SUB-PROGRAMME	NHS PRIORITIES FOR 2004-2009	ACTIVITIES FOR 2004-2009	NATIONAL DOH MEASURABLE OBJECTIVES FOR 2007-2009	INDICATOR	TARGET (07/08)	TARGET (08/09)	TARGET (09/10)
MEDICINE REGULATORY AFFAIRS: PHARMACEUTICAL & RELATED PRODUCT REGULATION & MANAGEMENT	Strengthen support services	Accelerate the re-registration of medicines	Implementation of an Electronic Document Management System (EDMS) to accelerate the registration and re-registration of medicines every five years,	EDMS Developed and implemented	Award tender for software by March 2007.	Configuration of software for specialist processes complete.	Report on pilot testing and training compiled
MEDICINES EVALUATION AND RESEARCH	Strengthen support services	Strengthen capacity for the evaluation of applications for registration of medicines and for assessment of amendments to registered medicines	Build Staff capacity for evaluation of the quality aspects of medicines.	Percentage of evaluations performed in-house.	At least 70% Evaluations performed in-house.	At least 80% Evaluations performed in-house.	At least 90% Evaluation performed in-house.

SUB-PROGRAMME	NHS PRIORITIES FOR 2004-2009	ACTIVITIES FOR 2004-2009	NATIONAL DOH MEASURABLE OBJECTIVES FOR 2007-2009	INDICATOR	TARGET (07/08)	TARGET (08/09)	TARGET (09/10)
MEDICINE REGULATORY AFFAIRS:	Strengthen support services	Strengthen capacity for the evaluation of bioequivalence protocols	Build capacity for the evaluation of bioquivalence protocols	Percentage of evaluations performed in-house.	At least 70% evaluations performed in-house.	At least 80% evaluations performed in-house.	At least 90% evaluations performed in-house
MEDICINES EVALUATION AND RESEARCH		Develop guidelines and systems for the registration of alternative and complementary medicines	Complete guidelines and systems for the registration of alternative and complementary medicines	Percent completion of guidelines and systems for the registration of alternative and complementary medicines	80% of guidelines and systems completed	90% of guidelines and systems completed	100% of guidelines and systems completed

SUB-PROGRAMME	NHS PRIORITIES FOR 2004-2009	ACTIVITIES FOR 2004-2009	NATIONAL DOH MEASURABLE OBJECTIVES FOR 2007-2009	INDICATOR	TARGET (07/08)	TARGET (08/09)	TARGET (09/10)
MEDICINE REGULATORY AFFAIRS: MEDICINES EVALUATION AND RESEARCH	Strengthen support services	Develop guidelines and systems for the registration of Traditional Medicines	Complete guidelines and systems for the registration of Traditional Medicines	Percent completion of guidelines and systems for registration of Traditional Medicines	80% of guidelines and systems completed	90% of guidelines and systems completed	100% of guidelines and systems completed
		Strengthen collaboration with international medicines regulatory authorities.	Established working relationships with international regulatory authorities for exchange of regulatory information.	Number of authorities with which relationships have been established.	Relationship established with at least one international regulatory authority.	Relationship established with at least two international regulatory authorities.	Relationship established with at least three international regulatory authorities.

SUB-PROGRAMME	NHS PRIORITIES FOR 2004-2009	ACTIVITIES FOR 2004-2009	NATIONAL DOH MEASURABLE OBJECTIVES FOR 2007-2009	INDICATOR	TARGET (07/08)	TARGET (08/09)	TARGET (09/10)
MEDICINE REGULATORY AFFAIRS: INSPECTIONS AND LE	Strengthen support services	Acquire membership of Pharmaceutical Inspection Cooperation Scheme (PIC/S)	Acquire membership of Pharmaceutical Inspection Cooperation Scheme (PIC/S)	Membership of PIC/S acquired building on the recommendations of the PIC/S assessment [Sept 2006]	Report on the Implement ation of the PIC/s recommendations compiled	Report on the implementation of the recommendations of second PIC/s inspection and implement compiled	Full membership of the . Pharmaceutical Inspection Cooperation Scheme (PIC/S)
			Improve in-house technical capacity of the Inspectorate.	Provide technical training by External GMP/GCP expert on GMP/GCP inspections.	60 %	80 %	Inspectorate compliant with PIC/s standard.
CE &T	Strengthen support services	Implement a system to deal with Patient Information Leaflet (PIL).	Implement a system to deal with Patient Information Leaflet (PIL).	System developed.	100%	100%	100%
				Percentage PIL's evaluated.	60%	80%	100%

SUB-PROGRAMME	NHS PRIORITIES FOR 2004-2009	ACTIVITIES FOR 2004-2009	NATIONAL DOH MEASURABLE OBJECTIVES FOR 2007-2009	INDICATOR	TARGET (07/08)	TARGET (08/09)	TARGET (09/10)
MEDICINE REGULATORY AFFAIRS: CE &T	Strengthen support services	Develop capacity in-house with a SOP to do technical screening and evaluation in Section 21 applications, Clinical and Pharmacovigilance evaluations.	Build Staff capacity to do technical screening and evaluation in Section 21 applications, Clinical and Pharmacovigilance evaluations.	Percentage of each application evaluated in-house: Clinical Trials	30%	40%	50%
				Percentage of each application evaluated in-house: Pharmacovigilance	50%	55%	60%
				Percentage of each application evaluated in-house: Section 21	40%	60%	75%
				Percentage of in-house staff trained to conduct technical evaluations: Clinical Trials	50%	75%	100%
				Percentage of in-house staff trained to conduct technical evaluations: Pharmacovigilance	50%	70%	100%
				Percentage of in-house staff trained to conduct technical evaluations: Section 21	50%	100%	100%

SUB-PROGRAMME	NHS PRIORITIES FOR 2004-2009	ACTIVITIES FOR 2004-2009	NATIONAL DOH MEASURABLE OBJECTIVES FOR 2007-2009	INDICATOR	TARGET (07/08)	TARGET (08/09)	TARGET (09/10)
MEDICINE REGULATORY AFFAIRS: CE &T	Strengthen support services	Develop guidelines to do evaluation of clinical data for registration purpose and start implementation	Finalise guidelines to do evaluation of clinical data for registration purpose and start implementation	Percentage completion of guidelines.	100%	100%	100%
				Percentage in-house staff trained.	50%	75%	100%
				Percentage of clinical dossiers evaluated in-house.	30%	50%	66%
		Strengthen pharmacovigilance in the country.	Develop pharmacovigilance plan for monitoring XDR TB Drugs.	% implementation of the Pharmacovigilance plan in place for monitoring XDR TB Drugs	50%	75%	100%