Manufacturing Practice	29
	Inspection of Good Distribution Practice	51
	Inspection of Good Practice for Preparation of Blood Products	23
	Inspection of Good Clinical Practise	6
	Inspection of Good Pharmacovigilance Practise	6
AVAILABILITY OF MEDICINES	Number of nofications for reexport of medicines	18 229
	Number of medicines planned to be reexported	1 096
	Number of packs of medicines planned to be reexported	4 025 714
	Number of medicines reexported	589
	Number of decisions not approving reexport	182
	Number of medicines not approved for reexport	27
	Number of packs not approved for reexport	57 446
DRUG PRECURSORS	Number of approved licences to dispense drug precursors	223
	Number of newly authorised medicines containing drug precursors	2
ADVERTISEMENT OF MEDICINES	Number of notifications concerning advertisement activities	1 613
	Number of controlled advertisement activities	19
FINANCIAL BALANCE	Revenues transfered to state budget	11 555 430
	Expenditures	4 511 664
	Number of SIDC staff	174