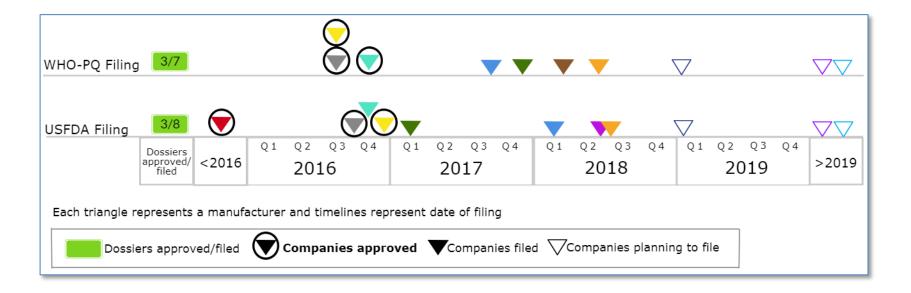


dolutegravir





- The above chart shows 12 MPP licensees are developing DTG 50mg, of which:
  - Seven companies have filed with WHO-PQ; of which Cipla, Hetero and Mylan have received approvals
  - Eight companies have filed with USFDA; of which Aurobindo, Cipla and
    Mylan have received approvals
- Sun Pharma has received Expert Review Panel (ERP) approval
- In total, **five companies** are ready to supply DTG 50mg



## **DTG 50mg: Country-wise Filing Status**

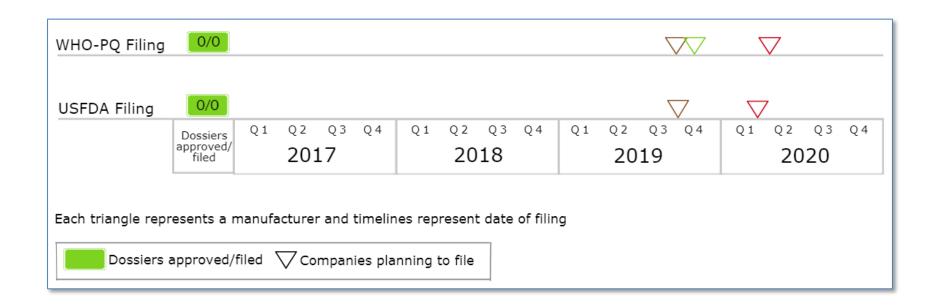
<b>Approved (17)</b> 60.6% PLHIV in LMICs		
Botswana	Nicaragua	
Cambodia	South Africa	
Congo	Tanzania	
DR Congo	Uganda	
Côte d'Ivoire	Ukraine	
India	Uzbekistan	
Kenya	Zambia	
Malawi	Zimbabwe	
Myanmar		

<b>Filed (20)</b> 25.6% PLHIV in LMICs		
Burundi	Namibia	
Cameroon	Nigeria	
El Salvador	Pakistan	
Ethiopia	Peru	
Gabon	Philippines	
Ghana	Rwanda	
Guyana	Senegal	
Kyrgyzstan	Sierra Leone	
Mauritius	Tajikistan	
Mozambique	Vietnam	

Generic DTG has been filed in 37 countries, of which approval is received from 17. Another 13 filings are planned from 2019 onwards, covering an additional 12.3% of people living with HIV (PLHIVs) in LMICs.



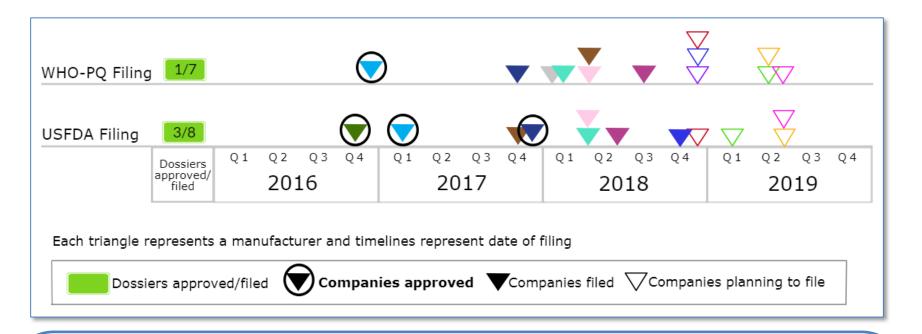
### DTG dispersible tablets



- Three MPP licensees are developing DTG dispersible formulation, of which:
  - ➤ Two plan to file with WHO-PQ in Q4-19 and one in Q2-20
  - ➤ One plans to file with USFDA in Q4-19 and another one in Q1-20



# TDF/3TC/DTG (TENOFOVIR DISOPROXIL/LAMIVUDINE/DOLUTEGRAVIR)



- 14 MPP licensees are currently developing TDF/3TC/DTG, of which:
  - > Seven have filed with WHO-PQ; of which **Mylan** has received approval
  - ➤ Eight have filed with USFDA; of which **Aurobindo**, **Hetero** and **Mylan** have received approvals
- Cipla, Macleods, Laurus and Sun have received ERP approvals
- In total, **seven companies** are ready to supply TLD



## TDF/3TC/DTG: country-wise filing status

<b>Approved (14)</b> 68.9% PLHIV in LMICs		
Benin	Nigeria	
Botswana	South Africa	
Congo	Tanzania	
Côte d'Ivoire	Uganda	
India	Uzbekistan	
Kenya	Zambia	
Malawi	Zimbabwe	

<b>Filed (24)</b> 19.5% PLHIV in LMICs			
Burkina Faso	Ghana	Niger	
Burundi	Haiti	Philippines	
Cambodia	Madagascar	Rwanda	
Cameroon	Mali	Senegal	
DR Congo	Mauritius	Sudan	
El Salvador	Mozambique	Thailand	
Ethiopia	Namibia	Ukraine	
Gabon	Nepal	Vietnam	

Generic TLD has been filed in 38 countries, of which approval is received from 14. Another 13 filings are planned from 2019 onwards (covering an additional 10.6% PLHIVs in LMICs).



### / TAF/FTC/DTG (TENOFOVIR ALAFENAMIDE/EMTRICITABINE/DOLUTEGRAVIR)



- Due to lack of clinical data, TAF is not on the WHO Guidelines as of now. However, generics have already started developing TAF combinations
- 11 MPP licensees are developing TAF/FTC/DTG, of which:
  - Mylan has filed with USFDA and received approval
  - > Another licensee has filed with USFDA in Dec 2018
- We anticipate development by additional licensees to accelerate once there is an update on WHO's position about use of TAF-containing formulations