NATIONAL DRUG AUTHORITY
SERVICE DELIVERY TIMELINES
AUGUST 2017

Safe Drugs Save Lives

REGULATORY AREA	ACTION	TIMELINE
Clinical Trial (CT) Oversight	Acknowledgement of receipt of a Clinical Trial Application (CTA)	5 days
	Feedback on screening of a CTA	10 days
	Regulatory decision on a CTA	70 days
	Annual renewal of ongoing trials	20 days
	Amendment of CT Authorisation - minor	10 days
	Amendment of CT Authorisation - major	20 days
Veterinary Field Trial Oversight	Acknowledgement of receipt of a field trial application (FTA)	5 days
	Feedback on screening of a FTA	10 days
	Regulatory decision on a FTA	50 days
Marketing Authorisation (MA)	Acknowledgement of receipt of a Marketing Authorisation (MA) application	5 days
	Feedback on screening of MA application for completeness	10 days
	GENERAL CONSIDERATIONS	
	Assessment of application and request for additional information	250 days

REGULATORY AREA	ACTION	TIMELINE
	on application for MA (Human drugs)	
	Assessment of application and request for additional information on application for MA (Veterinary drugs)	120 days
	Assessment of application and request for additional information on application for MA (Vaccines, Anti-cancer medicines, other vital medicines)	120 days
	Assessment of application and request for additional information on application for MA (herbal medicines - imported)	120 days
	Regulatory Decision on MA after additional information is received	90 days
	SPECIAL CATEGORIES	
	Regulatory Decision on MA for domestically manufactured products (herbal, conventional)	90 days
	Regulatory decision on MA for WHO Prequalified products	90 days
	Regulatory Decision on products already authorized for marketing by Stringent Regulatory Authorities and those approved under article 58 of EU regulations.	120 days
	VARIATION AND NOTIFICATION	
	Regulatory decision on minor variation	90 days
	Regulatory decision on major variation (if the application does not require physical verification)	120 days
	Regulatory decision on Annual or immediate notification of change	60 days

REGULATORY AREA	ACTION	TIMELINE
	DRUG REGISTER	
	Publication of the drug register	Monthly (5^{th} of the month)
Regulatory Inspection	Physical inspection after receipt of application– Foreign	180 days
	Physical inspection after receipt of application– Domestic	20 days
	Feedback on GMP desk audit after receipt of application	60 days
	Feedback after inspection – Foreign	20 days
	Feedback after inspection – Domestic	10 days
	Regulatory Decision after CAPA – Foreign	20 days
	Regulatory Decision after CAPA – Domestic	10 days
Premises Licensing	Physical inspection after receipt of application – New outlet	15 days
	Physical inspection after receipt of application – Renewal	40 days
	Regulatory decision after inspection - New and Renewal	10 days
	Publication of the list of licensed outlets	Monthly (5^{th} of the month)
Market Surveillance and Control	Verification of imports (Registered drugs)	3 days
	Verification of imports (un-registered drugs)	10 days
	Acknowledgement of receipt of an application for authorization of a drug advert/promotional material	2 days

REGULATORY AREA	ACTION	TIMELINE
	Regulatory decision on drug promotional materials	15 days
	Publication of the database of approved promotional materials/advert	Monthly (5^{th} of the month)
Vigilance	Acknowledgement of receipt of an ADE report (email/letter)	2 days
	Feedback on an ADE report	20 days
Laboratory Testing	Test results from mandatory testing after sampling (medicines)	20 days
	Test results from mandatory testing after sampling (medical devices)	30 days
	Test results from client request after acceptance by the lab (all products)	30 days
	Test results for pre market samples (Domestic Manufacturers)	60 days
National Regulatory System	Issuance of recall or alert for a substandard or falsified medicine or health care product	5 days
	Acknowledgement of receipt of a product complaint	2 days
	Feedback on a market (process, product, other) complaint	20 days
	Supervision of destruction of unwanted medical products after application	7 days
	Response to general letters/inquiries (email, print)	3 days
	Supplier and vendor payments	7 days

Notes

1. **All days stated are working days**
2. **All timelines are counted from day zero which is the date the application, service request or notification at NDA. For electronic submissions it is assumed that the date submitted is the date received**
3. **When a request is made to an applicant or client for additional information or clarification, the NDA clock stops until the client's response is received. The timelines presented therefore only represent the total time NDA has to undertake a particular action.**

NDA MANAGEMENT